
# Federal Register

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### WASHINGTON, DC

**WHEN:** September 24, 2002—9:00 a.m. to noon

**WHERE:** Office of the Federal Register
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## DEPARTMENT OF AGRICULTURE

### Federal Crop Insurance Corporation

### 7 CFR Part 457

### Common Crop Insurance Regulations; Sugarcane Crop Insurance Provisions

**AGENCY:** Federal Crop Insurance Corporation, USDA.

**ACTION:** Final rule; correction.

**SUMMARY:** This document contains corrections to the final rule, Common Crop Insurance Regulations; Sugarcane Crop Insurance Provisions that the Federal Crop Insurance Corporation published in the **Federal Register** on Friday, July 12, 2002 (67 FR 46093–46096).

**EFFECTIVE DATE:** August 14, 2002.

**FOR FURTHER INFORMATION CONTACT:** Arden Routh, Risk Management Specialist, Product Development Division, Federal Crop Insurance Corporation, United States Department of Agriculture, 6501 Beacon Drive, Kansas City, MO, 64133, telephone (816) 926–7730.

**SUPPLEMENTARY INFORMATION:** On page 46093, in the first column, under Summary, the year 2003 should read 2004, and on page 46095, in the second column, under Section 457.116, Sugarcane crop insurance provisions, introductory text, the year 2003 should read 2004. These changes are needed because the final rule was published after the contract change date for the 2003 crop year.

Signed in Washington DC, on August 7, 2002.

**Ross J. Davidson, Jr.,**

*Administrator, Federal Crop Insurance Corporation.*

[FR Doc. 02–20522 Filed 8–13–02; 8:45 am]

BILLING CODE 3410–08–P

## DEPARTMENT OF ENERGY

### 10 CFR Part 852

**RIN 1901–AA90**

### Guidelines for Physician Panel Determinations on Worker Requests for Assistance in Filing for State Workers' Compensation Benefits

**AGENCY:** Department of Energy.

**ACTION:** Final rule.

**SUMMARY:** The Department of Energy (DOE) is today publishing a final rule providing procedures to implement Part D of the Energy Employees Occupational Illness Compensation Program Act of 2000 under which a DOE contractor employee or an employee's estate or survivor can seek assistance from the DOE Office of Worker Advocacy (Program Office) in filing a claim with the appropriate State workers' compensation system based on an illness or death that arose out of exposure to a toxic substance during the course of employment at a DOE facility. These procedures deal with how: (1) An individual may submit an application to the Program Office for review and assistance; (2) the Program Office determines whether to submit an application to a Physician Panel; (3) a Physician Panel determines whether the illness or death of a DOE contractor employee arose out of and in the course of employment by a DOE contractor and through exposure to a toxic substance at a DOE facility; (4) the Program Office processes a determination by a Physician Panel; and (5) appeals may be undertaken.

**EFFECTIVE DATE:** September 13, 2002.

**FOR FURTHER INFORMATION CONTACT:** Ms. Loretta Young, telephone: 202–586–2819; fax: 202–586–0956; e-mail: *loretta.young@eh.doe.gov;* address: Office of Advocacy, EH–8, U.S. Department of Energy, 1000 Independence Avenue, Washington, DC 20585.

**SUPPLEMENTARY INFORMATION:**



## I. Introduction

Part A of the Energy Employees Occupational Illness Compensation Program Act of 2000 (''the Act'') (42 U.S.C. 7384, *et seq.*) establishes a program for compensating covered DOE and DOE contractor employees, as well as covered employees of certain private companies that did work for DOE and its predecessor agencies, including work involved in nuclear weapons production (Part A program). Covered workers with certain illnesses, including chronic beryllium disease, radiation-induced cancers, and silicosis, may be eligible for specified Federal benefits under the Part A program. Executive Order 13179 (65 FR 77487, December 7, 2000) assigns the Department of Labor (DOL) primary responsibility for that program. Workers with illnesses eligible for compensation under the Part A program, as well as workers with illnesses not eligible for the Part A program, may also apply to their respective State workers' compensation systems if they wish to receive benefits not provided by the Federal compensation system, notably lost wages and benefits for permanent partial disability.

Part D of the Act (42 U.S.C. 7385) authorizes the Secretary of Energy to enter into an agreement with each State to provide assistance to a DOE contractor employee in filing a claim under that State's workers' compensation system for an illness caused by exposure to a toxic substance at a DOE facility (''State Agreement''). An applicant can submit an application to the Program Office at DOE for assistance in filing a claim with that State's workers' compensation system. If the application comes within the terms and conditions of the relevant State Agreement and contains reasonable evidence that the illness or death of a covered worker may be related to employment at a DOE facility, then DOE must submit the application to a Physician Panel established under the

Act to determine the validity of the applicant's claim that the illness or death arose out of exposure to a toxic substance during the course of employment at a DOE facility. Section 3661(d) of Part D of the Act provides that a Physician Panel must make its determination ''under guidelines established by the Secretary [of Energy], by regulation.'' If a Physician Panel makes a positive determination and the Program Office accepts it, then the Program Office must assist the applicant in filing a claim with the relevant State's workers' compensation system. In addition, DOE may not contest the applicant's workers' compensation claim or any award made to settle the claim to the extent such claim or award is based on the same health condition that was the subject of a positive determination by a Physician Panel. And, to the extent permitted by law, DOE may direct a DOE contractor not to contest such a claim or award. Furthermore, if the DOE contractor employer contests the claim or award, the costs of contesting the claim or award are not allowable costs under a DOE contract.

Part D operates to ensure that DOE will assist, and not hinder, the processing of an applicant's claim under a State workers' compensation system if the claim is based on the same health condition that was the subject of a positive determination by a Physician Panel. DOE will not contest and DOE will direct its contractors not to contest such a claim. Part D, however, does not federalize State workers' compensation standards, or affect the normal operation of State workers' compensation systems other than the limits Part D places on the extent to which DOE and DOE contractors can contest certain claims. Part D does not expand or contract the scope of any State workers' compensation system, and does not change the rights, obligations, conditions, and compensation amounts for a claimant under any such system. Thus, significant variations will continue to exist among State workers' compensation systems with respect to matters such as benefit levels, length of coverage, and the types and computation of medical costs, lost wages and disabilities eligible for compensation. Moreover, neither Part D nor DOE's rules implementing Part D will make a worker eligible for compensation under a State workers' compensation system if the worker is not otherwise eligible. However, use contract administration to encourage DOE contractors to pay workers' compensation claims against which they might have technical defenses not going to the question of whether a contractor employee's illness arose out of employment at DOE. DOE will seek to carry out this statutory mandate faithfully.

DOE published a notice of proposed rulemaking (NOPR) under Part D on September 7, 2001, 66 FR 46742. DOE received numerous comments on the NOPR during the comment period, and continued to receive comments after the close of the comment period from various Members of Congress and their staffs, as well as other commenters.

## II. Discussion of Rule

### *A. What Is The Purpose of This Rule?*

The rule establishes procedures for implementing Part D of the Act. Section 852.1(a) of the final rule provides that these procedures address how: (1) An individual may obtain and submit an application to the Program Office for review and assistance; (2) the Program Office determines whether to submit an application to a Physician Panel; (3) a Physician Panel determines whether the illness or death of a DOE contractor employee arose out of and in the course of employment by a DOE contractor and through exposure to a toxic substance at a DOE facility; (4) the Program Office processes a determination by a Physician Panel; and (5) appeals may be undertaken.

### *B. What Is the Scope of This Rule?*

Section 852.1(b) makes clear that the procedures only cover applications that meet three criteria. First, the application must be filed by or on behalf of a DOE contractor employee, or a deceased employee's estate or survivor. Second, the application must be based on the illness or death of DOE contractor employee that may have been caused by exposure to a toxic substance. Third, the application must be based on an illness or death that may have been related to employment at a DOE facility.

Consistent with the statutory emphasis on State Agreements as a precondition for action under Part D of the Act, section 852.1(c) provides that all DOE actions under the Part D program must be pursuant to a relevant State Agreement and consistent with its terms and conditions.

### *C. What Definitions Are Used in This Rule?*

The rule contains definitions of ''Act'', ''Applicant'', ''DOE'', ''DOE contractor employee'', ''DOE facility'', ''Physician Panel'', ''Program Office'', ''State Agreement'', and ''Toxic Substance''.

### *D. What Is the Act?*

The Act is the Energy Employees Occupational Illness Compensation Program Act of 2000 (42 U.S.C. 7384, *et seq.*)

### *E. Who Is an Applicant?*

An applicant is an individual seeking assistance from the Program Office in filing a claim with the relevant State workers' compensation system, including but not limited to a living DOE contractor employee, the estate of a deceased DOE contractor employee, or any survivor of a deceased DOE contractor employee who is eligible to apply for a death benefit or a survivor's benefit under the State workers' compensation system for which the applicant is seeking assistance in filing a claim.

Proposed section 852.2 had defined an applicant as a DOE contractor employee or the employee's estate seeking assistance from the Program Office in filing a claim with the relevant State workers' compensation system. In the final rule, the definition has been extended to survivors because State workers' compensation systems generally provide income benefits to specific survivors, notably spouses and dependent children of deceased workers. The final rule permits such individuals to apply to DOE for assistance in filing for State workers' compensation benefits, based upon the illness or death of the deceased DOE contractor employee.

### *F. Who Is a DOE Contractor Employee?*

Section 852.2 defines a DOE contractor employee to be an individual who is or was in residence at a DOE facility as a researcher for one or more periods aggregating at least 24 months, or an individual who is or was employed at a DOE facility by either an entity that contracted with DOE to provide management and operating, management and integration, or environmental remediation at the facility, or a contractor or subcontractor that provided services, including construction and maintenance, at the facility. This definition repeats the language used to define a DOE contractor employee in section 3621(11) of the Act and is the same as the definition in the NOPR that referenced the definition found in section 3621(11) of the Act. DOE believes incorporating the actual statutory language into the rule will make the rule more understandable and easier to use.

The term ''DOE contractor employee'' does not include all employees eligible for the Part A program. It does not

include atomic weapons or beryllium vendor employees who were not employed by a DOE contractor at a DOE facility. In addition, it does not include Federal employees.

A commenter stated that the definition of a DOE contractor employee needs to include subcontractor employees. DOE agrees that subcontractor employees are covered by Part D of the Act, but no change in the rule is necessary to confirm this coverage. The definition of a DOE contractor employee clearly includes an individual who is or was employed at a DOE facility by a subcontractor that provided services at that facility.

*G. What Is a DOE Facility?*

As with the definition of DOE contractor employee, section 852.2 of this final rule defines ''DOE facility'' by repeating the definition found in section 3621(12) of the Act, rather than merely cross-referencing the statutory definition as the proposed rule did. This is a nonsubstantive change to the proposed rule, and is made only for the purposes of clarity in the text of the final rule. ''DOE facility'' thus is defined as any building, structure, or premise, including the grounds upon which such building, structure, or premise is located in which operations are, or have been, conducted by, or on behalf of, DOE and with regard to which DOE has or had a proprietary interest; or entered into a contract with an entity to provide management and operation, management and integration, environmental remediation services, construction, or maintenance services. Further, this definition specifically excludes facilities covered by Executive Order No. 12344, dated February 1, 1982 (42 U.S.C. 7158 note), pertaining to the Naval Nuclear Propulsion Program. DOE has published a list of facilities it considers to be DOE facilities for purposes of the Act. (66 FR 4003, January 17, 2001; revised 66 FR 31218, June 11, 2001).

*H. What Are Physician Panels?*

Physician Panels are appointed by the Secretary of Health and Human Services (HHS) in response to requests by DOE pursuant to Part D of the Act. Physician Panels provide DOE with impartial and independent determinations as to whether the illness or death of a DOE contractor employee arose out of and in the course of employment by a DOE contractor and exposure to a toxic substance at a DOE facility. Physician Panels may be asked to review new applications that have not undergone prior Physician Panel review, or to reexamine applications that have already undergone Physician Panel review.

*I. What Is the Program Office?*

The Program Office is the DOE Office of Worker Advocacy or any other DOE office subsequently designated by the Secretary of Energy.

*J. What Is a State Agreement?*

Section 852.2 defines ''State Agreement'' as an agreement negotiated between DOE and a State that sets forth the terms and conditions for dealing with an application for assistance under Part D of the Act in filing a claim with the State's workers' compensation system. The existence of a State Agreement with a particular State is necessary before the Program Office can refer to a Physician Panel a claim by an applicant who will file his/her worker's compensation claim in that State. Part D is clear that any action by DOE must be in accordance with the terms and conditions of the relevant State agreement.

*K. What Is a Toxic Substance?*

Section 852.2 defines ''toxic substance'' as ''any material that has the potential to cause illness or death because of its radioactive, chemical, or biological nature.'' This definition is the same as that proposed in the NOPR. DOE believes that this definition is consistent with the intent of Part D of the Act and will permit DOE to assist claimants with claims based on illnesses or deaths that arose from exposure to toxic substances to the extent such claims are recognized by a State workers' compensation system.

There were a number of comments on the NOPR definition of ''toxic substance.'' Many commenters supported the NOPR definition, though others suggested modifications to the definition. One commenter suggested that noise should be included as a toxic substance. DOE understands that noise can cause harm to workers in certain situations. However, the dictionary defines ''toxic'' as ''of, relating to, or caused by a poison or toxin.'' DOE does not believe that noise operates to poison people because it does not injure by chemical action. Hence, it does not fit comfortably within the ordinary meaning of ''toxic substance.'' Neither the text of Part D nor its legislative history suggests otherwise.

Another commenter suggested that only chemicals be considered toxic substances for the purpose of the rule. However, radioactive or biologically harmful substances are commonly described as being ''toxic,'' and these substances fit comfortably within the ordinary meaning of ''toxic substance.'' Given the content of the legislation, DOE does not believe it would be consistent with the general thrust of the Act to limit ''toxic substances'' to chemicals and to exclude other substances, or to define the term solely by reference to the chemical properties of a substance and to ignore radioactive or biological properties.

*L. How Does an Individual Obtain and Submit an Application for Review and Assistance?*

Section 852.3 describes how an individual obtains and submits an application for review and assistance. An application can be obtained in person from the Program Office, from any Resource Center, and from any DOE-sponsored Former Worker Program project. A Resource Center is a publicly accessible office administered jointly by DOE and DOL for the purpose of assisting an individual in applying for assistance or benefits under the programs established under the Act. There are currently ten Resource Centers located throughout the United States. There are presently approximately one dozen Former Worker Program projects throughout the United States. These pilot projects currently offer screening examinations for the detection of occupational illnesses for individuals formerly employed at some DOE facilities. The Program Office's current mailing address, phone number and web site, at time of publication of this final rule are included in this section. Any future changes in this contact information will be published in the **Federal Register** and noted on the Program Office's web site.

A commenter suggested that applications should also be obtainable in person from any DOE Operations or Area Offices, or from an employer who is currently a DOE contractor. Other commenters requested that section 852.3 include the Program Office's mailing address and web site. DOE finds that it would be logistically difficult for the Program Office to assure that complete application packages would be available at all times from all of the many DOE contractor facilities and DOE Operations and Area Offices. DOE believes that the nationwide network of Resource Centers, coupled with the availability of applications through mail or telephone requests to the Program Office, or in a printable format, from the Program Office's web site, provide adequate accessibility to application materials. The program has and will continue to be publicized so that potential applicants are aware of the

program and how to apply. In the final rule, section 852.3 has been revised to include the Program Office's current phone number and mailing address for requesting an application, as well as the web site from which application forms can be printed.

Section 852.3 also describes how an application is submitted. An application can be submitted in person to the Program Office, to any Resource Center, or to any DOE-sponsored Former Worker Program, where staff will be available to answer questions and assist the individual in filling out the application. An application can also be submitted by mail to the Program Office.

Section 852.4 describes the information and materials that the individual must submit as a part of the application for Physician Panel review, additional discretionary information and materials that the applicant may choose to submit, and the essential information that must be included in records released by a third party or submitted by the applicant in support of an application.

Section 852.4 specifies that the individual must complete and sign any application forms required by the Program Office. The application forms request basic information about the applicant and the worker upon whose illness or death the application is based.

In order to assure that the Program Office has reasonable evidence to determine whether an individual meets the eligibility criteria for Physician Panel review, and that the Physician Panel has sufficient information to make a causation determination on an application, section 852.4 requires the applicant to provide:

(a) the name and address of any licensed physician who is the source of a diagnosis based upon documented medical information that the employee has or had an illness and that the illness may have been related to exposure to a toxic substance while the employee was employed at a DOE facility and, to the extent practicable, a copy of the diagnosis and a summary of the information upon which the diagnosis is based; and

(b) a signed medical release, authorizing non-DOE sources of medical information to provide the Program Office with any diagnosis, medical opinion and medical records documenting the diagnosis or opinion relevant to whether the employee has or had an illness and whether the illness arose from exposure to a toxic substance while the employee was employed at a DOE facility.

The requirement that the applicant submit the information identified in section 852.4 is intended to satisfy the statutory provision that an applicant must supply the Program Office with reasonable evidence that the statutory threshold is met for referral to a Physician Panel. Among other things, and even though an applicant is not required to supply a physician's diagnosis as part of an application, applicants who wish to rely on such a diagnosis to support their applications should identify the diagnosing physician and submit a copy of the diagnosis. DOE encourages the submission of diagnoses where possible because they will enable the Program Office and Physician Panels to do their work more quickly, efficiently and reliably.

Part D neither directs DOE to provide nor bars DOE from providing assistance to an applicant in obtaining a medical diagnosis or developing other medical evidence to support the applicant's application before a decision is made whether to refer it to a Physician Panel. However, and while Part D makes clear that the applicant bears primary responsibility for submitting sufficient information to support his/her application and meet the requirements of section 852.6 of the final rule, DOE will assist applicants as it is able. Specifically, DOE may be able to provide certain types of information as discussed below in connection with section 852.6.

Section 852.4 of the final rule also permits the applicant to submit to the Program Office any other information or materials providing evidence that the employee has or had an illness that arose from exposure to a toxic substance during the course of employment at a DOE facility.

The applicant must sign an affidavit attesting to the authenticity and completeness of any information or materials submitted to the Program Office, or provide the Program Office with other evidence of authenticity of submitted materials, such as certification of submitted copies of originals.

To the extent practicable and appropriate, the records submitted by the worker or released by a third party must also include an occupational history obtained by a physician, an occupational health professional, or a DOE-sponsored Former Worker Program. DOE does not intend that a worker should incur financial or other hardship in having such a history taken, but instead requests that any such occupational history already in a worker's medical records be submitted to the Program Office by the applicant. If the worker's records do not already include such a history, then DOE requests that the worker have such a history obtained and have this history released to the Program Office, if the worker can readily have such a history obtained from a Former Worker Program or other source without incurring undue hardship. If such an occupational history is not reasonably available by these means, and is deemed by the Program Office to be needed for the fair adjudication of the claim, then the Program Office must assist the applicant in obtaining this history, if it can be obtained from the worker upon whom the application is based.

In section 852.4(d) of the NOPR, there was a provision for submission of an ''employment history'' as a part of the application. In the final rule, the requirement for submission of an ''employment history'' appears in section 852.4(a)(4), and the term ''employment history'' is changed to ''occupational history'' because the latter is in more general usage in the occupational health field. The other changes in this section were made to assure that an adequate occupational history is available for Physician Panel review.

Omitted from the final rule is section 852.4(c) of the NOPR which would have required an applicant to sign a release of information permitting the Program Office to obtain any records under the control of DOE and relevant to the application. Under the Privacy Act of 1974, as it pertains to DOE records system ''DOE–10 Worker Advocacy Records'' (66 FR 27307), such a release is not required for DOE to obtain records controlled by DOE for legitimate purposes related to this program.

*M. What Information May an Employer Submit in Response to an Application Submitted to a Physician Panel?*

New section 852.5 requires the Program Office to notify an employer when the Program Office has determined that an application by or on behalf of a current or former employee of that DOE contractor meets the requirements of section 852.4. After receiving this notification, the employer has 15 working days to provide the Program Office with any information deemed by the employer to be relevant to the application. The employer must sign an affidavit attesting to the authenticity and completeness of any information or materials submitted to the Program Office for this purpose, or provide the Program Office with other evidence of authenticity of submitted materials, such as certification of submitted copies of originals. DOE will provide the Physician Panel with

materials submitted by an employer for use in making its determination.

Two commenters expressed the opinion that the contractor has the right to be notified that a claim has been filed, and be given the opportunity to provide information relevant to the application, including information that might rebut the claim. Others noted that the employer may be the only source of certain relevant information, including information relating to the issue of causation, and noted that, under the proposed rule, the employer would not be able to present evidence to a Physician Panel or to present evidence to contest a determination by a Physician Panel in a State workers' compensation proceeding. Both commenters felt that the employer should be afforded the opportunity to provide the Program Office with evidence relevant to the application. DOE agrees with these commenters and has added this new section 852.5 to provide employers with notice and the opportunity to submit relevant information before the Program Office makes a determination whether to submit an application to a Physician Panel.

*N. How Does the Program Office Decide Which Applications To Submit to a Physician Panel?*

As proposed in the NOPR, section 852.6 (proposed as section 852.5) would have required DOE to apply eligibility criteria contained in the relevant State workers' compensation statutes and used by the relevant State in determining the validity of a workers' compensation claim. The criteria would have been specified in the State Agreement with the State in which the claim would be filed, as specified in proposed section 852.6. In the NOPR, DOE solicited comments on whether these State criteria should be applied by the Program Office, or alternatively, by State officials on a reimbursable basis. DOE also requested comments as to whether the use of a screening mechanism is consistent with the statutory framework and whether the use of applicable State criteria or uniform Federal criteria better achieves the statutory objectives.

Commenters generally opposed the application of State specific criteria during the screening of applications and urged that the Program Office submit to the Physician Panel those applications that meet the minimum statutory criteria identified in the Act. Commenters also expressed the concern that application of State specific criteria at this stage would erect barriers to claims that should be presented to the Physician Panel. Still other commenters urged the establishment of a uniform Federal standard for eligibility and causality.

Some States commented that they would not be willing to screen applications on a reimbursable basis. Several States also questioned whether DOE would be able to screen applications on the basis of whether an application presented a compensable claim under a State workers compensation system.

After considering the comments, DOE has decided that the eligibility criteria for referral of a claim to a Physician Panel should be based on the criteria specifically set forth in the Act, and should focus on whether the applicant provides reasonable evidence of an illness or death that may have been caused by exposure to a toxic substance during the course of employment at a DOE facility. Thus, section 852.6(a)(1) and section 852.6(a)(3) of the final rule track the language in Part D. Section 852.6(a)(2) further requires that an applicant submit reasonable evidence that the employee's illness or death ''may have been caused by exposure to a toxic substance.'' While this requirement does not appear in section 7385o(b)(2) of the statute, it reflects part of the determination that Part D requires a Physicians Panel to make if the panel is to render a determination in an applicant's favor. DOE believes that it is only logical for the applicant to be required to submit, and for the Program Office only to refer to Physician Panels applications in which the applicant has submitted, reasonable evidence in support of the determination the Physician Panel is being asked to make.

Consistent with the general tenor of the comments, today's final regulations provide that applications which satisfy these minimum criteria should be submitted to a Physician Panel for review. It is the role of the Physician Panel to determine if the applicant can satisfy the medical criteria for causation specified in these final regulations. Non-medical criteria, such as statutes of limitations, should not be used by the Program Office to screen applications, or by the Physician Panels to make medical causation determinations.

DOE is aware that by excluding non-medical criteria from the screening process, it may submit to a Physician Panel an application by an applicant whose State workers' compensation claim might be barred by non-medical criteria (such as the applicable statute of limitations). A Physician Panel could in turn make a causation determination in favor of an applicant, and the Program Office could accept such a determination even though there might be various medical or non-medical impediments to the applicant's State workers' compensation claim as will be discussed below. Part D is designed to remove obstacles to recovery of this type when it can do so through contract administration tools. These results do not impose a Federal standard on a State workers' compensation system. States will continue to have the ability to administer their workers' compensation systems in accordance with applicable State law. DOE's action merely would constitute a decision by DOE not to raise defenses to a workers' compensation claim by an applicant who has received a favorable Physician Panel determination.

Section 852.6 identifies the criteria the Program Office uses to determine whether to submit an application to a Physician Panel. An application must contain reasonable evidence allowing the Program Office to make an initial determination that the following three conditions are met. First, the application was filed by or on behalf of a DOE contractor employee or the employee's estate or survivor. Second, the illness or death of the DOE contractor employee may have been caused by exposure to a toxic substance. Third, the illness or death may have been related to employment at a DOE facility. The Program Office must refer to a Physician Panel any application that provides reasonable evidence meeting each of these criteria. Applicants with a medical diagnosis to support their applications should submit that diagnosis and supporting medical documentation because such information likely will constitute the strongest evidence in support of an applicant's causation argument. Applicants who do not submit a diagnosis by a licensed physician will have a more difficult time meeting the section 852.6 standard. However, the regulations do not require that a medical diagnosis be submitted before an application meets the applicable standard, and as section 852.4 makes clear, applicants are free to submit whatever information they have that they believe supports their application.

*O. What Provisions Does a State Agreement Contain?*

Proposed section 852.6 in the NOPR identified three elements to be included in a State Agreement: a provision that the State would identify the applicable criteria used to determine the validity of a workers' compensation claim under State workers' compensation law and describe how these criteria are applied in a State workers' compensation

proceeding; a provision that only those applications that could satisfy the identified applicable criteria would be submitted to a Physician Panel; and a provision that the Program Office would provide assistance only to those applicants that satisfy the applicable criteria.

DOE intends the State Agreement to be the understanding between DOE and a State as to the terms and conditions for dealing with an application for DOE assistance in filing a workers' compensation claim. State Agreements are not intended to alter State criteria.

As noted in the discussion of section 852.6, a number of commenters objected to the concept of the Program Office using State criteria to screen applicants for assistance prior to submission of an application to a Physician Panel. As a result, that section has been revised to eliminate consideration of State criteria at that point in the screening process. Similarly, several commenters objected to inclusion in the State Agreements of State criteria for determining causation and other medical eligibility issues. Some commenters stated that State Agreements should contain Federal standards to be applied in determining eligibility and causality. As will be discussed below, DOE believes that it is consistent with the statutory requirement and structure of the program under Part D for the Physician Panels to use a uniform federal standard for determining causation rather than the specific causation requirements of the workers' compensation system for the State in which an applicant will file his/her claim.

DOE also solicited comments as to what other provisions should be included in State Agreements. Commenters argued that the State Agreements should include a provision for reimbursement or indemnification to contractors or insurance carriers for claims accepted under Part D. DOE has determined that such provisions should not be placed in the State Agreements. Rather, section 852.19 of the final rule provides for reimbursement of contractors for additional workers' compensation costs incurred as a result of workers' compensation awards on claims based on the same health condition that was the subject of a positive Physician Panel determination. However, the Act does not authorize DOE to reimburse or indemnify insurers; nor does it authorize the appropriation of funds to do so. Therefore, neither the final regulations nor the State Agreements provide for reimbursement or indemnification of insurers.

Commenters also expressed concern for the precedential effect of a Physician Panel finding of medical causation. A positive finding by a Physician Panel is not binding on a State worker's compensation system or any person other than DOE and, if so directed by DOE, a DOE contractor. The effect of a positive Physician Panel determination is to obligate DOE to assist the applicant in the State worker's compensation proceeding. It does not prevent anyone other than DOE or a DOE contractor so directed by DOE from contesting causation or any other issue.

One commenter observed that Part D of the Act is permissive, not required, and that the Secretary has the option to decide not to negotiate State Agreements with States. While the commenter is correct that the program under Part D is discretionary and dependent on the negotiation of State Agreements, DOE believes Congress did not enact Part D in the expectation that DOE would make it a dead letter by refraining from attempting to negotiate any State Agreements. DOE therefore has determined that it should seek to negotiate agreements with the States as anticipated by this Part. Of course, implementation of the program under this Part with respect to any particular State or state workers' compensation program will depend on the successful negotiation of a State Agreement between DOE and the relevant State.

One commenter expressed concern that there are jurisdictions without a State agency to enter into such an agreement. DOE finds that all jurisdictions have a workers' compensation administrative agency with which DOE believes it can work.

As revised, section 852.7 provides for four standard provisions in State Agreements. First, the State Agreement must include a provision that an application will be submitted to a Physician Panel only if it contains reasonable evidence, including appropriate medical documentation, that (1) the worker who is the subject of the application is or was a DOE contractor employee, (2) the worker has, had or died of an illness that may have been caused by exposure to a toxic substance, and (3) the exposure occurred during the course of employment at a DOE facility.

Second, a State Agreement must include a provision that requires a Physician Panel to apply the standard of causation set forth in section 852.8 of DOE's regulations when making determinations of medical causation.

Third, a State Agreement must include a statement that the Program Office provides assistance only to an applicant who receives a positive determination from a Physician Panel.

Fourth, a State Agreement must include a statement that a positive determination by a Physician Panel has no effect on the normal operation of a State workers' compensation system. However, as provided elsewhere in this rule, the determination will prevent DOE from contesting a State workers' compensation claim or award with regard to the health condition that was the subject of the Physician Panel determination. It also will result in DOE's direction to the relevant DOE contractor not to contest such claims or awards. State processes concerning issues such as benefit level determinations, disability determinations such as permanent partial disability (PPD), and apportionment, will proceed according to routine State workers' compensation system operation.

*P. What Guidelines Does a Physician Panel Use To Determine Whether an Illness or Death Arose Out of and in the Course of Employment by a DOE Contractor and Exposure to a Toxic Substance at a DOE Facility?*

Section 852.8 provides that a Physician Panel determines whether an illness or death arose out of and in the course of employment by a DOE contractor and exposure to a toxic substance at a DOE facility based whether it is at least as likely as not that exposure to a toxic substance at a DOE facility during the course of the worker's employment by a DOE contractor was a significant factor in aggravating, contributing to or causing the worker's illness or death.

In proposed section 852.7 of the NOPR, a common federal causation standard and burden of proof were specified, namely, that it is more likely than not that exposure to a toxic substance at a DOE facility during the course of employment by a DOE contractor caused the illness or death. DOE solicited and received a number of comments on the appropriate burden of proof and causation standard to be applied by the Physician Panels. Some commenters expressed support for an ''as likely as not,'' or a ''more likely than not'' standard. Other commenters supported a standard of ''any contributing factor'' or ''a substantial contributing factor.'' Still other commenters suggested a standard of ''significant factor in aggravating, contributing to or causing illness, disability or death,'' and other commenters supported State-specific causation standards.

DOE has decided, for several reasons, that Physician Panels should not use standards of the individual States with regard to medical causality or burden of proof determinations, and that instead, the regulations should require Physician Panels to use the single uniform federal standard for burden of proof and medical causality set forth in section 852.8. First, while Part D certainly is susceptible of more than one interpretation on this point, DOE believes the best interpretation of the statutory text is that DOE should adopt a uniform federal standard. Nowhere does the statute indicate that Physician Panels should apply State standards for burden of proof or causation; indeed, 42 USC § 7385o(d)(3) speaks in terms that seem to call for a single federal standard (i.e., the panels shall determine ''whether the illness or death that is the subject of the application arose out of and in the course of employment by the Department of Energy and exposure to a toxic substance at a Department of Energy facility'').

Second, DOE believes it will better effectuate the purpose and policy of Part D for the Physician Panels to apply a uniform federal standard. In DOE's view, the primary purposes of Part D are for DOE to assist deserving applicants in applying for and obtaining State workers' compensation benefits, to ease the administrative burden on applicants when applying for State workers' compensation benefits, and to enable some applicants to gain benefits that they might not receive under normal operation of the State systems by requiring DOE and its contractors not to contest certain State workers' compensation claims, using contract administration tools to encourage outcomes of this type. These purposes can be better fulfilled through a uniform federal causation standard for the Physician Panels. If the Physician Panels were required to use State standards of causation and burden of proof, applicants potentially would be forced to endure the administrative burden at the Physician Panel stage that Part D in fact wishes to relieve applicants from bearing at the State worker compensation proceeding stage.

Third, DOE believes that application of a single federal standard by the Physician Panels will make administration of the Part D program much more equitable and efficient. A requirement that Physician Panels (as well as the Program Office in reviewing Physician Panel determinations) use State-specific causation and burden of proof standards would require that the panels and Program Office become intimately familiar with the laws of numerous different States, and likely would lead to inconsistencies in how State law is interpreted and applied by the States, the Program Office and the Physician Panels. Such inconsistencies could, in turn, lead to inequitable results and wasteful controversy and litigation. A single federal standard will be easier for the Program Office and the Physician Panels to administer and will allow DOE to treat equally similarly situated applicants in different States.

Fourth, DOE believes a uniform federal causation standard allows DOE to promote the purposes of Part D by setting the standard at a level that fairly interprets the statutory command while also attempting to assist the largest possible number of deserving applicants. The use of State-specific causation standards would prevent DOE from furthering the statutory purposes in this manner. Such a result would be particularly inequitable and would not be a sound policy choice or interpretation of Part D, simply because Part D quite clearly does not compel the Program Office or Physician Panels to use State-specific causation standards.

As to the federal standard to be adopted and promulgated in section 852.8, DOE has decided that a Physician Panel must render a causation determination in the applicant's favor if the panel determines that it is at least as likely as not that exposure to a toxic substance at a DOE facility during the course of employment by a DOE contractor was a significant factor in aggravating, contributing to or causing the illness or death of the worker at issue. DOE intends that, as used in this context, the word ''significant'' should have its normal dictionary definition and meaning—that is, ''meaningful'' and/or ''important.''

DOE believes that the standard set forth in section 852.8 fairly interprets the text of Part D. It also represents a policy decision by DOE to aggressively pursue the purposes of Part D by setting the causation standard at a level that is below the level of proof that applicants might be required to demonstrate to obtain workers' compensation benefits in some States.

DOE has decided to adopt the ''significant factor'' causation standard rather than the ''more likely than not'' standard proposed in the NOPR because the ''more likely than not'' standard is too high and could result in deserving applicants being denied the assistance Part D was intended to afford. On the other hand, DOE rejects extremely lenient standards (such as ''any contributing factor'') because such standards do not constitute a fair interpretation of the statutory language (*i.e.*, that the illness or death ''arose out of and in the course of'' employment at a DOE facility and exposure to a toxic substance).

DOE recognizes that the causation standard in section 852.8, and the causation standard applied by DOL for certain benefits determinations under other compensation programs established by the Act, are different. DOE further recognizes that this difference in causation standards may contribute to some applicants who file applications in both the DOE and DOL programs receiving inconsistent causation determinations from the two agencies. However, DOE determined that nothing in the Act required that the same causation standard be used for both the program administered by DOL and the Part D program administered by DOE. Indeed, the Act itself sets forth different causation standards for the different programs.

Furthermore, and as noted above, DOE intends to aggressively pursue the purposes of Part D. DOE believes as a policy matter that this objective can best be accomplished through DOE's adoption of the ''significant factor'' causation standard set forth in section 852.8 even thought it may differ from the standards that DOL is required by law to apply.

In addition, regardless what standard DOE adopts, it is extremely unlikely that all applicants would receive identical causation determinations from both the DOL and DOE programs. The statutory language for the two agencies' programs is different, the two programs focus on entirely different benefit mechanisms (i.e., DOE's program under Part D focuses on assisting applicants obtain State workers' compensation benefits while the program administered by DOL focuses on direct federal payments to applicants), the programs are administered by two different federal agencies, and the Act requires that independent Physician Panels make the causation determinations for the applications submitted to DOE under the Part D program. DOE believes that rather than adopting a causation standard set forth in another part of the Act in a vain attempt to assure consistency in outcomes between the DOE and DOL programs, it should adopt the ''significant factor'' causation standard set forth in section 852.8. This standard is similar to the causation tests applied by many State workers' compensation programs and is appropriate for all the other reasons explained above. In short, DOE believes that the standard it has adopted is appropriate and properly carries out the intent of Part D, and that DOE should

not adopt a causation standard that attempts to mandate the same result for all applicants from both the DOE and DOL programs when perfect consistency in outcomes is extremely unlikely regardless of the causation standard DOE adopts.

Section 852.8 further specifies that Physician Panels should use the ''at least as likely as not'' burden of proof when determining whether exposure to a toxic substance at a DOE facility during the course of employment by a DOE contractor was a significant factor in aggravating, contributing to or causing the illness or death of the worker at issue. The NOPR stated that a panel would make its determination based on ''whether there is sufficient information to support'' the applicant's requested finding; that language implied that panels should use a preponderance of the evidence burden of proof. The final rule adopted by DOE is more favorable to applicants in that it requires that they meet only an ''at least as likely as not'' burden of proof.

The standard adopted today in section 852.8 is, DOE believes, very favorable to applicants while at the same time being consistent with the statutory language and good policy. DOE believes this standard will result in its being able to assist the largest number of deserving claimants consistent with the structure and statutory text of Part D.

*Q. What Materials Must a Physician Panel Review Prior to Making a Determination?*

Section 852.9 (proposed as section 852.8) stipulates that the Physician Panel must review all records relating to the application that are provided by the Program Office. Such records may include medical records, employment records, exposure records, an occupational history, workers' compensation records, pertinent medical literature or reports, and any other records or evidence pertaining to the applicant's request for assistance, including additional discretionary information submitted by the applicant or the employer. For a deceased worker, such records may include a Medical Examiner's or Coroner's report or a death certificate. For an applicant who has also submitted a claim to DOL under the Act, such records may include any available information submitted as a part of such a claim or developed by DOL or HHS in the course of processing such a claim, including estimates of an applicant's cumulative radiation dose and the calculated probability that the employee's illness or death was caused by that radiation dose.

Proposed section 852.8 had stated that each Physician Panel should review all such records prior to making a determination. A commenter expressed an opinion that a Physician Panel must be required to review all relevant information, both supportive and non-supportive, and render a determination based on all of the information. DOE agrees that a fair and accurate adjudication of a claim is predicated on a Physician Panel reviewing all available information presented to it, and has accordingly changed ''should'' to ''must'' in section 852.9.

Several commenters asked questions or made suggestions as to what role DOE should have in assisting the applicant in gathering information in support of an application, including a suggestion that an independent medical examination might help expedite the Physician Panel review by focusing on information relevant to determining compensability under State law. Commenters expressed the opinion that DOE should pay for the development of medical evidence in support of an application, and suggested that DOE should use the Former Worker Medical Surveillance Program to accelerate and enhance implementation of Part D.

Part D does not authorize DOE to create a new program of examination and testing for applicants, nor does it authorize appropriations for this purpose. DOE believes that the Program Office's role is to assist an applicant in obtaining and assembling existing information relevant to a claim, including employment, exposure and medical information under the control of DOE and its contractors, information provided by the applicant, and information from outside sources whose transmittal to DOE has been authorized by the applicant.

However, where it is able, DOE will assist applicants by providing to them and to the Physician Panel relevant information in DOE's control. DOE's Former Worker Medical Surveillance Program currently consists of pilot projects run by consortia of universities, unions and occupational health experts funded through cooperative agreements with DOE for the purpose of providing former DOE contractor employees with medical surveillance examinations directed at detecting potential work-related disorders. The Former Worker Medical Surveillance Program is distinct from the program authorized by Part D of the Act and administered by the Program Office. The Program Office intends to utilize information generated by the Former Worker Program projects in the following manner. First, the Program Office will utilize the projects' hazard surveys of DOE sites (know as ''Phase I/Needs Assessments'') as sources of occupational exposure information for use by the Physician Panels. Second, if an applicant has previously received a medical surveillance examination through a Former Worker Program project, the Program Office will ask the applicant to sign a release so that the Program Office can obtain the results of this examination.

A commenter stated that in assisting the applicants seeking compensation from their State's workers compensation systems, DOE should make use of state-of-the-art analytical techniques to determine amounts of radionuclide body burdens that the applicants may have. As stated above, DOE is not funding further medical examinations of applicants under this program. However, HHS will be conducting radiation dose reconstructions for those applicants who have submitted a claim for cancer to DOL under Part A of EEOICPA and whose claim is not for compensation under provisions governing compensation for members of the Special Exposure Cohort. These dose reconstructions will evaluate and make use of existing information from DOE and other sources, including claimants, relevant to estimating the radiation doses incurred by cancer claimants in the performance of duty for DOE and it contractors. HHS will report the methods and results of these dose reconstructions to claimants, DOL and DOE. DOE intends to provide copies of these reports to the Physician Panels for radiation-related claims. In these cases, the applicant may also want to provide the Physician Panel with the probability of causation determination established by DOL based on the NIOSH dose reconstruction.

*R. How May a Physician Panel Obtain Additional Information or a Consultation That It Needs To Make a Determination?*

A Physician Panel may, on occasion, need additional information or consultations to make its determination. For expediency, documentation of evidence, maintenance of confidentiality, and records control, section 852.10 (proposed as section 852.9) requires the Physician Panel to make all requests for additional information through the Program Office. The panel may request an interview with the applicant, if the panel believes that only the applicant can supply the necessary information. Based upon the experiences of similar physician panels, including the Expert Panel of the

Fernald II Workers' Settlement Fund,[1] it is anticipated that such a request will be unusual, but may be necessary in rare cases in order to obtain essential information. The panel can also request that the applicant provide additional medical information. The Physician Panel may request consultation with specialists in fields relevant to its deliberations, if needed, as provided for in section 3661(d)(4) of the Act, or refer to relevant medical and scientific literature. The Program Office will maintain a roster of available specialists for this purpose.

New section 852.10(c) was added in the final regulations in order to codify within the rule a requirement of section 3661(d)(4) of the Act. Section 3661(d)(4) requires that, at the request of a Physician Panel, DOE or a DOE contractor who employed the DOE contractor employee must provide additional information relevant to the panel's deliberations. Under new section 852.10(c), a Physician Panel may also request additional information under the control of DOE or its contractors. It is anticipated that these will be important sources of information in many cases.

One commenter expressed an opinion that a duty to produce the historical exposure records should be placed on the contractor, instead of placing it wholly on the Program Office. DOE notes that section 3661(d)(4) of the Act (42 U.S.C. 7385o(d)(4)) implicitly places this obligation on both DOE and on the DOE contractor. Section 852.10(c) permits a Physician Panel to request relevant information in control of DOE or its contractors. DOE intends that all relevant information should be provided to a Physician Panel whether in possession of DOE or its contractor, to the extent permitted by law.

A commenter stated that requiring applicants to interview before a Physician Panel may result in a financial burden and physical hardship on applicants and stated that alternative methods of obtaining information should be explored. This commenter asked who will pay for any travel associated with an applicant's interview, if a panel requests such an interview. This commenter also asked whether a specialist will be paid, when consultation with a specialist is required, and what the rate of pay for specialists will be.

DOE recognizes the hardships for the applicant associated with an interview, and anticipates that such an interview will only be required in those unusual instances when essential information is not available from any other source. When an interview with the applicant is required, the Program Office will strive to arrange such an interview at a time and place convenient to the applicant and consider alternatives (e.g., telephone interviews) to face to face meetings. As discussed previously, the applicant is responsible for developing the medical information upon which the applicant bases its claim, and therefore DOE is not responsible for paying for the development of new medical information. However, to the extent the Physician Panel requests a consultation with a specialist to discuss medical information already in its possession, DOE will pay the costs associated with this consultation.

*S. How Is a Physician Panel To Carry Out Its Deliberations and Arrive at a Determination?*

After each member of a Physician Panel reviews the information submitted to the panel, the panel members will discuss an application and arrive at a determination. Because it is anticipated that Physician Panels will be spread out geographically, section 852.11 (proposed as section 852.10) permits teleconferencing. This system has worked well for prior Physician Panels, such as the Expert Panel of the Fernald II Workers' Settlement Fund.[2]

In the NOPR, DOE proposed that the panel members be required to reach a ''common'' determination. The NOPR did not explain what might happen if such a common or unanimous determination could not be reached. Some commenters objected to the requirement for panel unanimity, apparently on the ground that this could result in a single panel member defeating the will of the majority to make a causation determination in an applicant's favor.

DOE has decided that a panel determination should require only a majority of the panel members approving that determination, and thus DOE had modified the text of section 852.11 accordingly. This approach will promote the purposes of the statute by enabling more deserving employees to receive favorable panel determinations. This approach also will promote efficient administration of the program by eliminating the problems that otherwise might arise with respect to a non-unanimous panel. Furthermore, allowing panel determinations to be based on a majority rather than a unanimous decision by the panel members better accommodates the inherent uncertainty of some medical and medical causation decisions, and ensures that applicants will receive a fair determination even in situations where, for whatever reason, the determination is not unanimous.

*T. How Must a Physician Panel Issue Its Determination?*

In order to ensure that a Physician Panel has made its determination based upon the relevant evidence and that it has provided the basis for its determination, section 852.12 (proposed as section 852.11) requires the Physician Panel to identify the materials it has reviewed in making its determination, and express the determination and its basis in a series of findings that logically links the evidence reviewed to the conclusions drawn.

DOE anticipates that some covered workers who have applied for benefits under the DOL program will also apply for assistance from the Program Office in filing a claim with a State workers' compensation system. However, filing a claim under the DOL program is not a requirement for the DOE program. In addition, and as explained above, some applicants who submit applications in both the DOE and DOL programs may receive different causation determinations from the two agencies. For example, under the DOL program, a member of a Special Exposure Cohort, as defined in section 3621(14) of the Act (42 U.S.C. 7384l(14)), who has a specified cancer could establish entitlement to benefits for a specified cancer without showing that the disease is the result of exposure to a toxic substance because the statute dispenses with that requirement for Special Exposure Cohort members in the DOL program. A Physician Panel, however, can make a positive determination only if sufficient evidence is provided to meet the standard as specified in section 852.8. As to non-Special Cohort members in the DOL program, factual findings made by DOL, including findings based on dose reconstructions performed by HHS regarding the likelihood that cancer was caused by occupational exposure to radiation, while relevant to a panel's assessment, are not binding on a Physician Panel. A

[1] The Fernald II Workers' Settlement Fund was established to settle a class action lawsuit by the employees of National Lead of Ohio (NLO), which operated the Feed Materials Production Center (Fernald) DOE facility from 1951 to 1985. A component of this settlement fund is an Expert Panel Review to determine the work relatedness of an illness claimed by an NLO employee as resulting from exposure to radioactive material or other toxins. The Expert Panel consists of three Occupational/Environmental Health physicians who have the option of interviewing a claimant, but rarely need such an interview to make a determination, relying in most cases on existing written records.

[2] Ibid.

Physician Panel would be expected to explain the extent to which it based its determination on the findings of any agency in its report to the Program Office.

Proposed section 852.11(c)(4) in the NOPR required a Physician Panel, if explicitly requested by the Program Office, to provide the Program Office with a finding as to whether a specific criterion in a State Agreement has been satisfied. Three commenters asserted that Physician Panels should not be called upon to interpret State law. Another stated that State workers' compensation systems recognize and accept physicians' findings as to causality, and do not rely on physicians to make findings as to compensability.

DOE agrees that the role of the Physician Panel is to make a determination as to the relationship between a claimed illness and exposures to a toxic substance at a DOE facility. Accordingly, the Physician Panel will not be required to provide a specific interpretation of a non-medical provision of a State workers' compensation system. However, if a State Agreement provides for a Physician Panel to make a determination concerning a medical issue in addition to causation and specifies the medical criteria to be applied, then panels will make such determinations in appropriate cases. For example, a State Agreement could set forth the State criteria for determining the extent of disability or impairment and provide for the Physician Panels to make determinations on these medical issues. However, the panel determinations with respect to such issues will not affect whether a ''positive'' or ''favorable'' determination is rendered for an applicant with all its attendant consequences under this program. Whether a positive or favorable determination is rendered is to be based solely on the standard and criteria set forth in section 852.8.

*U. When Must a Physician Panel Issue Its Determination?*

Section 852.13 (proposed as section 852.12) requires a Physician Panel to submit its determination to the Program Office within 30 working days of receiving the application materials, unless granted an extension by the Program Office, which then sets the new deadline. New section 852.13(b) further stipulates that, when a Physician Panel requests additional information or a consultation necessary to the panel's deliberations, the deadline for panel determination is extended to 15 working days after receipt of the requested information or the consultant's recommendations.

A commenter stated that the rule should define the ''applicant's material'' and describe the Physician Panel's obligation if the ''applicant's material'' is deemed incomplete or otherwise inadequate for consideration.

Because section 852.4 allows some discretion on the part of the applicant and the employer as to what materials are submitted, and because there will be a wide variation in the type and amount of information available from other sources, it is not possible to define precisely what the application materials will consist of, beyond the materials that the applicant is required to submit, as outlined in section 852.4. In those instances where the Physician Panel deems the application materials to be insufficient, the Physician Panel's obligations are defined in section 852.10, which requires the Physician Panel to request any additional information needed. New section 852.13 further requires a Physician Panel to issue a determination in a timely fashion after receiving additional requested information or a consultation with a specialist.

*V. What Precautions Must Each Physician Panel Member and Each Specialist Take in Order To Keep an Applicant's Personal and Medical Information Confidential?*

Because records for review by the Physician Panels and by medical specialists consulted at the request of these panels contain confidential, personal, and medical information, section 852.14 (proposed as section 852.13) is included to provide safeguards that Physician Panels and specialists must follow to preserve the confidentiality of this information. Physician Panel members and specialists are required to comply with all provisions of the Privacy Act of 1974 applicable to worker advocacy records, including maintaining paper records in locked cabinets and desks. Release of information to a third party is also barred, unless such release is authorized by the applicant.

*W. What Actions Must a Physician Panel Member Take if a Member of the Panel Has a Potential Conflict of Interest in Relation to a Specific Application Submitted to the Panel?*

In order to ensure objectivity and fairness, section 852.15 (proposed as section 852.14) requires each panel member to report to the Program Office any real or perceived conflict of interest with regard to a particular application to the Program Office, and to cease reviewing the application pending instruction by the Program Office. The Program Office will then take appropriate actions to remedy the situation, which generally will mean referring the application to a different Physician Panel. At least two Physician Panels will be designated to review applications submitted by employees of each DOE facility.

A commenter suggested that the proposed section 852.14 did not go far enough in addressing potential conflicts of interest, and called for public disclosure of potential conflicts of interest. It is DOE's position that, in addition to the reporting requirements of section 852.15, adequate safeguards have been taken to avoid potential conflicts of interest because, among other things, the selection of Physician Panel members will be performed by HHS independently of DOE.

*X. When May the Program Office Ask a Physician Panel To Reexamine an Application That Has Undergone Prior Physician Panel Review?*

Section 852.16 (proposed as section 852.15) provides that the Program Office may refer a case for reexamination to the same panel or to a different panel, after the original panel has made a determination if: there is significant evidence contrary to the panel determination; the Program Office obtains new information the consideration of which would be reasonably likely to result in a different determination; the Program Office becomes aware of a real or potential conflict of interest on the part of a member of the original panel in relation to the application under review; or reexamination is necessary to ensure consistency among panels.

Several commenters felt that the Program Office's review powers were too broad in the NOPR. DOE agrees that a Physician Panel determination should be accorded deference and DOE generally anticipates accepting a Physician Panel determination in favor of an applicant. The statute does, however, specifically contemplate review and discretion by the Program Office in determining whether to accept such a determination, in that the statute specifies that the Program Office shall accept such a finding unless there is ''significant evidence to the contrary.'' In the final rule, the discretion of the Program Office to ask a Physician Panel to reexamine an application has been delineated to balance these competing considerations.

*Y. Must the Program Office Accept the Determination of a Physician Panel?*

Unless a reexamination is requested pursuant to section 852.16, section 852.17 (proposed as section 852.16) requires the Program Office to accept a Physician Panel's determination, except where the Program Office determines there is significant evidence contrary to the panel determination. The Program Office must notify the applicant and the employer, in a timely fashion, of its acceptance or rejection of a Physician Panel determination.

Proposed section 852.16 required only the prompt notification of the applicant of a determination. In the final rule, notification is extended to the relevant DOE contractor employers because of the potential impact of the Program Office's determination on those parties.

*Z. Is There an Appeals Process?*

Section 852.18 (proposed as section 852.17) provides that an applicant may request DOE's Office of Hearings and Appeals (OHA) to review certain Program Office decisions. An applicant may appeal a decision by the Program Office not to submit an application to a Physician Panel, a negative determination by a Physician Panel that is accepted by the Program Office, and a final decision by the Program Office not to accept a Physician Panel determination in favor of an applicant. An applicant may not, however, appeal to OHA a Program Office decision to submit an application for reexamination pursuant to section 852.16.

An applicant must file a notice of appeal with OHA on or before 30 days from the date of a letter from the Program Office notifying the applicant of a decision appealable under this section. OHA will consider appeals in accordance with its procedures set forth in 10 CFR Part 1003. A decision by OHA constitutes DOE's final determination with respect to an application.

A commenter agreed that an applicant should have a right to appeal a determination not to submit the application to the Physician Panel, but expressed concern about the independence of OHA. OHA is an office within DOE. However, apart from being within the same agency, it is administratively and functionally independent of the Program Office. Although a decision by OHA constitutes DOE's final determination with respect to an application, it is not the final remedy for an applicant. Regardless of DOE's final determination on a claim, an applicant may still file a claim with the applicable State workers' compensation program.

*AA. What Is the Effect of the Acceptance by the Program Office of a Determination by a Physician Panel in Favor of an Applicant?*

Section 852.19 (proposed as section 852.18) sets forth the effect of acceptance by the Program Office of a determination by a Physician Panel in an applicant's favor. In the event the Program Office accepts such a determination by a Physician Panel, the Program Office must assist the applicant in filing a claim with the relevant State's workers' compensation system and cannot contest the claim or any award made regarding the health condition that was the subject of the Physician Panel determination in the applicant's favor.

There were many comments regarding proposed section 852.18. Commenters expressed concerns about what actions DOE will take in order to ensure that claims based upon positive Physician Panel determination will not be contested by its contractors. Section 852.19 requires the Program Office to advise the cognizant Secretarial Officer to recommend to the relevant Contracting Officer that, to the extent permitted by law, the DOE contractor be directed not to contest the claim or award. Furthermore, any cost of contesting the claim or award is not an allowable cost under a DOE contract.

All workers' compensation costs incurred as a result of an award on a claim based on the health condition that was the subject of a Physician Panel determination in favor of an applicant are allowable, reimbursable contract costs to the fullest extent permitted under a contract. This final provision of section 852.19 was added in final rulemaking in order to ensure that a DOE contractor who incurs additional workers' compensation award costs as a result of the rule is able to recover such costs from DOE.

Part D only provides that DOE may direct its contractors not to contest a determination by a Physician Panel. It neither affects nor authorizes DOE to give directives to persons who are not DOE contractors. Thus, it will not affect persons who have no privity of contract with DOE, such as insurers. Likewise, it will not affect persons who lease DOE facilities for commercial purposes. While leases may be considered contracts, they typically have no provisions that would permit DOE to direct a lessee not to contest a workers' compensation claim or that would require DOE to reimburse the lessee for a workers' compensation claim. In addition, DOE may direct its contractors not to contest a determination by a Physician Panel only to the extent permitted by law. Thus, DOE cannot direct a contractor to take action that would violate the contractor's obligations under a State workers' compensation system or other legal obligations such as a contractual obligation to an insurer.

Part D further provides that, in the case of a Physician Panel determination in an applicant's favor that has been accepted by the Program Office, DOE must assist an applicant in filing a claim under the appropriate State workers' compensation system. DOE notes that there is nothing in Part D of the Act requiring an applicant to file a claim after the Program Office accepts a positive Physician Panel determination. The applicant is responsible for evaluating the merits of filing a claim. If an applicant elects to seek relief under a State workers' compensation Program, Part D places an obligation upon DOE to assist the applicant in filing a claim. This assistance will include the provision of the determination and other information developed by a Physician Panel. It will not include representation or other such assistance after the filing of a claim with a State workers' compensation system.

A commenter stated that even when causation has been established, there is still a disability determination that needs to be made under the State workers' compensation system. DOE believes that all such determinations should be made in the normal course of the operation of State workers' compensation statutes and administrative procedures. A commenter was concerned that costs associated with a disability determination would not be allowable. DOE has concluded that the disallowance of costs associated with contesting a claim that has been the subject of a Physician Panel determination in an applicant's favor pertains to all costs of supporting arguments or activities with the intent or effect of delaying or defeating a claimant's ability to recover State workers' compensation benefits for the health condition for which the applicant has received a final favorable Physician Panel determination. This obviously applies not only to ''contesting'' claims before the relevant State workers'' compensation authority, but also to ''contesting'' such claims on appeal or in any other administrative or judicial forum. Subsequent employer costs are allowable to the extent that, and if consistent with the contractor's contract with DOE, under the applicable State workers' compensation statutes, it is customary for the employer to take an

active role in settling issues related to the claim, such as the extent of injury, allocation of liability among multiple employers, or calculation of actual benefits, but only to the extent such activities do not have the intent or effect of delaying or defeating a claimant's ability to recover workers' compensation benefits. If a State Agreement provides for a Physician Panel to determine a State-specific medical issue such as the degree of disability or impairment, DOE may direct a contractor not to contest that determination in a State proceeding and may not reimburse costs incurred in contesting such a determination.

A commenter noted that this program will result in increased workers' compensation premiums to its contractors, and that additional workers' compensation claims will affect a contractor's State experience rating as a result of its workers' compensation experience. To the extent premium increases do occur or experience ratings are adversely affected, those effects are the necessary results of the Program established by Congress under Part D.

*BB. General Comments on the NOPR*

A number of workers, former workers, their survivors and representatives had general comments on the NOPR without specific reference to a particular section. A number of commenters stated that the affected workers had endured exposure to many hazards, and deserved a program of real assistance. Two commenters noted the patriotism of these workers. A number of commenters felt that the rule, as proposed, was not assisting sick workers, as intended by the Act.

In this notice of final rulemaking, DOE has carefully considered the major issues emerging from the comments on the NOPR, and believes that the final rule has addressed those issues. DOE believes that the final rule goes as far as the Act authorizes DOE to go in providing assistance.

A commenter expressed concern about the status of applications for Physician Panel review already received under this Act. The commenter wanted to know if these filings are null and void, pending negotiation of the State Agreements. DOE will retain and act on these filings when the administrative machinery is in place to process them. Under the Act, the promulgation of this rule is the necessary first step in that endeavor. The establishment of State Agreements can now begin. That in turn will allow DOE to begin processing these claims.

A commenter asked for clarification on how DOE will respond to cases where State has already considered and denied a workers' compensation claim for the same or related health condition that will be the basis for the applicants claim under the Part D program. The Program Office will process these claims in the same manner as other claims. It must be noted, however, that the Act does not change the normal operation of any State workers' compensation system, and does not create any new grounds for re-opening any decision already rendered under State law.

## III. Regulatory Review and Procedural Requirements

*A. Review Under Executive Order 12866*

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

*B. Review Under the Regulatory Flexibility Act*

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires preparation of an initial regulatory flexibility analysis for any rule that by law must be for public comment, unless the agency certifies that the rule, if promulgated, will not have a significant economic impact on a substantial number of small entities. The rule would provide guidelines for the operation and determinations of Physician Panels established to provide expert opinion to DOE on the cause of a worker's illness or death. It would not impose costs or burdens on any small business or other small entity. DOE, therefore, certifies that the rule will not have a significant economic impact on a substantial number of small entities.

*C. Review Under the Paperwork Reduction Act*

The rule provides that an individual may submit an application for review and assistance to the Program Office that contains information relating to the individual's employment by a DOE contractor, the nature of the illness or death, and the relationship between the illness or death and the individual's employment at a DOE facility. The application is required for DOE to determine whether reasonable evidence exists for submitting the individual's application to a Physician Panel.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection has been reviewed and assigned a control number by OMB. DOE submitted the proposed collection of information in the rule to OMB, simultaneously with the publication of the NOPR for review and approval under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* OMB has approved the collection of information in the rule and assigned it control number 1910.

*D. Review Under the National Environmental Policy Act*

DOE has concluded that promulgation of the rule falls into a class of actions that would not individually or cumulatively have a significant impact on the human environment, as determined by DOE's regulations implementing the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*). Specifically, the rule deals only with Physician Panel procedures, and, therefore, is covered under the Categorical Exclusion for rulemakings that are strictly procedural in paragraph A6 of Appendix A to subpart D, 10 CFR part 1021. Accordingly, neither an environmental assessment nor an environmental impact statement is required.

*E. Review Under Executive Order 13132*

Executive Order 13132, ''Federalism,'' 64 FR 43255 (August 4, 1999), imposes certain requirements on Agencies formulating and implementing policies or regulations that preempt State law or that have federalism implications. Agencies are required to 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.'' On March 14, 2000, DOE published a statement of policy describing the intergovernmental consultation process it will follow in the development of such regulations (65 FR 13735). DOE has examined today's rule and has determined that it does 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. The scope of the rule is limited to defining how a Physician Panel established under the Act will determine whether the illness

or death that is the subject of an application for assistance in filing a claim under a State's workers' compensation system arose out of and in the course of employment by DOE and exposure to a toxic substance at a DOE facility. Referral of an application to a Physician Panel can occur only by agreement with the applicable State. The rule would leave to the State the determination of benefits. Thus, the rule would not preempt State workers' compensation law. No further action is required by Executive Order 13132.

*F. Review Under Executive Order 12988*

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

*G. Review Under the Unfunded Mandates Reform Act*

Title II of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) requires each Federal Agency to prepare a written assessment of the effects of any Federal mandate in a proposed or final rule that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million in any single year. The Act also requires a Federal Agency to develop an effective process to permit timely input by elected officers of State, local, and tribal governments on a proposed ''significant intergovernmental mandate,'' and it requires an Agency to develop a plan for giving notice and opportunity for timely input to potentially affected small governments before establishing any requirement that might significantly or uniquely affect small governments. The rule published today does not contain any Federal mandate, so these requirements do not apply.

*H. Review Under the Treasury and General Government Appropriations Act, 1999*

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

*I. Review Under Executive Order 13211*

Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use,'' 66 FR 28355 (May 22, 2001) requires Federal agencies to prepare and submit to the Office of Information and Regulatory Affairs (OIRA), Office of Management and Budget, a Statement of Energy Effects for any proposed significant energy action. A ''significant energy action'' is defined as any action by an agency that promulgates or is expected to lead to the promulgation of a final rule, and that: (1) Is a significant regulatory action under Executive Order 12866, or any successor order; and (2) is likely to have a significant adverse effect on the supply, distribution, or use of energy; or (3) is designated by the Administrator of OIRA, as a significant energy action. For any proposed significant energy action, the agency must give a detailed statement of any adverse effects on energy supply, distribution, or use should the proposal be implemented, and of reasonable alternatives to the action and their expected benefits energy supply, distribution, and use.

Today's rule is not a significant energy action. Accordingly, DOE has not prepared a Statement of Energy Effects.

*J. Congressional Notification*

As required by 5 U.S.C. 801, DOE will submit to Congress a report regarding issuance of today's final rule prior to the effective date set forth at the outset of this notice. The report will state that it has been determined that the rule is not a ''major rule'' as defined by 5 U.S.C. 801(2).

**List of Subjects in 10 CFR Part 852**

Administrative practice and procedure, Government contracts, Hazardous substances, Workers' compensation.

Issued in Washington, DC, on August 7, 2002.

**Beverly A. Cook,**

*Assistant Secretary for Environment, Safety and Health.*

For the reasons stated in the preamble, DOE hereby amends Chapter III of title 10 of the Code of Federal Regulations by adding part 852 to read as follows:

## PART 852—GUIDELINES FOR PHYSICIAN PANEL DETERMINATIONS ON WORKER REQUESTS FOR ASSISTANCE IN FILING FOR STATE WORKERS' COMPENSATION BENEFITS

Sec.

**Authority:** 42 U.S.C. 7384, *et seq.*; 42 U.S.C. 2201 and 7101, *et seq.*; 50 U.S.C. 2401 *et seq.*

### § 852.1 What is the purpose and scope of this part?

(a) This part implements Part D of the Act by establishing the procedures under which:

(1) An individual may obtain and submit an application to the Program Office for review and assistance;

(2) The Program Office processes and submits eligible applications to a Physician Panel;

(3) Physician Panels determine whether the illness or death of a DOE contractor employee arose out of and in the course of employment by a DOE contractor and through exposure to a toxic substance at a DOE facility;

(4) The Program Office processes a determination by a Physician Panel; and,

(5) Appeals may be undertaken.

(b) This part covers applications filed by or on behalf of a DOE contractor employee, or a deceased employee's estate or survivor, with respect to an illness or death of a DOE contractor employee that may have been caused by exposure to a toxic substance during the course of employment at a DOE facility.

(c) All actions under this part must be pursuant to the relevant State Agreement and consistent with its terms and conditions.

### § 852.2 What are the definitions of terms used in this part?

*Act* means the Energy Employees Occupational Illness Compensation Program Act of 2000, 42 U.S.C. 7384 *et seq.*

*Applicant* means an individual seeking assistance from the Program Office in filing a claim with the relevant State workers' compensation system, including but not limited to, a living DOE contractor employee, the estate of a deceased DOE contractor employee, or any survivor of a deceased DOE contractor employee who is eligible to apply for a death benefit or a survivor's benefit under the State workers' compensation system for which the applicant is seeking assistance in filing a claim.

*DOE* means the U.S. Department of Energy, and its predecessor agencies, including the Manhattan Engineering District, the Atomic Energy Commission, and the Energy Research and Development Administration.

*DOE contractor employee* means any of the following:

(a) An individual who is or was in residence at a DOE facility as a researcher for one or more periods aggregating at least 24 months.

(b) An individual who is or was employed at a DOE facility by

(i) An entity that contracted with DOE to provide management and operation, management and integration, or environmental remediation at the facility; or

(ii) A contractor or subcontractor that provided services, including construction and maintenance, at the facility.

*DOE facility* means any building, structure or premise, including the grounds upon which such building, structure, or premise is located:

(a) In which operations are, or have been, conducted by, or on behalf of DOE (except for buildings, structures, premises, grounds, or operations covered by Executive Order No. 12344, dated February 1, 1982 (42 U.S.C. 7158 note), pertaining to the Naval Nuclear Propulsion Program); and

(b) With regard to which DOE has or had

(i) A proprietary interest; or

(ii) Entered into a contract with an entity to provide management and operation, management and integration, environmental remediation services, construction, or maintenance services.

*Physician panel* means a group of three physicians appointed by the Secretary of Health and Human Services, pursuant to Part D of the Act, to evaluate potential claims of DOE contractor employees under the appropriate State workers' compensation system.

*Program office* means the Office of Worker Advocacy within DOE's Office of Environment, Safety and Health, or any other DOE office subsequently assigned to perform the functions of the Secretary of Energy under Part D of the Act.

*State agreement* means an agreement negotiated between DOE and a State that sets forth the terms and conditions for dealing with an application for assistance under Part D of the Act in filing a claim with the State's workers' compensation system.

*Toxic substance* means any material that has the potential to cause illness or death because of its radioactive, chemical, or biological nature.

### § 852.3 How does an individual obtain and submit an application for review and assistance?

(a) An individual obtains an application for review and assistance:

(1) In person from the Program Office, from any of the Resources Centers listed in Appendix A to this section, or from any DOE-sponsored Former Worker Program project;

(2) Through a written request mailed to Assistant Secretary, Office of Environment, Safety and Health, Office of Worker Advocacy, U.S. Department of Energy, 1000 Independence Ave., SW., Washington, DC 20585. or to any other address that DOE may subsequently publish by notice in the **Federal Register**;

(3) Through telephone request to 1–877–447–9756 or to any other telephone number that DOE may subsequently publish by notice in the **Federal Register**; or

(4) In printable format, from the Program Office's Web site at *http://tis.eh.doe.gov/advocacy/* or from any other Web site that DOE may subsequently publish by notice in the **Federal Register**.

(b) An individual submits an application for review and assistance—

(1) In person to the Program Office, to any Resource Center, or to any DOE-sponsored Former Worker Program project.

(2) By mail to the Program Office at the address identified in paragraph (a)(2) of this section, or to any other address that DOE may subsequently publish by notice in the **Federal Register**.

### § 852.4 What information and materials does an individual submit as a part of the application for review and assistance?

(a) As a part of the application for review and assistance, an individual must submit, in writing:

(1) Any application forms required by the Program Office.

(2) The name and address of any licensed physician who is the source of a diagnosis based upon documented medical information that the employee has or had an illness and that the illness may have resulted from exposure to a toxic substance while the employee was employed at a DOE facility and, to the extent practicable, a copy of the diagnosis and a summary of the information upon which the diagnosis is based.

(3) A signed medical release, authorizing non-DOE sources of medical information to provide the Program Office with any diagnosis, medical opinion and medical records documenting the diagnosis or opinion

that the employee has or had an illness and that the illness may have resulted from exposure to a toxic substance while the employee was employed at a DOE facility.

(4) To the extent practicable and appropriate, an occupational history obtained by a physician, an occupational health professional, or a DOE-sponsored Former Worker Program. (If such an occupational history is not reasonably available and is deemed by the Program Office to be needed for the fair adjudication of the claim, then the Program Office will assist the applicant in obtaining this history.)

(5) Any other information or materials deemed by the Program Office to be necessary to provide reasonable evidence that the employee has or had an illness that may have arisen from exposure to a toxic substance while employed at a DOE facility.

(b) The applicant may also submit directly to the Program Office any other information or materials providing evidence that the employee has or had an illness that may have resulted from exposure to a toxic substance during the course of employment at a DOE facility.

(c) The applicant must sign an affidavit attesting to the authenticity and completeness of any information or materials submitted to the Program Office, or provide the Program Office with other evidence of authenticity of submitted materials, such as certification of submitted copies of originals.

### § 852.5 What information and materials may an employer submit in response to a submission of an application to a Physician Panel?

(a) Upon receipt of an application and the Program Office's determination that the application meets the requirements of § 852.4, the Program Office must notify each of the applicant's relevant DOE contractor employers in writing of:

(1) The existence of the application;

(2) The name of the employee;

(3) The diagnosis claimed; and

(4) The likely date of onset or date of diagnosis, if known.

(b) The employer has 15 working days from receipt of this notification to submit to the Program Office any information deemed by the employer to be relevant to either the Program Office's determination of whether to refer an application to a Physician Panel, or to adjudication of the application by a Physician Panel.

(c) The employer must sign an affidavit attesting to the authenticity and completeness of any information provided to the Program Office under this section, or provide the Program Office with other evidence of authenticity of submitted materials, such as certification of submitted copies of originals.

### § 852.6 Which applications are submitted to a Physician Panel?

(a) The Program Office must submit an application and any information submitted under § 852.5 of this part to a Physician Panel if there is reasonable evidence to make an initial determination that:

(1) The application was filed by or on behalf of a DOE contractor employee or a deceased DOE contractor employee's estate or survivor;

(2) The illness or death of the DOE contractor employee may have been caused by exposure to a toxic substance; and,

(3) The illness or death of the DOE contractor employee may have been related to employment at a DOE facility.

(b) The Program Office must promptly notify the applicant in writing of an initial determination under this section.

### § 852.7 What provisions are set forth in State Agreements?

DOE may not execute a State Agreement that does not contain the following provisions:

(a) A statement that an application is submitted to a Physician Panel only if the application satisfies the criteria in § 852.6 of this part:

(1) The application was filed by or on behalf of a DOE contractor employee or a deceased DOE contractor employee's estate or survivor;

(2) The illness or death of the DOE contractor employee may have been caused by exposure to a toxic substance; and

(3) The illness or death of the DOE contractor employee may have been related to employment at a DOE facility.

(b) An agreement that a Physician Panel must apply the standards set forth in § 852.8 of this part when making a determination that an illness or death arose from exposure to a toxic substance during the course of employment at a DOE facility;

(c) An agreement that the Program Office must provide assistance to only those applicants with a positive determination from the Physician Panel; and

(d) An agreement that a positive determination by the Physician Panel has no effect on the scope of State workers' compensation proceedings, the conditions for compensation, or the rights and obligations of the participants in the proceeding; provided that consistent with Part D of the Act such a determination will prevent DOE and may prevent a DOE contractor from contesting an applicant's workers' compensation claim.

### § 852.8 How does a Physician Panel determine whether an illness or death arose out of and in the course of employment by a DOE contractor and exposure to a toxic substance at a DOE facility?

A Physician Panel must determine whether the illness or death arose out of and in the course of employment by a DOE contractor and exposure to a toxic substance at a DOE facility on the basis of whether it is at least as likely as not that exposure to a toxic substance at a DOE facility during the course of employment by a DOE contractor was a significant factor in aggravating, contributing to or causing the illness or death of the worker at issue.

### § 852.9 What materials must a Physician Panel review prior to making a determination?

The Physician Panel must review all records relating to the application that are provided by the Program Office, including but not limited to:

(a) Medical records;

(b) Employment records;

(c) Exposure records;

(d) Occupational history;

(e) Workers' compensation records;

(f) Medical literature or reports;

(g) Any other records or evidence pertaining to the applicant's request for assistance;

(h) A medical examiner's report, coroner's report, or death certificate for any application submitted by an estate or survivor of a deceased worker; and

(i) Information submitted as a part of such a claim or developed by the Department of Labor (DOL) or by the Department of Health and Human Services (HHS) in the course of processing a claim for the applicant, including, where applicable, estimates of an applicant's cumulative radiation dose and the calculated probability that this dose was responsible for a cancer that is the subject of the claim, for any application submitted by an applicant also applying to DOL for benefits available under the Act.

### § 852.10 How may a Physician Panel obtain additional information or a consultation that it needs to make a determination?

If, after reviewing all materials provided by the Program Office, a Physician Panel finds that it needs additional information or consultation with a specialist in order to make a determination, it must request this information or consultation through the Program Office. A Physician Panel may request:

(a) A recorded interview under oath with the applicant, by an individual designated by the Program Office, if the Physician Panel believes only the applicant can provide the necessary information.

(b) That the applicant provide additional medical information;

(c) Additional relevant information under the control of DOE or its contractors;

(d) Consultation with designated specialists in fields relevant to its deliberations;

(e) Specific articles or reports, or assistance searching the medical or scientific literature; or

(f) Other needed information or materials.

**§ 852.11 How is a Physician Panel to carry out its deliberations and arrive at a determination?**

(a) Each panel member reviews all materials relating to the application.

(b) All panel members meet in conference, in person, or by teleconference in order to discuss the application and arrive at a determination agreed to by a majority of the members of the Physician Panel.

**§ 852.12 How must a Physician Panel issue its determination?**

A Physician Panel must submit its determination under § 852.8 and the findings that provide the basis for its determination to the Program Office. The determination and the findings must be in writing and signed by all panel members. The findings must include:

(a) Each illness or cause of death that is the subject of the application.

(b) For each illness or cause of death listed under paragraph (a) of this section:

(1) Diagnosis;

(2) Approximate date of onset;

(3) Date of death, if applicable;

(4) Whether the illness or death arose out of and in the course of employment by a DOE contractor and exposure to a toxic substance at a DOE facility;

(5) The basis for the determination under paragraph (b)(4) of this section;

(6) A determination concerning any other medical issue identified in the relevant State Agreement; and

(7) The basis for the determination under paragraph (b)(6) of this section.

(c) The Physician Panel must provide the Program Office with:

(1) Any evidence to the contrary of the panel's determination, and why the panel finds this evidence is not persuasive.

(2) A listing of information and materials reviewed by the panel in making its determination, including:

(i) Information and materials provided by the Program Office; and,

(ii) Information and materials obtained by the panel, including consultations with specialists, scientific articles, and the record of any interview with an applicant.

(3) Any other information the panel concludes that the Program Office should have in order to understand the panel's deliberations and determination.

**§ 852.13 When must a Physician Panel issue its determination?**

(a) A Physician Panel must submit its determination and findings to the Program Office within 30 working days of the time that panel members have received the complete application for review from the Program Office.

(b) The Program Office may extend the deadline for a panel determination under the following circumstances:

(1) The Physician Panel indicates to the Program Office that it needs additional information or a consultation in order to carry out its deliberations, as provided for in § 852.10. In this case, the panel's determination is due 15 working days after receipt of the additional information (or notice from the Program Office that the requested information is unavailable), or 15 working days after receiving the consultant's recommendations, whichever is applicable; or

(2) The Physician Panel has requested and the Program Office has granted an extension.

(c) If an extension is granted pursuant to section 852.13(b)(2), the Program Office will specify the new deadline.

**§ 852.14 What precautions must each Physician Panel member and each specialist take in order to keep an applicant's personal and medical information confidential?**

In order to maintain the confidentiality of an applicant's personal and medical information, each Physician Panel member and each specialist consulted at the request of a Physician Panel must take the following precautions:

(a) Maintain the confidentiality of applicant records, keep them in a secure, locked location, and, upon completion of panel deliberations, follow the instructions of the Program Office with regard to the disposal or temporary retention of these records;

(b) Conduct all case reviews and conferences in private, in such a fashion as to prevent the disclosure of personal applicant information to any individual who has not been authorized to access this information;

(c) Release no information to a third party, unless authorized to do so in writing by the applicant; and

(d) Adhere to the provisions of the Privacy Act of 1974 regarding Worker Advocacy Records.

**§ 852.15 What actions must a Physician Panel member take if that member has a potential conflict of interest in relation to a specific application?**

(a) If a panel member has a past or present relationship with an applicant, an applicant's employer, or an interested third party that may affect the panel member's ability to objectively review the application, or that may create the appearance of a conflict of interest, then that panel member must immediately:

(1) Cease review of the application; and

(2) Notify the Program Office and await further instruction from the Office.

(b) The Program Office must then take such action as is necessary to assure an objective review of the application.

**§ 852.16 When may the Program Office ask a Physician Panel to reexamine an application that has undergone prior Physician Panel review?**

The Program Office may direct the original Physician Panel or a different Physician Panel to reexamine an application that has undergone prior Physician Panel review if:

(a) There is significant evidence contrary to the panel determination;

(b) The Program Office obtains new information the consideration of which would be reasonably likely to result in a different determination;

(c) The Program Office becomes aware of a real or potential conflict of interest of a member of the original panel in relation to the application under review; or

(d) Reexamination is necessary to ensure consistency among panels.

**§ 852.17 Must the Program Office accept the determination of a Physician Panel?**

(a) Subject to the ability of the Program Office to direct a reexamination pursuant to § 852.16, the Program Office must accept the determination by the Physician Panel unless the Program Office determines there is significant evidence contrary to the panel determination.

(b) The Program Office must promptly notify an applicant and the relevant DOE contractor(s) of its acceptance or rejection of a determination by a Physician Panel.

**§ 852.18 Is there an appeals process?**

(a) An applicant may request DOE's Office of Hearings and Appeals (OHA) to review:

(1) A decision by the Program Office not to submit an application to a Physician Panel;

(2) A negative determination by a Physician Panel that is accepted by the Program Office; and

(3) A final decision by the Program Office not to accept a determination in the applicant's favor by a Physician Panel.

(b) An applicant must file a notice of appeal with OHA on or before 30 days from the date of a letter from the Program Office notifying the applicant of a determination appealable under this section.

(c) An appeal under this section is subject to the procedures of OHA in 10 CFR Part 1003.

(d) A decision by OHA constitutes DOE's final determination with respect to an application.

**§ 852.19 What is the effect of the acceptance by the Program Office of a determination by a Physician Panel in favor of an applicant?**

In the event the Program Office accepts a determination by a Physician Panel in favor of an applicant:

(a) The Program Office must assist the applicant in filing a claim with the relevant State's workers' compensation system by providing the determination and other information provided to the Program Office by a Physician Panel pursuant to§ 852.12 of this part;

(b) The Program Office may not contest the determination;

(c) The Program Office must advise the cognizant DOE Secretarial Officer to recommend to the Contracting Officer (CO) for a DOE contractor that, to the extent permitted by law, the CO direct the contractor not to contest an applicant's workers' compensation claim or award in any administrative or judicial forum with respect to the same health condition for which the applicant received a favorable final Physician Panel determination;

(d) Any costs of contesting a claim or award identified in paragraph (c) of this section—that is, any costs of supporting arguments or activities with the intent or effect of delaying or defeating such a claim or award—are not allowable costs under a DOE contract; and,

(e) All workers' compensation costs incurred as a result of a workers' compensation award on a claim based on the same health condition that was the subject of a positive Physician Panel determination are allowable, reimbursable contract costs to the full extent permitted under the DOE contractor's contract with DOE.

[FR Doc. 02–20459 Filed 8–13–02; 8:45 am]

BILLING CODE 6450–01–P

## DEPARTMENT OF TRANSPORTATION

## Federal Aviation Administration

## 14 CFR Part 23

**[Docket No. CE172, Special Condition 23–125–SC]**

## Special Conditions; GROB–WERKE, Burkhurt Grob e.k., Unternehmensbereich Luft-und Raumfahrt, Model G120A Airplane; Protection of Systems From High Intensity Radiated Fields (HIRF): Correction

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Final special conditions; correction.

**SUMMARY:** The FAA published a document in the **Federal Register** on February 5, 2002, concerning final special conditions on the GROB–WERKE, Burkhurt Grob e.k., Unternehmensbereich Luft-und Raumfahrt, Model G120A airplane. There was an inadvertent error in the special condition number in the document. This document contains a correction to the special condition number for the final special conditions.

**DATES:** The effective date of these corrected special conditions is January 29, 2002.

**FOR FURTHER INFORMATION CONTACT:** Ervin Dvorak, Aerospace Engineer, Standards Office (ACE–110), Small Airplane Directorate, Aircraft Certification Service, Federal Aviation Administration, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone (816) 329–4123.

**SUPPLEMENTARY INFORMATION:**

### Need for Correction

The FAA published a document on February 5, 2002 (67 FR 5196) that issued final special conditions. In the document heading, a special condition number appears that had already been issued for another set of special conditions with a different docket number. This document corrects that error.

### Correction of Publication

Accordingly, the special condition number, which appears in the heading of Docket No. CE172, is revised from 23–110–SC to 23–125–SC.

Issued in Kansas City, Missouri on July 25, 2002.

**James E. Jackson,**

*Acting Manager, Small Airplane Directorate, Aircraft Certification Service.*

[FR Doc. 02–20628 Filed 8–13–02; 8:45 am]

BILLING CODE 4910–13–P

## DEPARTMENT OF TRANSPORTATION

## Federal Aviation Administration

## 14 CFR Part 23

**[Docket No. CE170, Special Condition 23–124–SC]**

## Special Conditions; Byerly Aviation, Twin Commander Models 690, 690A, 690B, 690C, 690D, 695, 695A, and 695B; Protection of Systems From High Intensity Radiated Fields (HIRF): Correction

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Final special conditions; correction.

**SUMMARY:** The FAA published a document in the **Federal Register** on October 5, 2001, concerning final special conditions on the Byerly Aviation Twin Commander Models 690, 690A, 690B, 690C, 690D, 695, 695A, and 695B airplane. There was an inadvertent error in the special condition number in the document. This document contains a correction to the special condition number for the final special conditions.

**DATES:** The effective date of these corrected special conditions is September 17, 2001.

**FOR FURTHER INFORMATION CONTACT:** Ervin Dvorak, Aerospace Engineer, Standards Office (ACE–110), Small Airplane Directorate, Aircraft Certification Service, Federal Aviation Administration, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone (816) 329–4123.

**SUPPLEMENTARY INFORMATION:**

### Need for Correction

The FAA published a document on October 5, 2001 (66 FR 50819) that issued final special conditions. In the document heading, a special condition number appears that had already been issued for another set of special conditions with a different docket number. This document corrects that error.

### Correction of Publication

Accordingly, the special condition number, which appears in the heading of Docket No. CE170, is revised from 23–109–SC to 23–124–SC.

Issued in Kansas City, Missouri on July 25, 2002.

**James E. Jackson,**

*Acting Manager, Small Airplane Directorate, Aircraft Certification Service.*

[FR Doc. 02–20630 Filed 8–13–02; 8:45 am]

**BILLING CODE 4910–13–P**

## DEPARTMENT OF TRANSPORTATION

## Federal Aviation Administration

## 14 CFR Part 23

**[Docket No. CE150, Special Condition 23–122–SC]**

## Special Conditions; Raytheon Aircraft Company, Raytheon Model 390 Airplane; Protection of Systems From High Intensity Radiated Fields (HIRF): Correction

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Final special conditions; correction.

**SUMMARY:** The FAA published a document in the **Federal Register** on December 28, 1998, concerning final special conditions on the Raytheon Aircraft Company Model 390 airplane. There was an inadvertent error in the special condition number in the document. This document contains a correction to the special condition number for the final special conditions.

**DATES:** The effective date of these corrected special conditions is December 11, 1998.

**FOR FURTHER INFORMATION CONTACT:** Ervin Dvorak, Aerospace Engineer, Standards Office (ACE–110), Small Airplane Directorate, Aircraft Certification Service, Federal Aviation Administration, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone (816) 329–4123.

**SUPPLEMENTARY INFORMATION:**

### Need for Correction

The FAA published a document on December 28, 1998 (63 FR 71369) that issued final special conditions. In the document heading, a special condition number appears that had already been issued for another set of special conditions with a different docket number. This document corrects that error.

### Correction of Publication

Accordingly, the special condition number, which appears in the heading of Docket No. CE150, is revised from 23–094–SC to 23–122–SC.

Issued in Kansas City, Missouri on July 25, 2002.

**James E. Jackson,**

*Acting Manager, Small Airplane Directorate, Aircraft Certification Service.*

[FR Doc. 02–20629 Filed 8–13–02; 8:45 am]

**BILLING CODE 4910–13–P**

## DEPARTMENT OF TRANSPORTATION

## Federal Aviation Administration

## 14 CFR Part 23

**[Docket No. CE186, Special Condition 23–126–SC]**

## Special Conditions; S–TEC on the New Piper Aircraft Corporation, PA 34–200T, Seneca V; Protection of Systems From High Intensity Radiated Fields (HIRF): Correction

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Final special conditions; correction.

**SUMMARY:** The FAA published a document in the **Federal Register** on July 17, 2002, concerning final special conditions for S–TEC on the New Piper Aircraft Corporation Model PA 34–200T airplane. There was an inadvertent error in the special condition number in the document. This document contains a correction to the special condition number for the final special conditions.

**DATES:** The effective date of these corrected special conditions is July 5, 2002.

**FOR FURTHER INFORMATION CONTACT:** Ervin Dvorak, Aerospace Engineer, Standards Office (ACE–110), Small Airplane Directorate, Aircraft Certification Service, Federal Aviation Administration, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone (816) 329–4123.

**SUPPLEMENTARY INFORMATION:**

### Need for Correction

The FAA published a document on July 17, 2002, that issued final special conditions. In the document heading, a special condition number appears that had already been issued for another set of special conditions with a different docket number. This document corrects that error.

### Correction of Publication

Accordingly, the special condition number, which appears in the heading of Docket No. CE186, is revised from 23–119–SC to 23–126–SC.

Issued in Kansas City, Missouri on July 25, 2002.

**James E. Jackson,**

*Acting Manager, Small Airplane Directorate, Aircraft Certification Service.*

[FR Doc. 02–20631 Filed 8–13–02; 8:45 am]

**BILLING CODE 4910–13–P**

## DEPARTMENT OF TRANSPORTATION

## Federal Aviation Administration

## 14 CFR Part 39

**[Docket No. 2001–NM–346–AD; Amendment 39–12853; AD 2002–16–14]**

**RIN 2120–AA64**

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

**AGENCY:** Federal Aviation Administration, DOT.

**ACTION:** Final rule.

**SUMMARY:** This amendment adopts a new airworthiness directive (AD) that is applicable to certain Bombardier Model CL–600–2B19 series airplanes. This AD requires inspection of certain installed electrical relays to determine whether they have certain manufacturing date codes, and replacement of the electrical relays with those date codes with new relays with different manufacturing date codes. This action is necessary to prevent the failure of an electrical relay due to a defective moving blade assembly, which could result in the inability to generate electrical power from the emergency system, if needed. This action is intended to address the identified unsafe condition.

**DATES:** Effective September 18, 2002.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of September 18, 2002.

**ADDRESSES:** 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 Federal Aviation Administration (FAA), Transport Airplane Directorate, Rules Docket, 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:** Luciano Castracane, Aerospace Engineer, Systems and Flight Test

Branch, ANE–172, FAA, New York Aircraft Certification Office, 10 Fifth Street, Third Floor, Valley Stream, New York 11581; telephone (516) 256–7535; fax (516) 568–2716.

**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 Bombardier Model CL–600–2B19 series airplanes was published in the **Federal Register** on April 4, 2002 (67 FR 16067). That action proposed to require inspection of certain installed electrical relays to determine whether they have certain manufacturing date codes, and replacement of the electrical relays with those date codes with new relays with different manufacturing date codes.

**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.

**Explanation of Credit Language**

Since the language in Notes 2, 3, and 4 of the proposed AD is regulatory in nature, the notes have been redesignated as paragraphs (b), (e), and (g) in this final rule. The remaining paragraphs of this final rule have been redesignated to accommodate these changes.

**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 with the changes described previously. The FAA had determined that these changes will neither increase the economic burden on any operator nor increase the scope of the AD.

**Cost Impact**

The FAA estimates that 160 airplanes of U.S. registry will be affected by this AD. It will take approximately 1 work hour per airplane to accomplish the required inspection at an average labor rate of $60 per work hour. Based on these figures, the cost impact of the required inspection on U.S. operators is estimated to be $9,600, or $60 per airplane.

It will take approximately 2 work hours per airplane to accomplish the required replacement of suspect relay K1XC at an average labor rate of $60 per work hour. There will be no charge for the replacement part. Based on these figures, the cost impact of the required replacement of suspect relay K1XC on U.S. operators is estimated to be a maximum of $19,200, or $120 per airplane.

It will take approximately 2 work hours per airplane to accomplish the required replacement of suspect relays K2XD and K3XD at an average labor rate of $60 per work hour. There will be no charge for the replacement parts. Based on these figures, the cost impact of the required replacement of suspect relays K2XD or K3XD on U.S. operators is estimated to be a maximum of $19,200, or $120 per airplane.

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:

**2002–16–14 Bombardier, Inc. (Formerly Canadair):** Amendment 39–12853. Docket 2001–NM–346–AD.

*Applicability:* Model CL–600–2B19 series airplanes, serial numbers 7003 through 7495 inclusive, 7497 through 7502 inclusive, and 7505 through 7507 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 (i) 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 the failure of an electrical relay due to a defective moving blade assembly, which could result in the inability to generate electrical power from the emergency system, if needed, accomplish the following:

**Inspection**

(a) Within 14 days after the effective date of this AD: Perform an inspection to determine whether installed Leach 'H' series power transfer relays K1XC, K2XD, and K3XD, all having part number (P/N) H–A4A–039, have a manufacturing date code of 0011 through 0050. The inspection for such ''suspect relays'' is to be performed in accordance with Bombardier Alert Service Bulletin A601R–24–105, Revision 'A', dated July 20, 2001.

(b) Inspections accomplished prior to the effective date of this AD in accordance with Bombardier Alert Service Bulletin A601R–24–105, dated July 4, 2001, are considered acceptable for compliance with the applicable action specified in this amendment.

(c) As of the effective date of this AD: For airplanes determined to have suspect Leach 'H' series relays K1XC or K2XD installed, dispatch with an inoperative integrated-drive generator (IDG) or auxiliary power unit (APU) is prohibited until replacement of the relay with a new relay is accomplished in accordance with paragraphs (d) and (f) of this AD.

**Replacement**

(d) Within 500 flight hours after the effective date of this AD: Replace suspect relay K1XC with a new relay having a manufacturing date code other than 0011 through 0050, in accordance with Bombardier Alert Service Bulletin A601R–24–105, Revision 'A', dated July 20, 2001.

(e) Replacement of suspect relay K1XC accomplished prior to the effective date of this AD in accordance with Bombardier Alert Service Bulletin A601R–24–105, dated July 4, 2001, is considered acceptable for compliance with the applicable action specified in this amendment.

(f) Within 1,000 flight hours after the effective date of this AD: Replace suspect relays K2XD and K3XD with new relays having a manufacturing date code other than 0011 through 0050, in accordance with Bombardier Alert Service Bulletin A601R–24–105, Revision 'A', dated July 20, 2001.

(g) Replacement of suspect relays K2XD and K3XD accomplished prior to the effective date of this AD in accordance with Bombardier Alert Service Bulletin A601R–24–105, dated July 4, 2001, is considered acceptable for compliance with the applicable action specified in this amendment.

**Spares**

(h) As of the effective date of this AD, no person shall install a Leach 'H' series electrical relay having P/N H–A4A–039 that has a manufacturing date code of 0011 through 0050 on any airplane.

**Alternative Methods of Compliance**

(i) 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.

**Note 2:** 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**

(j) 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**

(k) Unless otherwise specified in this AD, the actions shall be done in accordance with Bombardier Alert Service Bulletin A601R–24–105, Revision 'A', dated July 20, 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 Bombardier, Inc., Canadair, Aerospace Group, P.O. Box 6087, Station Centreville, 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 3:** The subject of this AD is addressed in Canadian airworthiness directive CF–2001–27, dated July 24, 2001.

**Effective Date**

(l) This amendment becomes effective on September 18, 2002.

Issued in Renton, Washington, on August 5, 2002.

**Vi Lipski,**

*Manager, Transport Airplane Directorate, Aircraft Certification Service.*

[FR Doc. 02–20268 Filed 8–13–02; 8:45 am]

**BILLING CODE 4910–13–P**

## DEPARTMENT OF TRANSPORTATION

## Federal Aviation Administration

## 14 CFR Part 39

**[Docket No. 2001–NE–37–AD; Amendment 39–12857; AD 2002–16–18]**

**RIN 2120–AA64**

## Airworthiness Directives; CFM International CFM56–5B and –7B Series Turbofan Engines

**AGENCY:** Federal Aviation Administration, DOT.

**ACTION:** Final rule.

**SUMMARY:** This amendment adopts a new airworthiness directive (AD), that is applicable to CFM International (CFMI) CFM56–5B and –7B series turbofan engines. This amendment requires retirement of stage 2 low pressure turbine (LPT) nozzle segments and stage 3 LPT nozzle segments, listed in Table 1 of this AD, from service before accumulating 25,000 cycles-since-new (CSN) or at the next LPT module shop visit when either stage 2 LPT nozzle segments or stage 3 LPT nozzle segments are exposed, whichever occurs first. This amendment also requires installation of new design (either new or reworked) nozzle segments, that will aid in containment of the LPT rotor in the event of LPT shaft failure. This amendment is prompted by a report of an LPT shaft failure caused by a hydromechanical unit (HMU) malfunction that induced a higher than anticipated LPT rotor overspeed. The actions specified by this AD are intended to aid in containment of the LPT rotor in the event of LPT shaft failure, which could result in uncontained engine failure and damage to the airplane.

**DATES:** Effective September 18, 2002.

**ADDRESSES:** The service information referenced in this AD may be obtained from CFM International, Technical Publications Department, 1 Neumann Way, Cincinnati, OH 45215; telephone (513) 552–2800; fax (513) 552–2816.

**FOR FURTHER INFORMATION CONTACT:** James Rosa, Aerospace Engineer, Engine Certification Office, FAA, Engine and Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803–5299; telephone (781) 238–7152; 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 CFMI CFM56–5B and –7B series turbofan engines was published in the **Federal Register** on April 4, 2002 (67 FR 16069). That action proposed to require retirement of stage 2 LPT nozzle segments and stage 3 LPT nozzle segments, listed in Table 1 of that proposed AD, from service before accumulating 25,000 cycles-since-new (CSN), or by October 31, 2008, whichever occurs earlier.

**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.

**Remove Compliance Date**

Three commenters request that the compliance date of October 31, 2008, be removed. This date would not provide enough engine operating time to reach scheduled major maintenance when the affected parts would be exposed.

The FAA agrees. The alternate AD compliance requirement of retiring stage 2 LPT nozzle segments and stage 3 LPT nozzle segments from service before accumulating 25,000 CSN meets the manufacturer's removal criteria. In addition, the FAA wishes to clarify that compliance with this AD is required before accumulating 25,000 CSN or at the next LPT module shop visit when either stage 2 LPT nozzle segments or stage 3 LPT nozzle segments are exposed, whichever occurs first.

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 economic burden on any operator nor increase the scope of the AD.

**Economic Analysis**

There are approximately 3,187 CFMI CFM56–5B and –7B series engines of the affected design in the worldwide fleet. The FAA estimates that 910 engines installed on airplanes of U.S. registry would be affected by this AD. The FAA also estimates that it would take approximately 10 work hours per engine to perform the actions, and that the average labor rate is $60 per work hour. Required parts would cost approximately $34,984 per engine. Based on these figures, the total cost of the AD on U.S. operators is estimated to be $32,381,440.

**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, 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:

**2002–16–18 CFM International:** Amendment 39–12857. Docket No. 2001–NE–37–AD.

**Applicability**

This airworthiness directive (AD) is applicable to CFM International (CFMI) CFM56–5B and –7B series turbofan engines. These engines are installed on, but not limited to Boeing 737–600, –700, –800, and –900; and Airbus A319, A320, and A321 airplanes.

**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 before accumulating 25,000 cycles-since-new (CSN) on the parts listed in Table 1 of this AD, or at the next low pressure turbine (LPT) module shop visit when either stage 2 LPT nozzle segments or stage 3 LPT nozzle segments are exposed, whichever occurs first, unless already done.

To aid in containment of the LPT rotor in the event of LPT shaft failure, which could result in uncontained engine failure and damage to the airplane, do the following:

(a) Retire from service stage 2 LPT nozzle segments and stage 3 LPT nozzle segments listed in the following Table 1, and install new design (either new or reworked) nozzle segments:

TABLE 1.—STAGE 2 AND STAGE 3 LPT NOZZLE SEGMENT PART NUMBERS TO BE RETIRED

| Nozzle segments | Part numbers |
|---|---|
| (1) Stage 2 ..... | 338–109–104–0, 338–109–105–0, 338–109–106–0, 338–109–204–0, 338–109–205–0, 338–109–206–0, 338–109–304–0, 338–109–305–0, 338–109–306–0. |
| (2) Stage 3. ..... | 338–109–702–0, 338–109–802–0. |

(b) Information on reworking stage 2 LPT nozzle segments and stage 3 LPT nozzle segments, listed in Table 1 of this AD, can be found in CFM International Service Bulletins (SB's) 72–0328, dated May 25, 2000, for CFM56–5 series engines, and SB 72–0241, dated May 25, 2000, for CFM56–7 series engines.

**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 airplane to a location where the requirements of this AD can be done.

**Effective Date**

(e) This amendment becomes effective on September 18, 2002.

Issued in Burlington, Massachusetts, on August 5, 2002.

**Jay J. Pardee,**

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

[FR Doc. 02–20515 Filed 8–13–02; 8:45 am]

BILLING CODE 4910–13–P

## DEPARTMENT OF THE TREASURY

## Customs Service

## 19 CFR Part 4

**[T.D. 02–48]**

## Pleasure Vessels of Marshall Islands Entitled to Cruising Licenses

**AGENCY:** U.S. Customs Service, Department of the Treasury.

**ACTION:** Final rule.

**SUMMARY:** This document amends the Customs Regulations by adding the Marshall Islands to the list of countries whose pleasure vessels may be issued U.S. cruising licenses. Customs has been informed that yachts used and

employed exclusively as pleasure vessels belonging to any resident of the U.S. are allowed to arrive at and depart from the Marshall Islands ports and cruise in the waters of the Marshall Islands without being subject to formal entry and clearance procedures. Therefore, Customs is extending reciprocal privileges to Marshall Islands-flag pleasure vessels.

**EFFECTIVE DATES:** These reciprocal privileges became effective for the Marshall Islands on July 9, 2002. This amendment is effective August 14, 2002.

**FOR FURTHER INFORMATION CONTACT:** Glen Vereb, Entry Procedures and Carriers Branch, (202) 572–8730.

**SUPPLEMENTARY INFORMATION:**

**Background**

Section 4.94(a), Customs Regulations (19 CFR 4.94(a)), provides that U.S. documented vessels with a recreational endorsement, used exclusively for pleasure, not engaged in any trade, and not violating the Customs or navigation laws of the U.S., may proceed from port to port in the U.S. or to foreign ports without entering or clearing, as long as they have not visited hovering vessels. When returning from a foreign port or place, such pleasure vessels are required to report their arrival pursuant to § 4.2, Customs Regulations (19 CFR 4.2).

Generally, foreign-flag yachts entering the U.S. are required to comply with the laws applicable to foreign vessels arriving at, departing from, and proceeding between ports of the U.S. However, as provided in § 4.94(b), Customs Regulations (19 CFR 4.94(b)), Customs may issue cruising licenses to pleasure vessels from certain countries if it is found that yachts of the United States are exempt from formal entry and clearance procedures (e.g., filing manifests, obtaining permits to proceed and paying entry and clearance fees) in those countries.

If a foreign-flag yacht is issued a cruising license, the yacht, for a stated period not to exceed one year, may arrive and depart from the United States and to cruise in specified waters of the United States without entering and clearing, without filing manifests and obtaining or delivering permits to proceed, and without the payment of entrance and clearance fees, or fees for receiving manifests and granting permits to proceed, duty on tonnage, tonnage tax, or light money. Upon arrival at each port in the U.S., the master of a foreign-flag yacht with a cruising license must report the fact of arrival to the appropriate Customs office. A list of countries whose yachts are eligible for cruising licenses is set forth in § 4.94(b).

By an exchange of diplomatic notes between the Government of the Marshall Islands and the United States Department of State, the Marshall Islands and the United States agree to extend to yachts of each other's country reciprocal privileges. Accordingly, U.S.-flag yachts, used exclusively as pleasure vessels and belonging to any resident of the U.S., may arrive at and depart from Marshall Islands ports and to cruise the waters of the Marshall Islands without entering and clearing the Marshall Islands Customs and without payment of any charges for entering or clearing, dues, duty per ton, tonnage taxes, or charges for cruising licenses. Marshall Islands yachts will be entitled to reciprocal privileges in the United States.

On July 22, 2002, the Department of State advised the Acting Chief, Entry Procedures and Carriers Branch, U.S. Customs Service, of the agreement between the United States and the Marshall Islands, which became effective July 9, 2002. The Acting Chief, Entry Procedures and Carriers Branch, is of the opinion that satisfactory evidence has been furnished to establish the reciprocity required in § 4.94(b), effective July 9, 2002. Accordingly, the Marshall Islands is added to the list of countries set forth in § 4.94(b). The authority to amend this section of the Customs Regulations has been delegated to the Chief, Regulations Branch.

**Inapplicability of Public Notice and Delayed Effective Date Requirements, the Regulatory Flexibility Act and Executive Order 12866**

Because this amendment merely implements a statutory requirement and confers a benefit upon the public, pursuant to 5 U.S.C. 553(b)(B), notice and public procedure are unnecessary for this amendment. Further, for the same reasons, good cause exists for the dispensing with a delayed effective date under 5 U.S.C. 553(d)(1) and (3). Since this document is not subject to notice and public procedure requirements of 5 U.S.C. 553, it is not subject to the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). This document does not meet the criteria for a ''significant regulatory action'' as specified in Executive Order 12866.

**Drafting Information**

The principal author of this document was Janet Johnson, Regulations Branch, U.S. Customs Service. However, personnel from other offices participated in its development.

**List of Subjects in 19 CFR Part 4**

Customs duties and inspection, Maritime carriers, Vessels, Yachts.

**Amendment to the Regulations**

To reflect the reciprocal privileges granted to vessels registered in the Marshall Islands, Part 4, Customs Regulations (19 CFR Part 4), is amended as set forth below.

## PART 4—VESSELS IN FOREIGN AND DOMESTIC TRADES

1. The general authority for Part 4 and the specific authority for § 4.94 continue to read as follows:

**Authority:** 5 U.S.C. 301; 19 U.S.C. 66, 1431, 1433, 1434, 1624; 46 U.S.C. App. 3, 91.

* * * * *

Section 4.94 also issued under 19 U.S.C. 1441; 46 U.S.C. App. 104.

* * * * *

2. Section 4.94(b), Customs Regulations (19 CFR 4.94(b)), is amended by inserting, in appropriate alphabetical order, ''Marshall Islands'' in the list of countries.

Dated: August 8, 2002.

**Harold M. Singer,**

*Chief, Regulations Branch.*

[FR Doc. 02–20563 Filed 8–13–02; 8:45 am]

**BILLING CODE 4820–02–P**

## DEPARTMENT OF THE TREASURY

### Internal Revenue Service

### 26 CFR Part 1

**[TD 9014]**

**RIN 1545–AX27**

## Furnishing Identifying Number of Income Tax Return Preparer

**AGENCY:** Internal Revenue Service (IRS), Treasury.

**ACTION:** Final regulations.

**SUMMARY:** This document contains final regulations that allow income tax return preparers to elect an alternative to their social security number for purposes of identifying themselves on returns they prepare. The regulations are needed to implement section 6109(a) as amended by the Internal Revenue Service Restructuring and Reform Act of 1998. The regulations affect individual preparers who elect to identify themselves using a number other than their social security number.

**DATES:** *Effective Date:* These regulations are effective August 12, 2002.

*Applicability Date:* For dates of applicability, see §§ 1.6109–2A(d) and 1.6109–2(d).

**FOR FURTHER INFORMATION CONTACT:** Michelle B. Baxter, (202) 622–4910 (not a toll-free call).

**SUPPLEMENTARY INFORMATION:**

## Background

Section 6109(a)(4) of the Internal Revenue Code provides that any return or claim for refund prepared by an income tax return preparer must bear the identifying number of the preparer as required by regulations prescribed by the Secretary. Prior to the amendment of section 6109(a) by the Internal Revenue Service Restructuring and Reform Act of 1998 (Public Law 105–206, 112 Stat. 685 (RRA '98)), section 6109(a) limited the identifying number of an individual preparer to that preparer's social security number.

Section 3710 of RRA '98 amended section 6109(a) by removing the requirement that an individual preparer's identifying number be the preparer's social security account number. Instead, under section 6109(a)(4), the Secretary may prescribe alternatives to the social security account number for purposes of identifying individual preparers.

On December 21, 1998, the IRS published Notice 98–63, 1998–2 C.B. 760, to inform preparers of the IRS's intention to develop a system of alternative identifying numbers. On August 12, 1999, the Service published a temporary regulation (TD 8835) permitting a preparer to use an alternative identifying number. **Federal Register** (64 FR 43910). On August 12, 1999, the Service also published a notice of proposed rulemaking (REG–105237–99) allowing a preparer to use an alternative to their social security number for purposes of identifying themselves on returns they prepare. **Federal Register** (64 FR 43969). No public hearing was requested or held. No written comments were received. The proposed regulations are adopted by this Treasury decision, and the corresponding temporary regulations are removed.

## Explanation of Provisions

This document contains amendments to the Income Tax Regulations (26 CFR part 1) to allow individual preparers to either use their social security number or elect an alternative identifying number for purposes of identifying themselves on returns they prepare. The IRS developed Form W–7P, Application for Preparer Tax Identification Number, on which preparers may apply for an alternative identifying number.

## Effective Date

The final regulations under § 1.6109–2 apply to returns or claims for refund filed after December 31, 1999. The current rules of § 1.6109–2, which are retained in § 1.6109–2A, continue to apply with respect to returns or claims for refund filed prior to January 1, 2000.

## Special Analyses

It has been determined that this Treasury decision is not a significant regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment is not required. It also has been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations, and because these regulations do not impose a collection of information on small entities, the Regulatory Flexibility Act (5 U.S.C. chapter 6) does not apply. Pursuant to section 7805(f) of the Internal Revenue Code, these regulations will be submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on their impact on small business.

## Drafting Information

The principal author of these regulations is Michelle B. Baxter, Office of Associate Chief Counsel (Procedure and Administration), Administrative Provisions and Judicial Practice Division. However, other personnel from the IRS and Treasury Department participated in their development.

## List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

## Adoption of Amendments to the Regulations

Accordingly, 26 CFR part 1 is amended as follows:

## PART 1—INCOME TAXES

**Paragraph 1.** The authority citation for part 1 continues to read in part as follows:

**Authority:** 26 U.S.C. 7805 * * *

**Par. 2.** Immediately following § 1.6115–1, an undesignated center heading is added to read as follows: REGULATIONS APPLICABLE TO RETURNS OR CLAIMS FOR REFUND FILED PRIOR TO JANUARY 1, 2000.

**Par. 3.** Section 1.6109–2 is redesignated as § 1.6109–2A, and transferred immediately after the undesignated center heading ''REGULATIONS APPLICABLE TO RETURNS OR CLAIMS FOR REFUND FILED PRIOR TO JANUARY 1, 2000.''

**Par. 4.** The second sentence of redesignated § 1.6109–2A(d) is revised to read:

### § 1.6109–2A Furnishing identifying number of income tax return preparer.

* * * * *

(d) * * * For returns or claims for refund filed after December 31, 1999, see § 1.6109–2(a).

* * * * *

**Par. 5.** New § 1.6109–2 is added to read as follows:

### § 1.6109–2 Income tax return preparers furnishing identifying numbers for returns or claims for refund filed after December 31, 1999.

(a) *Furnishing identifying number.*— (1) Each return of tax, or claim for refund of tax, under subtitle A of the Internal Revenue Code prepared by one or more income tax return preparers must include the identifying number of the preparer required by § 1.6695–1(b) to sign the return or claim for refund. In addition, if there is a partnership or employment arrangement between two or more preparers, the identifying number of the partnership or employer must also appear on the return or claim for refund. For the definition of the term ''income tax return preparer'' (or ''preparer'') see section 7701(a)(36) and § 301.7701–15 of this chapter.

(2) The identifying number of a preparer who is an individual (not described in paragraph (a)(3) of this section) is that individual's social security account number, or such alternative number as may be prescribed by the Internal Revenue Service in forms, instructions, or other appropriate guidance.

(3) The identifying number of a preparer (whether an individual, corporation, or partnership) who employs or engages one or more persons to prepare the return or claim for refund (other than for the preparer) is that preparer's employer identification number.

(b) and (c) [Reserved]. For further guidance, see § 1.6109–2A(b) and (c).

(d) *Effective date.* Paragraph (a) of this section and this paragraph (d) apply to returns or claims for refund filed after December 31, 1999. For returns or claims for refund filed prior to January 1, 2000, see § 1.6109–2A(a).

### § 1.6109–2T [Removed]

**Par. 6.** Section 1.6109–2T is removed.

Approved: August 8, 2002.

**David A. Mader,**

*Acting Deputy Commissioner of Internal Revenue.*

**Pamela F. Olson,**

*Acting Assistant Secretary of the Treasury.*

[FR Doc. 02–20621 Filed 8–12–02; 2:56 pm]

**BILLING CODE 4830–01–P**

## DEPARTMENT OF TRANSPORTATION

## Coast Guard

## 33 CFR Part 165

**[CGD01–02–093]**

**RIN 2115–AA97**

## Safety Zones; Coast Guard Activities New York

**AGENCY:** Coast Guard, DOT.

**ACTION:** Temporary final rule.

**SUMMARY:** The Coast Guard is establishing two temporary safety zones for the Hudson Riverway Grand Opening located on the Hudson River and Midland Beach Fireworks located on Lower New York Bay. This action is necessary to provide for the safety of life on navigable waters during the event. This action is intended to restrict vessel traffic in the affected waterways.

**DATES:** This rule is effective from 4 p.m. on August 10, 2002, to 10 p.m. on August 18, 2002.

**ADDRESSES:** The Waterways Oversight Branch of Coast Guard Activities New York maintains the public docket for this rulemaking. 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 CGD01–02–093 and are available for inspection or copying at Waterways Oversight Branch, Coast Guard Activities New York, 212 Coast Guard Drive, room 204, Staten Island, New York 10305, between 8 a.m. and 3 p.m., Monday through Friday, except Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** Lieutenant Commander E. Morton, Waterways Oversight Branch, Coast Guard Activities New York at (718) 354–4012.

**SUPPLEMENTARY INFORMATION:**

### Regulatory Information

We did not publish a notice of proposed rulemaking (NPRM) for this regulation. Under 5 U.S.C. 553(b)(3), the Coast Guard finds that good cause exists for not publishing an NPRM. Due to the date the Application for Approval of Marine Event was received, there was insufficient time to draft and publish an NPRM. A permanent safety zone has been published at 33 CFR 100.122 for the Hudson Riverway Waterski show on the Hudson River effective on the first Sunday after July 4th. The date for this year's event has been moved to August 10, 2002. The zone will only be enforced for one hour and 45 minutes, which is a much shorter period than in previous years. Further, it is an annual, local event. The City of Albany is closing the public boat launch located within the safety zone during this event.

The Midland Beach safety zone will have minimal impact on Lower New York Bay. Vessels may still transit around the zone during the event. The zone will only be enforced for one and one half hours; vessels can be given permission to transit the zone for all but about 20 minutes during this time. Additionally, vessels would not be precluded from mooring at or getting underway from commercial or recreational piers in the vicinity of the zone.

Under 5 U.S.C. 553(d)(3), the Coast Guard further finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Any delay encountered in this rule's effective date would be unnecessary and contrary to public interest since immediate action is needed to close the waterways and protect the maritime public from the hazards associated with a water ski show in confined waters and fireworks launched from a barge in the area.

### Background and Purpose

The Coast Guard received an application to hold a water ski show on the waters of the Hudson River. This rule would establish a safety zone in all waters of the Hudson River from the Dunn Memorial Bridge (river mile 145.4) to the Albany Rensselaer Swing Bridge (river mile 146.2). The safety zone would be enforced from 4 p.m. until 5:45 p.m. on Saturday, August 10, 2002. The safety zone would prevent vessels from transiting a portion of the Hudson River and is needed to protect boaters from the hazards associated with a water ski show held in the area. There are no commercial or recreational piers within the zone. The City of Albany is closing the public boat launch located within the safety zone during this event. Public notifications will be made prior to the event via the Local Notice to Mariners and Marine Information Broadcasts.

This safety zone covers the minimum area needed and imposes the minimum restrictions necessary to ensure the protection of all vessels and water ski show participants.

The Coast Guard received an application to hold a fireworks program on the waters of Lower New York Bay. This rule would establish a safety zone in all waters of Lower New York Bay within a 300-yard radius of the fireworks barge in approximate position 40°34′12.0″ N 074°04′29.6″ W (NAD 1983), about 800 yards southeast of Midland Beach. The safety zone would be enforced from 8:30 p.m. until 10 p.m. on Saturday, August 17, 2002. If the event is cancelled due to inclement weather, then this safety zone would be enforced from 8:30 p.m. until 10 p.m. on Sunday, August 18, 2002. The safety zone would prevent vessels from transiting a portion of Lower New York Bay and is needed to protect boaters from the hazards associated with fireworks launched from a barge in the area. Marine traffic would still be able to transit around the zone during this event. Additionally, recreational vessels would not be precluded from mooring at or getting underway from piers in the vicinity of the zone. Public notifications will be made prior to the event via the Local Notice to Mariners.

The size of this safety zone was determined using National Fire Protection Association and New York City Fire Department standards for ten inch mortars fired from a barge, combined with the Coast Guard's knowledge of tide and current conditions in the area.

### 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 Transportation (DOT) (44 FR 11040, February 26, 1979).

We expect the economic impact of this rule to be so minimal that a full Regulatory Evaluation under paragraph 10e of the regulatory policies and procedures of DOT is unnecessary.

This finding is based on: the minimal time that vessels would be restricted from the zones; the Hudson Riverway water ski show is an annual, local event; the zone is only in effect for one hour and 45 minutes, which is less than half the enforcement period in previous years; there are no commercial or recreational piers within the zone; and the City of Albany is closing the public boat launch located within the safety

zone during this event. The Midland Beach Fireworks zone is only in effect for one and one half hours; and vessels can be given permission to transit the zone for all but about 20 minutes during this time. Advance notifications will be made to the local maritime community by Local Notice to Mariners and marine information broadcasts.

**Small Entities**

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

The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

This rule will affect the following entities, some of which might be small entities: the owners or operators of vessels intending to transit or anchor in a portion of the Hudson River and Lower New York Bay during the time these zones are activated.

These safety zones will not have a significant economic impact on a substantial number of small entities for the following reasons: the Hudson Riverway water ski show is an annual, local event of relatively short duration; there are no commercial or recreational piers within the zone; the minimal time that vessels will be restricted from the zones; and the City of Albany is closing the public boat launch located within the safety zone during this event. Recreational vessels may still transit around the Midland Beach zone during the event and will not be precluded from mooring at or getting underway from piers in the vicinity of the zone; the zone is only in effect for one and one half hours; and vessels can be given permission to transit the zone for all but about 20 minutes during this time. We will ensure wide dissemination of maritime advisories to users of the Hudson River and Lower New York Bay via the Local Notice to mariners and marine information broadcasts.

**Assistance for Small Entities**

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 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.

**Collection of Information**

This rule would call 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 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 affect 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 might 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. It has not been designated by the Administrator of the Office of Information and Regulatory Affairs as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

**Environment**

We have considered the environmental impact of this rule and concluded that, under figure 2–1, paragraph 34(g), of Commandant Instruction M16475.1D, this rule is categorically excluded from further environmental documentation. This rule fits paragraph 34(g) as it establishes two safety zones. A ''Categorical Exclusion Determination'' is available in the docket for inspection or copying 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; 49 CFR 1.46.

2. From 4 p.m. August 10, 2002, to 10 p.m. August 18, 2002, add temporary § 165.T01–093 to read as follows:

**§ 165.T01–093 Safety Zones; Coast Guard Activities New York.**

(a) The following areas are established as safety zones:

(1) *Hudson Riverway Water Ski Show.*

(i) *Location.* All waters of the Hudson River from the Dunn Memorial Bridge (river mile 145.4) to the Albany Rensselaer Swing Bridge (river mile 146.2).

(ii) *Enforcement period.* Paragraph (a)(1)(i) of this section will be enforced from 4 p.m. to 5:45 p.m. on Saturday, August 10, 2002.

(2) *Lower New York Bay Safety Zone.* (i) *Location.* All waters of Lower New York Bay within a 300-yard radius of the fireworks barge in approximate position 40°34′12.0″ N 074°04′29.6″ W, (NAD 1983) about 800 yards southeast of Midland Beach.

(ii) *Enforcement period.* Paragraph (a)(2)(i) of this section will be enforced from 8:30 p.m. to 10 p.m. on Saturday, August 17, 2002. In the event of inclement weather on that date, this section will be enforced from 8:30 p.m. to 10 p.m. on Sunday, August 18, 2002.

(b) *Regulations.* (1) The general regulations contained in 33 CFR 165.23 apply.

(2) All persons and vessels shall comply with the instructions of the Coast Guard Captain of the Port or the designated on-scene-patrol personnel. These personnel comprise commissioned, warrant, and petty officers of the Coast Guard.

Upon being hailed by a U. S. Coast Guard vessel by siren, radio, flashing light, or other means, the operator of a vessel shall proceed as directed.

Dated: July 25, 2002.

**C.E. Bone,**

*Captain, U.S. Coast Guard, Captain of the Port, New York.*

[FR Doc. 02–20624 Filed 8–9–02; 4:02 pm]

**BILLING CODE 4910–15–P**

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

**[OPP–2002–0181; FRL–7192–9]**

### Chlorsulfuron; Pesticide Tolerance

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of chlorsulfuron; (2-chloro-*N*-[(4-methoxy-6-methyl-1,3,5-triazin-2-yl)aminocarbonyl]benzenesulfonamide) in or on grass, forage and grass, hay. E.I. du Pont de Nemours and Company, Inc. requested these tolerances under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

**DATES:** This regulation is effective August 14, 2002. Objections and requests for hearings, identified by docket ID number OPP–2002–0181, must be received on or before October 15, 2002.

**ADDRESSES:** Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION.** To ensure proper receipt by EPA, your objections and hearing requests must identify docket ID number OPP-2002–0181 in the subject line on the first page of your response.

**FOR FURTHER INFORMATION CONTACT:** By mail: Joanne I. Miller, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: 703–305–6224; e-mail address: miller.joanne@epa.gov.

**SUPPLEMENTARY INFORMATION:**

#### I. General Information

*A. Does this Action Apply to Me?*

You may be affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

| Categories | NAICS | Examples of Potentially Affected Entities |
|---|---|---|
| Industry | 111<br>112<br>311<br>32532 | Crop production<br>Animal production<br>Food manufacturing<br>Pesticide manufacturing |

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT.**

*B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?*

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at *http://www.epa.gov/.* To access this document, on the Home Page select ''Laws and Regulations,'' ''Regulations and Proposed Rules,'' and then look up the entry for this document under the ''**Federal Register**—Environmental documents.'' You can also go directly to the **Federal Register** listings at *http://www.epa.gov/fedrgstr/.* A frequently updated electronic version of 40 CFR part 180 is available at *http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html,* a beta site currently under development. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at *http://www.epa.gov/opptsfrs/home/guidelin.htm.*

2. *In person.* The Agency has established an official record for this action under docket ID number OPP–2002–0181. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

#### II. Background and Statutory Findings

In the **Federal Register** of March 8, 2002 (67 FR pages 10722 – 10727) (FRL–6825–8), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, as amended by the Food Quality Protection Act of 1996 (FQPA) (Public Law 104–170), announcing the filing of a pesticide petition (PP 6F4752) by E.I. du Pont de Nemours and Company, Inc., P.O. Box 30, Newark, Delaware 19714–0030. This notice included a summary of the petition prepared by E.I. du Pont de Nemours and Company, the registrant. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.405 be amended by establishing tolerances for residues of the herbicide chlorsulfuron; (2-chloro-*N*-[(4-methoxy-6-methyl-1,3,5-triazin-2-yl)aminocarbonyl]benzenesulfonamide), in or on grass, forage at 11.0 part per million (ppm) and grass, hay at 19.0 ppm.

Section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical

residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL–5754–7).

## III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2), for tolerances for residues of chlorsulfuron in or on grass, forage at 11.0 ppm and grass, hay at 19.0 ppm. EPA's assessment of exposures and risks associated with establishing the tolerances follows.

### *A. Toxicological Profile*

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by chlorsulfuron are discussed in the following Table 1 as well as the no observed adverse effect level and the lowest observed adverse effect level from the toxicity studies reviewed.

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY

| Guideline No. | Study Type | Results |
|---|---|---|
| 870.3150 | 6 Month oral toxicity in nonrodents | NOAEL = 18.5 mg/kg/day<br>LOAEL = 82.3 mg/kg/day based on decreased body weight and body-weight gain. |
| 870.3700 | Prenatal developmental in rodents | Maternal NOAEL = 165 mg/kg/day<br>LOAEL = 500 mg/kg/day based on clinical signs, vaginal discharge with associated alopecia.<br>Developmental NOAEL = 500 mg/kg/day<br>LOAEL = 1500 mg/kg/day based on decreased fetal body weight. |
| 870.3700 | Prenatal developmental in nonrodents | Maternal NOAEL = 75 mg/kg/day<br>LOAEL = 200 mg/kg/day based on decreased body weight gain.<br>Developmental NOAEL = 200 mg/kg/day<br>LOAEL = 400 mg/kg/day based on a slight increase in visceral malformations and decreased fetal body weight. |
| 870.3800 | 3-Generation Reproduction in rodents | Parental NOAEL = 125 mg/kg/day<br>LOAEL is greater than 125 mg/kg/day, no effects observed.<br>Reproductive NOAEL = 5 mg/kg/day<br>LOAEL = 25 mg/kg/day based on decreased female fertility<br>Offspring NOAEL = 125 mg/kg/day<br>LOAEL = 125 mg/kg/day, no effects observed. |
| 870.4100 | Chronic toxicity dogs | NOAEL = 60.6 mg/kg/day<br>LOAEL = 215 mg/kg/day based on decreased body-weight gain, erythrocyte counts and hemoglobin levels. |
| 870.4200 | Carcino-genicity mice | NOAEL = 108 mg/kg/day<br>LOAEL = 750 mg/kg/day based on decreased body weight and body-weight gain.<br>(no) evidence of carcinogenicity |
| 870.4300 | Carcinogenicity rats | NOAEL = 5 mg/kg/day<br>LOAEL = 25 mg/kg/day based on decreased body weight in males.<br>(no) evidence of carcinogenicity |
| 870.5385 | Cytogenetics | No evidence of chromosomal aberrations |
| 870.7485 | Metabolism and pharmacokinetics | Chlorsulfuron is rapidly absorbed, metabolized, and excreted following oral exposure. The major routes of elimination are the urine (58% – 72%) and feces (20% – 35%). |

*B. Toxicological Endpoints*

The dose at which no adverse effects are observed (the NOAEL) from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). However, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intraspecies differences. The 3-generation reproductive toxicity study is classified unacceptable, and it is considered a datagap. Reproductive toxicity was observed but was of questionable significance in both litters of the $F_3$ generation, as evidenced by decreased female fertility. Offspring toxicity was not observed. This study had numerous deficiencies including but not limited to:

1. No assessment of estrous cyclicity, sperm parameters.
2. No assessment of male reproductive performance.
3. Parental animals not subjected to gross pathology or histopathology examinations.
4. No assessment of developmental landmarks.
5. Pup histopathology evaluations conducted only for the $F_{3B}$ generation.

Although this reproduction study on chlorsulfuron conformed to the old guideline requirements, it is unacceptable under the current guideline requirement in light of the fact that most of the parameters used for FQPA assessment are not provided in the available study. The Agency applied a FQPA database uncertainty factor of 3X to account for the unacceptable reproduction study. Exposure estimates are upper bound and will not underestimate exposure to chlorsulfuron. The 3X FQPA database uncertainty factor applies to all dietary and non-dietary residential exposure scenarios and no Special FQPA safety factor is required.

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (acute RfD or chronic RfD) where the RfD is equal to the NOAEL divided by the appropriate UF (RfD = NOAEL/UF). Where an additional safety factor is retained due to concerns unique to the FQPA, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of FQPA Safety Factor.

For non-dietary risk assessments (other than cancer) the UF is used to determine the LOC. For example, when 100 is the appropriate UF (10X to account for interspecies differences and 10X for intraspecies differences) the LOC is 100. To estimate risk, a ratio of the NOAEL to exposures (margin of exposure (MOE) = NOAEL/exposure) is calculated and compared to the LOC.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk is expressed as $1 \times 10^{-6}$ or one in a million). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a ''point of departure'' is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure ($MOE_{cancer}$ = point of departure/exposures) is calculated. A summary of the toxicological endpoints for chlorsulfuron used for human risk assessment is shown in the following Table 2:

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR CHLORSULFURON FOR USE IN HUMAN RISK ASSESSMENT

| Exposure Scenario | Dose Used in Risk Assessment, UF | FQPA SF* and Level of Concern for Risk Assessment | Study and Toxicological Effects |
|---|---|---|---|
| Acute Dietary females 13–50 years of age | no appropriate endpoint for this exposure scenario was identified | | |
| Acute Dietary general population including infants and children | no appropriate endpoint for this exposure scenario was identified | | |
| Chronic Dietary all populations | NOAEL = 5 mg/kg/day<br>UF = 300 .....<br>Chronic RfD = 0.02 mg/kg/day | FQPA SF = 1<br>cPAD = chronic RfD ÷ FQPA SF = 0.02 mg/kg/day. | rat chronic toxicity/carcinogenicity LOAEL = 25 mg/kg/day based on decreased body weight in males |
| Incidental Oral, Short-Term Residential Only | NOAEL = 75 mg/kg/day<br>UF=300 ..... | FQPA SF = 1<br>LOC for MOE = 300 ..... | developmental toxicity study in rabbits LOAEL=200 mg/kg/day based on decreased body-weight gain |
| Incidental Oral, Intermediate-Term Residential Only | NOAEL = 75 mg/kg/day<br>UF=300 ..... | FQPA SF = 1<br>LOC for MOE = 300 ..... | developmental toxicity study in rabbits LOAEL=200 mg/kg/day based on decreased body-weight gain |
| Short-Term Dermal (1 to 7 days) (Residential) | NOAEL = 75 mg/kg/day<br>UF = 300 ..... | FQPA SF = 1<br>LOC for MOE = 300 (Residential). | developmental toxicity study in rabbits LOAEL = 200 mg/kg/day based on decreased body-weight gain |

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR CHLORSULFURON FOR USE IN HUMAN RISK ASSESSMENT—Continued

| Exposure Scenario | Dose Used in Risk Assessment, UF | FQPA SF* and Level of Concern for Risk Assessment | Study and Toxicological Effects |
|---|---|---|---|
| Intermediate-Term Dermal (1 week to several months) (Residential) | NOAEL = 75 mg/kg/day<br>UF = 300 ..... | FQPA SF = 1<br>LOC for MOE = 300 (Residential). | developmental toxicity study in rabbits LOAEL = 200 mg/kg/day based on decreased body-weight gain |
| Long-Term Dermal (several months to lifetime) (Residential) | NOAEL = 5 mg/kg/day<br>UF = 300 when appropriate) ..... | FQPA SF = 1<br>LOC for MOE = 300 (Residential). | chronic toxicity/carcinogenicity study in rats LOAEL = 25 mg/kg/day based on decreased body weight in males |
| Short-Term Inhalation (1 to 7 days) (Residential) | NOAEL = 75 mg/kg/day<br>UF = 300 ..... | FQPA SF = 1<br>LOC for MOE = 300 (Residential). | developmental toxicity study in rabbits LOAEL = 200 mg/kg/day based on decreased body-weight gain |
| Intermediate-Term Inhalation (1 week to several months) (Residential) | NOAEL = 75 mg/kg/day<br>UF = 300) ..... | FQPA SF = 1<br>LOC for MOE = 300 (Residential). | developmental toxicity study in rabbits LOAEL = 200 mg/kg/day based on decreased body weight gain |
| Long-Term Inhalation (several months to lifetime) (Residential) | NOAEL = 5 mg/kg/day<br>UF = 300) ..... | FQPA SF = 1<br>LOC for MOE = 300 (Residential). | chronic toxicity/carcinogenicity study in rats LOAEL = 25 mg/kg/day based on decreased body weight in males |

*The reference to the FQPA Safety Factor refers to any additional safety factor retained due to concerns unique to the FQPA.

*C. Exposure Assessment*

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.405) for the residues of chlorsulfuron, in or on a variety of raw agricultural commodities. Risk assessments were conducted by EPA to assess dietary exposures from chlorsulfuron in food as follows:

i. *Acute exposure.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a one day or single exposure. No toxicological endpoint attributable to a single exposure was identified in the available toxicology studies. No appropriate studies available show any acute dietary effects of concern.

ii. *Chronic exposure.* In conducting this chronic dietary risk assessment the Dietary Exposure Evaluation Model (DEEM®) analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–1992 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: Residue levels are at the recommended tolerances and 100% crop treated with chlorsulfuron. Results of dietary analyses showed exposure to chlorsulfuron consumed no more than 19.3% of the cPAD.

iii. *Cancer.* Chlorsulfuron was classified as having ''no evidence of carcinogenicity'' based upon lack of evidence of carcinogenicity in rats and mice. Therefore, a cancer dietary exposure analysis was not performed.

2. *Dietary exposure from drinking water.* The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for chlorsulfuron in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the physical characteristics of chlorsulfuron.

The Agency uses the First Index Reservoir Screening Tool (FIRST) or the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS), to produce estimates of pesticide concentrations in an index reservoir. The Screening Concentration in Ground Water (SCI-GROW) model is used to predict pesticide concentrations in shallow groundwater. For a screening-level assessment for surface water EPA will use FIRST (a tier 1 model) before using PRZM/EXAMS (a tier 2 model). The FIRST model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. While both FIRST and PRZM/EXAMS incorporate an index reservoir environment, the PRZM/EXAMS model includes a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin.

None of these models include consideration of the impact processing (mixing, dilution, or treatment) of raw water for distribution as drinking water would likely have on the removal of pesticides from the source water. The primary use of these models by the Agency at this stage is to provide a coarse screen for sorting out pesticides for which it is highly unlikely that drinking water concentrations would ever exceed human health levels of concern.

Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use estimated environmental concentrations (EECs) from these models to quantify drinking water exposure and risk as a %RfD or %PAD. Instead, drinking water levels of comparison (DWLOCs) are calculated and used as a point of comparison against the model estimates of a pesticide's concentration in water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, and from residential uses. Since DWLOCs address total aggregate exposure to chlorsulfuron, they are further discussed in the aggregate risk sections in Unit III. E. of this preamble.

Based on the FIRST and SCI-GROW models the EECs of total chlorsulfuron residues (both parent and degradation products) for acute exposures are estimated to be 59.7 parts per billion (ppb) and for chronic exposures are estimated to be 41.3 ppb in surface water. The EECs for acute and chronic exposures of chlorsulfuron (parent only) are estimated to be 3.5 ppb in ground water.

3. *From non-dietary exposure.* The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Chlorsulfuron is currently registered for use on the following residential non-dietary sites: Lawns. The risk assessment was conducted using the following residential exposure assumptions: Adult handlers and adult and toddler postapplication exposure to treated turf. Residential exposure risk was assessed using the Residential Exposure Assessment Standard Operating Procedures (ResSOPs) standard values and assumptions. Adult handler exposure risk was not of concern with MOEs ranging between 8,800 and 190,000. Postapplication exposure risks for adults and toddlers also exceeded target MOEs, ranging between 770 and 400,000. Since the ResSOPs ranged between median and high end assessments, and the use assessed was for spot treatment, not the entire lawn, the residential postapplication exposure risk assessment was conservative.

4. *Cumulative exposure to substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

EPA does not have, at this time, available data to determine whether chlorsulfuron has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, chlorsulfuron does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that chlorsulfuron has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

### *D. Safety Factor for Infants and Children*

1. *In general.* FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base on toxicity and exposure unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

2. *Prenatal and postnatal sensitivity.* The toxicology database for chlorsulfuron contains acceptable guideline developmental studies which show no quantitative or qualitative evidence of increased susceptibility following *in utero* exposure. Susceptibility cannot be assessed in the 3-generation reproduction study in rats. The Agency determined that a 2-generation reproduction study is required for chlorsulfuron.

3. *Conclusion.* The existing toxicological database for chlorsulfuron, while not complete, supports the establishment of permanent tolerances for chlorsulfuron per se and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. For dietary exposure estimates, a FQPA safety factor of 3 was used. Due to data deficiencies in the toxicology database, the Agency determined that an additional 3X database UF is needed for the protection of infants and children. An UF of 3X (as opposed to a 10X) is adequate because the chronic RfD is based on the NOAEL of 5 mg/kg/day established in the Combined Chronic/Carcinogenicity Study in Rats. This dose (5 mg/kg/day) is 25X lower than the highest dose tested (125 mg/kg/day) in the existing 3-generation Reproduction Study in which the effects noted were considered of questionable toxicological significance.

### *E. Aggregate Risks and Determination of Safety*

To estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses, the Agency calculates DWLOCs which are used as a point of comparison against the model estimates of a pesticide's concentration in water (EECs). DWLOC values are not regulatory standards for drinking water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food and residential uses. In calculating a DWLOC, the Agency determines how much of the acceptable exposure [(i.e., the PAD) is available for exposure through drinking water e.g., allowable chronic water exposure (mg/kg/day) = cPAD - (average food + residential exposure)]. This allowable exposure through drinking water is used to calculate a DWLOC.

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values as used by the USEPA are used to calculate DWLOCs: 2L/70 kg (adult male), 2L/60 kg (adult female), and 1L/10 kg (child). Default body weights and drinking water consumption values vary on an individual basis. This variation will be taken into account in more refined screening-level and quantitative drinking water exposure assessments. Different populations will have different DWLOCs. Generally, a DWLOC is calculated for each type of risk assessment used: acute, short-term, intermediate-term, chronic, and cancer.

When EECs for surface water and groundwater are less than the calculated DWLOCs, EPA concludes with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposure for which EPA has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because EPA considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of comparison in drinking water may vary as those uses change. If new uses are added in the future, EPA will reassess the potential impacts of residues of the pesticide in drinking water as a part of the aggregate risk assessment process.

1. *Acute risk.* An appropriate endpoint attributable to a single dose was not identified, therefore, no acute risk is expected.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to chlorsulfuron from food will utilize no more than 6.6% of the cPAD for the U.S. population, 7.3% of the cPAD for all infants and 19.3% of the cPAD for children 1–6 years old. Based on the use pattern, chronic

residential exposure to residues of chlorsulfuron is not expected. Since no chronic residential scenarios have been identified, chronic DWLOCs for chlorsulfuron were calculated based on residues in food alone. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in the following Table 3:

TABLE 3.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO CHLORSULFURON

| Population Subgroup | cPADmg/kg/day | %cPAD (Food) | Surface Water EEC (ppb) | Ground Water EEC (ppb) | Chronic DWLOC (ppb) |
|---|---|---|---|---|---|
| U.S. Population | 0.02 | 6.6 | 41.3 | 3.5 | 654 |
| Females 13–50 years old | 0.02 | 4.3 | 41.3 | 3.5 | 574 |
| Children 1–6 years old | 0.02 | 19.3 | 41.3 | 3.5 | 161 |
| All Infants | 0.02 | 7.3 | 41.3 | 3.5 | 185 |

3. *Short-term risk.* Short-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Chlorsulfuron is currently registered for use that could result in short-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic food and water and short-term exposures for chlorsulfuron.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded that food and residential exposures aggregated result in aggregate MOEs of 1,265 for adult males, 1,274 for adult females and 722 for toddlers. These aggregate MOEs do not exceed the Agency's level of concern for aggregate exposure to food and residential uses. In addition, short-term DWLOCs were calculated and compared to the EECs for chronic exposure of chlorsulfuron in ground and surface water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect short-term aggregate exposure to exceed the Agency's level of concern, as shown in the following Table 4:

TABLE 4.—AGGREGATE RISK ASSESSMENT FOR SHORT-TERM EXPOSURE TO CHLORSULFURON

| Population Subgroup | Aggregate MOE (Food + Residential) | Aggregate Level of Concern (LOC) | Surface Water EEC (ppb) | Ground Water EEC (ppb) | Short-Term DWLOC (ppb) |
|---|---|---|---|---|---|
| Adult Male | 1,265 | 300 | 41.3 | 3.5 | 6,674 |
| Adult Female | 1,274 | 300 | 41.3 | 3.5 | 5,734 |
| Toddler | 722 | 300 | 41.3 | 3.5 | 1,461 |

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). The intermediate-term aggregate risk is the same as the short-term aggregate risk (Table 4) since the toxicity end points are the same for both exposures.

5. *Aggregate cancer risk for U.S. population.* The carcinogenic potential of chlorsulfuron was classified as no evidence of carcinogenicity. Therefore, no cancer risk is expected.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, and to infants and children from aggregate exposure to chlorsulfuron residues.

## IV. Other Considerations

### *A. Analytical Enforcement Methodology*

Methods are available for the enforcement of tolerances for chlorsulfuron residues in/on plant and animal commodities. PAM Vol. II lists Methods I and II, High performance liguid chromotography methods with photoconductivity detection, for the determination of chlorsulfuron residues in plants and livestock commodities and milk.

### *B. International Residue Limits*

There are no Codex, Canadian, or Mexican maximum residue limits, therefore, issues of compatibility do not exist.

### *C. Conditions*

The following data gaps must be fulfilled; a 21–day repeat dermal toxicity study, a subchronic inhalation study, and a 2-generation reproduction study.

## V. Conclusion

Therefore, tolerances are established for residues of chlorsulfuron in or on grass, forage at 11.0 ppm and grass, hay at 19.0 ppm.

## VI. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made.

The new section 408(g) provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d), as was provided in the old FFDCA sections 408 and 409. However, the period for filing objections is now 60 days, rather than 30 days.

*A. What Do I Need to Do to File an Objection or Request a Hearing?*

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP–2002–0181 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before October 15, 2002.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. C400, Waterside Mall, 401 M St., SW., Washington, DC 20460. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 260–4865.

2. *Tolerance fee payment.* If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it ''Tolerance Petition Fees.''

EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305–5697, by e-mail at tompkins.jim@epa.gov, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.2. Mail your copies, identified by docket ID number OPP–2002–0181, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. You may also send an electronic copy of your request via e-mail to: opp-docket@epa.gov. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

*B. When Will the Agency Grant a Request for a Hearing?*

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

## VII. Regulatory Assessment Requirements

This final rule establishes a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this 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). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 et seq., or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 et seq.) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process

to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, 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.'' ''Policies that have tribal implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, 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, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

### VIII. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 et seq., as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

### List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: July 30, 2002.

**Donald R. Stubbs,**

*Director, Registration Division, Office of Pesticide Programs.*

Therefore, 40 CFR chapter I is amended as follows:

## PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:

**Authority:** 21 U.S.C. 321(q), 346(a) and 371.

2. Section 180.405 is revised to read as follows:

**§ 180.405 Chlorsulfuron; tolerances for residues.**

(a) *General.* (1) Tolerances are established for the combined residues of chlorsulfuron (2-chloro-*N*-[(4-methoxy-6-methyl-1,3,5-triazin-2-yl)aminocarbonyl]benzenesulfonamide) and its metabolite, 2-chloro-5-hydroxy-*N*-[(4-methoxy-6-methyl-1,3,5-triazin-2-yl)aminocarbonyl] benzenesulfonamide in or on the following raw agricultural commodities:

| Commodity | Parts per million |
|---|---|
| Barley, grain | 0.1 |
| Barley, straw | 0.5 |
| Oat, forage | 20.0 |
| Oat, grain | 0.1 |
| Oat, straw | 0.5 |
| Wheat, forage | 20.0 |
| Wheat, grain | 0.1 |
| Wheat, straw | 0.5 |

(2) Tolerances are established for residues of chlorsulfuron (2-chloro-*N*-[(4-methoxy-6-methyl-1,3,5-triazin-2-yl)aminocarbonyl] benzenesulfonamide) in or on the following raw agricultural commodities.

| Commodity | Parts per million |
|---|---|
| Cattle, fat | 0.3 |
| Cattle, meat | 0.3 |
| Cattle, meat byproducts | 0.3 |
| Goat, fat | 0.3 |
| Goat, meat | 0.3 |
| Goat, meat byproducts | 0.3 |
| Grass, forage | 11.0 |
| Grass, hay | 19.0 |
| Hog, fat | 0.3 |
| Hog, meat | 0.3 |
| Hog, meat byproducts | 0.3 |
| Horse, fat | 0.3 |
| Horse, meat | 0.3 |
| Horse, meat byproducts | 0.3 |
| Milk | 0.1 |
| Sheep, fat | 0.3 |
| Sheep, meat | 0.3 |
| Sheep, meat byproducts | 0.3 |

(b) *Section 18 emergency exemptions.* [Reserved].

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[FR Doc. 02–20229 Filed 8–13–02; 8:45 am]

BILLING CODE 6560–50–S

## FEDERAL COMMUNICATIONS COMMISSION

### 47 CFR Part 73

**[DA 02–1898, MM Docket No. 01–161, RM–10181]**

### Digital Television Broadcast Service; Victoria, TX

**AGENCY:** Federal Communications Commission.

**ACTION:** Final rule.

**SUMMARY:** The Commission, at the request of Surtsey Productions, Inc., license of station KVCT–TV, Victoria, Texas, substitutes DTV channel 11 for DTV channel 34 at Victoria. *See* 66 FR 39727, August 1, 2001. DTV channel 11 can be allotted to Victoria, Texas, in compliance with the principle community coverage requirements of Section 73.625(a) at reference coordinates 28–50–26 N. and 97–07–47 W. with a power of 18, HAAT of 311 meters and with a DTV service population of 229 thousand. Since the community of Victoria is located within 275 kilometers of the U.S.-Mexican border, concurrence from the Mexican government has been obtained for this allotment.

With this action, this proceeding is terminated.

**DATES:** Effective September 23, 2002.

**FOR FURTHER INFORMATION CONTACT:** Pam Blumenthal, Media Bureau, (202) 418–1600.

**SUPPLEMENTARY INFORMATION:** This is a synopsis of the Commission's Report and Order, MM Docket No. 01–161, adopted August 2, 2002, and released August 9, 2002. The full text of this document is available for public inspection and copying during regular

business hours in the FCC Reference Information Center, Portals II, 445 12th Street, SW., Room CY–A257, Washington, DC. This document may also be purchased from the Commission's duplicating contractor, Qualex International, Portals II, 445 12th Street, SW, CY–B402, Washington, DC, 20554, telephone 202–863–2893, facsimile 202–863–2898, or via e-mail *qualexint@aol.com*.

**List of Subjects in 47 CFR Part 73**

Digital television broadcasting, Television.

Part 73 of Title 47 of the Code of Federal Regulations is amended as follows:

## PART 73—[AMENDED]

1. The authority citation for Part 73 continues to read as follows:

**Authority:** 47 U.S.C. 154, 303, 334 and 336.

**§ 73.622 [Amended]**

2. Section 73.622(b), the Table of Digital Television Allotments under Texas, is amended by removing DTV channel 34 and adding DTV channel 11 at Victoria.

Federal Communications Commission.

**Barbara A. Kreisman,**

*Chief, Video Division, Media Bureau.*

[FR Doc. 02–20590 Filed 8–13–02; 8:45 am]

**BILLING CODE 6712–01–P**

## FEDERAL COMMUNICATIONS COMMISSION

### 47 CFR Part 73

**[DA 02–1899, MB Docket No. 02–104, RM–10390]**

### Digital Television Broadcast Service; Dawson, Pelham, Savannah, Waycross, and Wrens, GA

**AGENCY:** Federal Communications Commission.

**ACTION:** Final rule.

**SUMMARY:** The Commission, at the request of Georgia Public Telecommunications Commission, licensee of stations WCES–TV, WVAN–TV, WXGA–TV, WACS–TV, and WABW–TV, substitutes DTV channel *2 for DTV channel *36 at Wrens; DTV channel *13 for DTV channel *46 at Savannah; DTV channel *9c for DTV channel *18 at Waycross; DTV channel *8 for DTV channel *26c at Dawson; and DTV channel *5 for DTV channel DTV *20 at Pelham. See 67 FR 36137, May 23, 2002. DTV channels *2, *13, *9c, *8 and *5 can be allotted to Wrens, Savannah, Waycross, Dawson, and Pelham, Georgia, in compliance with the principle community coverage requirements of Section 73.625(a). DTV Channel *2 can be allotted with a power of 4.9, (HAAT) of 436 meters; DTV channel *13 with a power of 10, (HAAT) of 293; DTV channel *9 with a power of 4.6 and (HAAT) of 286 meters; DTV channel *8 with a power of 4.9 and (HAAT) of 331 meters; and DTV channel *5 with a power of 0.75 and (HAAT) of 474 meters. With this action, this proceeding is terminated.

**DATES:** Effective September 23, 2002.

**FOR FURTHER INFORMATION CONTACT:** Pam Blumenthal, Media Bureau, (202) 418–1600.

**SUPPLEMENTARY INFORMATION:** This is a synopsis of the Commission's Report and Order, MB Docket No. 02–104, adopted August 2, 2002, and released August 9, 2002. The full text of this document is available for public inspection and copying during regular business hours in the FCC Reference Information Center, Portals II, 445 12th Street, SW., Room CY–A257, Washington, DC. This document may also be purchased from the Commission's duplicating contractor, Qualex International, Portals II, 445 12th Street, SW., CY–B402, Washington, DC, 20554, telephone 202–863–2893, facsimile 202–863–2898, or via e-mail *qualexint@aol.com.*

**List of Subjects in 47 CFR Part 73**

Digital television broadcasting, Television.

Part 73 of Title 47 of the Code of Federal Regulations is amended as follows:

## PART 73—[AMENDED]

1. The authority citation for Part 73 continues to read as follows:

**Authority:** 47 U.S.C. 154, 303, 334 and 336.

**§ 73.622 [Amended]**

2. Section 73.622(b), the Table of Digital Television Allotments under Georgia, is amended by removing DTV Channel *26c and adding DTV Channel *8 at Dawson.

3. Section 73.622(b), the Table of Digital Television Allotments under Georgia, is amended by removing DTV Channel *20 and adding DTV Channel *5 at Pelham.

4. Section 73.622(b), the Table of Digital Television Allotments under Georgia, is amended by removing DTV Channel *46 and adding DTV Channel *13 at Savannah.

5. Section 73.622(b), the Table of Digital Television Allotments under Georgia, is amended by removing DTV Channel *18 and adding DTV Channel *9c at Waycross.

6. Section 73.622(b), the Table of Digital Television Allotments under Georgia, is amended by removing DTV Channel*36 and adding DTV Channel *2 at Wrens.

Federal Communications Commission.

**Barbara A. Kreisman,**

*Chief, Video Division, Media Bureau.*

[FR Doc. 02–20591 Filed 8–13–02; 8:45 am]

**BILLING CODE 6712–01–P**

## FEDERAL COMMUNICATIONS COMMISSION

### 47 CFR Part 73

**[DA 02–1914, MB Docket No. 02–93, RM–10414]**

### Digital Television Broadcast Service; Sacramento, CA

**AGENCY:** Federal Communications Commission.

**ACTION:** Final rule.

**SUMMARY:** The Commission, at the request of La Dov Educational Outreach, Inc., an applicant for a new television station to operate on NTSC channel *52, substitutes DTV channel *43 for NTSC channel *52 at Sacramento. *See* 67 FR 34669, May 15, 2002. DTV channel *43 can be allotted to Sacramento in compliance with the principal community coverage requirements of section 73.625(a) at reference coordinates 38–37–49 N. and 120–51–20 W. with a power of 100, HAAT of 304 meters and with a DTV service population of 1557 thousand. With this action, this proceeding is terminated.

**DATES:** Effective September 23, 2002.

**FOR FURTHER INFORMATION CONTACT:** Pam Blumenthal, Media Bureau, (202) 418–1600.

**SUPPLEMENTARY INFORMATION:** This is a synopsis of the Commission's Report and Order, MB Docket No. 02–93, adopted August 8, 2002, and released August 9, 2002. The full text of this document is available for public inspection and copying during regular business hours in the FCC Reference Information Center, Portals II, 445 12th Street, SW., Room CY–A257, Washington, DC. This document may also be purchased from the Commission's duplicating contractor, Qualex International, Portals II, 445 12th Street, SW, CY–B402, Washington, DC, 20554, telephone 202–863–2893, facsimile 202–863–2898, or via e-mail *qualexint@aol.com.*

**List of Subjects in 47 CFR Part 73**

Digital television broadcasting, Television.

Part 73 of Title 47 of the Code of Federal Regulations is amended as follows:

## PART 73—[AMENDED]

1. The authority citation for part 73 continues to read as follows:

**Authority:** 47 U.S.C. 154, 303, 334 and 336.

**§ 73.606 [Amended]**

2. Section 73.606(b), the Table of Television Allotments under California, is amended by removing TV channel *52 at Sacramento.

**§ 73.622 [Amended]**

3. Section 73.622(b), the Table of Digital Television Allotments under California, is amended by adding DTV channel *43 at Sacramento.

Federal Communications Commission.

**Barbara A. Kreisman,**

*Chief, Video Division, Media Bureau.*

[FR Doc. 02–20599 Filed 8–13–02; 8:45 am]

**BILLING CODE 6712–01–P**

## FEDERAL COMMUNICATIONS COMMISSION

### 47 CFR Part 73

**[DA 02–1915, MB Docket No. 02–96, RM–10410]**

### Digital Television Broadcast Service; Amarillo, TX

**AGENCY:** Federal Communications Commission.

**ACTION:** Final rule.

**SUMMARY:** The Commission, at the request of Amarillo Junior College District, licensee of noncommercial station KACV–TV, substitutes DTV channel *8c for DTV channel *21 at Amarillo, Texas. *See* 67 FR 31753, May 10, 2002. DTV channel *8c can be allotted to Amarillo in compliance with the principal community coverage requirements of Section 73.625(a) at reference coordinates 35–22–30 N. and 101–52–56 W. with a power of 5, HAAT of 519 meters and with a DTV service population of 282 thousand. With this action, this proceeding is terminated.

**DATES:** Effective September 23, 2002.

**FOR FURTHER INFORMATION CONTACT:** Pam Blumenthal, Media Bureau, (202) 418–1600.

**SUPPLEMENTARY INFORMATION:** This is a synopsis of the Commission's Report and Order, MB Docket No. 02–96, adopted August 2, 2002, and released August 9, 2002. The full text of this document is available for public inspection and copying during regular business hours in the FCC Reference Information Center, Portals II, 445 12th Street, SW., Room CY–A257, Washington, DC. This document may also be purchased from the Commission's duplicating contractor, Qualex International, Portals II, 445 12th Street, SW, CY–B402, Washington, DC, 20554, telephone 202–863–2893, facsimile 202–863–2898, or via e-mail *qualexint@aol.com.*

**List of Subjects in 47 CFR Part 73**

Digital television broadcasting, Television.

Part 73 of Title 47 of the Code of Federal Regulations is amended as follows:

## PART 73—[AMENDED]

1. The authority citation for part 73 continues to read as follows:

**Authority:** 47 U.S.C. 154, 303, 334 and 336.

**§ 73.622 [Amended]**

2. Section 73.622(b), the Table of Digital Television Allotments under Texas, is amended by removing DTV channel *21 and adding DTV channel *8c at Amarillo.

Federal Communications Commission.

**Barbara A. Kreisman,**

*Chief, Video Division, Media Bureau.*

[FR Doc. 02–20600 Filed 8–13–02; 8:45 am]

**BILLING CODE 6712–01–P**

## FEDERAL COMMUNICATIONS COMMISSION

### 47 CFR Part 73

**[DA 02–1916, MB Docket No. 02–75, RM–10151]**

### Digital Television Broadcast Service; Lynchburg, VA

**AGENCY:** Federal Communications Commission.

**ACTION:** Final rule.

**SUMMARY:** The Commission, at the request of WSET, Inc., licensee of station WSET–TV, NTSC channel 13, Lynchburg, Virginia, substitutes DTV channel 34 for DTV channel 56 at Lynchburg. *See* 67 FR 17041, April 9, 2002. DTV channel 34 can be allotted to Lynchburg in compliance with the principle community coverage requirements of Section 73.625(a) at reference coordinates 37–18–52 N. and 79–38–04 W. with a power of 660, HAAT of 625 meters and with a DTV service population of 1048 thousand. With this action, this proceeding is terminated.

**DATES:** Effective September 23, 2002.

**FOR FURTHER INFORMATION CONTACT:** Pam Blumenthal, Media Bureau, (202) 418–1600.

**SUPPLEMENTARY INFORMATION:** This is a synopsis of the Commission's Report and Order, MB Docket No. 02–75, adopted August 2, 2002, and released August 9, 2002. The full text of this document is available for public inspection and copying during regular business hours in the FCC Reference Information Center, Portals II, 445 12th Street, S.W., Room CY–A257, Washington, DC. This document may also be purchased from the Commission's duplicating contractor, Qualex International, Portals II, 445 12th Street, SW, CY–B402, Washington, DC, 20554, telephone 202–863–2893, facsimile 202–863–2898, or via e-mail *qualexint@aol.com.*

**List of Subjects in 47 CFR Part 73**

Digital television broadcasting, Television.

Part 73 of Title 47 of the Code of Federal Regulations is amended as follows:

## PART 73—[AMENDED]

1. The authority citation for part 73 continues to read as follows:

**Authority:** 47 U.S.C. 154, 303, 334 and 336.

**§ 73.622 [Amended]**

2. Section 73.622(b), the Table of Digital Television Allotments under Virginia, is amended by removing DTV channel 56 and adding DTV channel 34 at Lynchburg.

Federal Communications Commission.

**Barbara A. Kreisman,**

*Chief, Video Division, Media Bureau.*

[FR Doc. 02–20601 Filed 8–13–02; 8:45 am]

**BILLING CODE 6712–01–P**

## FEDERAL COMMUNICATIONS COMMISSION

### 47 CFR Part 73

**[DA 02–1763; MM Docket No.01–279; RM–10290]**

### Radio Broadcasting Services; Rocksprings, TX

**AGENCY:** Federal Communications Commission.

**ACTION:** Final rule.

**SUMMARY:** This document allots Channel 235C3 to Rocksprings, Texas, in

response to a petition filed by Linda Crawford. *See* 66 FR 53192, October 19, 2001. The coordinates for Channel 235C3 at Rocksprings are 30–07–06 and 100–19–18. There is a site restriction 16 kilometers (9.9 miles) northwest of the community. With this action, this proceeding is terminated. A filing window for Channel 235C3 at Rocksprings will not be opened at this time. Instead, the issue of opening this allotment for auction will be addressed by the Commission in a subsequent order.

**DATES:** Effective September 16, 2002.

**FOR FURTHER INFORMATION CONTACT:** Kathleen Scheuerle, Media Bureau, (202) 418–2180.

**SUPPLEMENTARY INFORMATION:** This is a summary of the Commission's Report and Order, MM Docket No. 01–279, adopted July 17, 2002, and released August 2, 2002. The full text of this Commission decision is available for inspection and copying during regular business hours in the FCC Information Center, Portals II, 445 12th Street, SW, Room CY–A257, Washington, DC 20554. The complete text of this decision may also be purchased from the Commission's duplicating contractor, Qualex International, Portals II, 445 12th Street, SW, Room CY–B402, Washington, DC, 20554, (202) 863–2893, facsimile (202) 863–2898, or via e-mail *qualexint@aol.com*.

**List of Subjects in 47 CFR Part 73**

Radio, Radio broadcasting.

Part 73 of title 47 of the Code of Federal Regulations is amended as follows:

## PART 73—RADIO BROADCAST SERVICES

1. The authority citation for Part 73 continues to read as follows:

**Authority:** 47 U.S.C. 154, 303, 334 and 336.

**§ 73.202 [Amended]**

2. Section 73.202(b), the Table of FM Allotments under Texas, is amended by adding Channel 235C3 at Rocksprings.

Federal Communications Commission.

**John A. Karousos,**

*Assistant Chief, Audio Division, Media Bureau.*

[FR Doc. 02–20585 Filed 8–13–02; 8:45 am]

**BILLING CODE 6712–01–P**

## FEDERAL COMMUNICATIONS COMMISSION

### 47 CFR Part 73

**[DA 02–1765; MM Docket No.01–280; RM–10291]**

### Radio Broadcasting Services; Benjamin, TX

**AGENCY:** Federal Communications Commission.

**ACTION:** Final rule.

**SUMMARY:** This document allots Channel 237C3 to Benjamin, Texas, in response to a petition filed by Katherine Pyeatt. *See* 66 FR 52735, October 17, 2001. The coordinates for Channel 237C3 at Benjamin are 33–44–27 and 99–48–54. There is a site restriction 17.5 kilometers (10.9 miles) north of the community. With this action, this proceeding is terminated. A filing window for Channel 237C3 at Benjamin will not be opened at this time. Instead, the issue of opening this allotment for auction will be addressed by the Commission in a subsequent order.

**DATES:** Effective September 16, 2002.

**FOR FURTHER INFORMATION CONTACT:** Kathleen Scheuerle, Media Bureau, (202) 418–2180.

**SUPPLEMENTARY INFORMATION:** This is a summary of the Commission's Report and Order, MM Docket No. 01–280, adopted July 17, 2002, and released August 2, 2002. The full text of this Commission decision is available for inspection and copying during regular business hours in the FCC Information Center, Portals II, 445 12th Street, SW, Room CY–A257, Washington, DC 20554. The complete text of this decision may also be purchased from the Commission's duplicating contractor, Qualex International, Portals II, 445 12th Street, SW, Room CY–B402, Washington, DC, 20554, (202) 863–2893, facsimile (202) 863–2898, or via e-mail *qualexint@aol.com*.

**List of Subjects in 47 CFR Part 73**

Radio, Radio broadcasting.

Part 73 of title 47 of the Code of Federal Regulations is amended as follows:

## PART 73—RADIO BROADCAST SERVICES

1. The authority citation for Part 73 continues to read as follows:

**Authority:** 47 U.S.C. 154, 303, 334 and 336.

**§ 73.202 [Amended]**

2. Section 73.202(b), the Table of FM Allotments under Texas, is amended by adding Benjamin, Channel 237C3.

Federal Communications Commission.

**John A. Karousos,**

*Assistant Chief, Audio Division, Media Bureau.*

[FR Doc. 02–20586 Filed 8–13–02; 8:45 am]

**BILLING CODE 6712–01–P**

## FEDERAL COMMUNICATIONS COMMISSION

### 47 CFR Part 73

**[DA 02–1877; MM Docket No. 98–155; RM–9082, RM–9133]**

### Radio Broadcasting Services; Alva, Mooreland, Tishomingo, and Woodward, OK

**AGENCY:** Federal Communications Commission.

**ACTION:** Final rule, application for review.

**SUMMARY:** At the request of Ralph Tyler this document reallots Channel 259C3 from Tishomingo to Tuttle, Oklahoma, and modifies the Station KTSH license to specify Tuttle as the community of license. See 65 FR 82296, published December 28, 2000. In order to accommodate this reallotment, this document substitutes Channel 260C1 for Channel 259C1 at Alva, Oklahoma, and modifies the Station KXLS license to specify operation on Channel 260C1 at Alva. This document also substitutes Channel 292C1 for Channel 261C1 at Woodward, Oklahoma, and modifies the Station KWFX license to specify operation on Channel 292C1 at Woodward. The reference coordinates for the Channel 259C3 allotment at Tuttle, Oklahoma, are 35–17–33 and 97–42–58. The reference coordinates for the Channel 292C1 allotment at Woodward, Oklahoma, are 36–25–42 and 99–24–10. The reference coordinates for the Channel 260C1 allotment at Alva, Oklahoma, are 36–35–41 and 98–15–38. In view of the grant of the reallotment of Channel 259C3 to Tuttle, the Application for Review filed by Ralph Tyler directed against an earlier action denying this reallotment is dismissed. With this action, the proceeding is terminated.

**DATES:** Effective September 17, 2002.

**FOR FURTHER INFORMATION CONTACT:** Robert Hayne, Mass Media Bureau, (202) 418–2177.

**SUPPLEMENTARY INFORMATION:** This is a synopsis of the Commission's *Memorandum Opinion and Order* in MM Docket No. 98–155 adopted July 31, 2002, and released August 2, 2002. The full text of this decision is available for inspection and copying during normal

business hours in the FCC's Reference Information Center at Portals II, CY–257, 445 12th Street, SW, Washington, DC. The complete text of this decision may also be purchased from the Commission's copy 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*.

**List of Subjects in 47 CFR Part 73**

Radio, Radio broadcasting.

Part 73 of Title 47 of the Code of Federal Regulations is amended as follows:

## PART 73—RADIO BROADCAST SERVICES

1. The authority citation for Part 73 continues to read as follows:

**Authority:** 47 U.S.C. 154, 303, 334, 336.

**§ 73.202 [Amended]**

2. Section 73.202(b), the Table of FM Allotments under Oklahoma, is amended by removing Channel 259C1 and adding Channel 260C1 at Alva; by removing Tishomingo, Channel 259C3, and adding Tuttle, Channel 259C3; and by removing Channel 261C1 and adding Channel 292C1 at Woodward.

Federal Communications Commission.

**John A. Karousos,**

*Assistant Chief, Audio Division, Media Bureau.*

[FR Doc. 02–20587 Filed 8–13–02; 8:45 am]

**BILLING CODE 6712–01–P**

## FEDERAL COMMUNICATIONS COMMISSION

## 47 CFR Part 73

**[DA 02–1861; MM Docket No. 99–246; RM–9593, RM–9770]**

## Radio Broadcasting Services; Camp Verde, Mayer, and Sun City West and Winslow, AZ

**AGENCY:** Federal Communications Commission.

**ACTION:** Final rule, application for review.

**SUMMARY:** At the request of Desert West Air Ranchers Corporation, this document reallots Channel 236C from Winslow to Sun City West, Arizona, and modifies the Station KFMR license to specify Sun City West as the community of license. This document also sets aside an earlier action reallotting Channel 236C to Mayer, Arizona. *See* 66 FR 29237, published May 30, 2001. In addition, this document dismisses an Application for Review filed by Desert West Air Ranchers Corporation directed against that earlier action. The reference coordinates for the Channel 236C allotment at Sun City West, Arizona, are 34–14–33 and 112–21–53. With this action, the proceeding is terminated.

**DATES:** Effective September 17, 2002.

**FOR FURTHER INFORMATION CONTACT:** Robert Hayne, Mass Media Bureau, (202) 418–2177.

**SUPPLEMENTARY INFORMATION:** This is a synopsis of the Commission's *Memorandum Opinion and Order* in MM Docket No. 99–246, adopted July 31, 2002, and released August 2, 2002. The full text of this decision is available for inspection and copying during normal business hours in the FCC's Reference Information Center at Portals II, CY–A257, 445 12th Street, SW, Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractor, Qualex International, Portals ll, 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*.

**List of Subjects in 47 CFR Part 73**

Radio, Radio broadcasting.

Part 73 of Title 47 of the Code of Federal Regulations is amended as follows:

## PART 73—RADIO BROADCAST SERVICES

1. The authority citation for Part 73 continues to read as follows:

**Authority:** 47 U.S.C. 154, 303, 334, 336.

**§ 73.202 [Amended]**

2. Section 73.202(b), the Table of FM Allotments under Arizona, is amended by removing Mayer, Channel 236C and adding Sun City West, Channel 236C.

Federal Communications Commission.

**John A. Karousos,**

*Assistant Chief, Audio Division, Media Bureau.*

[FR Doc. 02–20588 Filed 8–13–02; 8:45 am]

**BILLING CODE 6712–01–P**

## FEDERAL COMMUNICATIONS COMMISSION

## 47 CFR Part 73

**[DA 02–1813; MM Docket No. 99–196; RM–9619, RM–9874]**

## Radio Broadcasting Services; Bethel Springs, Martin, Tiptonville, Trenton, and South Fulton, TN

**AGENCY:** Federal Communications Commission.

**ACTION:** Final rule, petition for reconsideration.

**SUMMARY:** This document grants a petition for reconsideration filed by Thunderbolt Broadcasting Company, licensee of Station WCMT–FM, Channel 269A, Martin, TN, and grants Option I of its counterproposal that had been denied in the *Report and Order* in this proceeding. *See* 66 FR 63653, published December 10, 2001. The document reasons that the public interest benefits of upgrading and reallotting Station WCMT–FM to South Fulton, TN, outweigh downgrading vacant Channel 267C3 at Tiptonville, TN, to Channel 247A because a first local service will be provided to South Fulton. The reference coordinates for Channel 267C3 at South Fulton, TN, are 36–26–27 and 88–58–00. The reference coordinates for Channel 247A at Tiptonville, TN, are 36–22–42 and 89–23–18. To accommodate the South Fulton allotment, this document also substituted Channel 249C3 for Channel 248C3 at Trenton, TN, and modified the license for Station WTNE–FM, Trenton, to specify operation on Channel 249C3. The reference coordinates for Channel 249C3 at Trenton are 36–05–10 and 88–54–39.

**DATES:** Effective September 16, 2002.

**FOR FURTHER INFORMATION CONTACT:** Andrew J. Rhodes, Media Bureau, (202) 418–2180.

**SUPPLEMENTARY INFORMATION:** This is a synopsis of the Commission's *Memorandum Opinion and Order* in MM Docket No. 99–196, adopted July 17, 2002, and released August 2, 2002. The full text of this decision is available for inspection and copying during normal business hours in the FCC's Reference Information Center at Portals II, CY-A257, 445 12th Street, SW, Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractor, Qualex International, Portals ll, 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.*

**List of Subjects in 47 CFR Part 73**

Radio, Radio broadcasting.

Part 73 of Title 47 of the Code of Federal Regulations is amended as follows:

## PART 73—RADIO BROADCAST SERVICES

1. The authority citation for Part 73 continues to read as follows:

**Authority:** 47 U.S.C. 154, 303, 334, 336.

**§ 73.202 [Amended]**

2. Section 73.202(b), the Table of FM Allotments under Tennessee, is amended by removing Martin, Channel 269A, by adding South Fulton, Channel 267C3, and by removing Channel 267C3 and adding Channel 247A at Tiptonville.

Federal Communications Commission.

**John A. Karousos,**

*Assistant Chief, Audio Division, Media Bureau.*

[FR Doc. 02–20589 Filed 8–13–02; 8:45 am]

**BILLING CODE 6712–01–P**

## FEDERAL COMMUNICATIONS COMMISSION

### 47 CFR Part 73

**[DA 02–1764; MM Docket No. 01–307; RM–10307]**

### Radio Broadcasting Services; Camp Wood, TX

**AGENCY:** Federal Communications Commission.

**ACTION:** Final rule.

**SUMMARY:** This document allots Channel 271A to Camp Wood, Texas, in response to a petition filed by Linda Crawford. *See* 66 FR 56630, November 9, 2001. The coordinates for Channel 271A at Camp Wood are 29–48–01 and 100–02–35. There is a site restriction 14.8 kilometers (9.2 miles) north of the community. Although Mexican concurrence has been requested for the allotment of Channel 271A at Camp Wood, notification has not been received. Therefore, operation with the facilities specified for Camp Wood herein is subject to modification, suspension, or termination without right to hearing, if found by the Commission to be necessary in order to conform to the 1992 USA-Mexico FM Broadcast Agreement or if specifically objected to by Mexico. With this action, this proceeding is terminated. A filing window for Channel 271A at Camp Wood will not be opened at this time. Instead, the issue of opening this allotment for auction will be addressed by the Commission in a subsequent order.

**DATES:** Effective September 16, 2002.

**FOR FURTHER INFORMATION CONTACT:** Kathleen Scheuerle, Media Bureau, (202) 418–2180.

**SUPPLEMENTARY INFORMATION:** This is a summary of the Commission's Report and Order, MM Docket No. 01–307, adopted July 17, 2002, and released August 2, 2002. The full text of this Commission decision is available for inspection and copying during regular business hours in the FCC Information Center, Portals II, 445 12th Street, SW., Room CY–A257, Washington, DC 20554. The complete text of this decision may also be purchased from the Commission's duplicating contractor, Qualex International, Portals II, 445 12th Street, SW., Room CY–B402, Washington, DC, 20554, (202) 863–2893, facsimile (202) 863–2898, or via e-mail *qualexint@aol.com.*

**List of Subjects in 47 CFR Part 73**

Radio, Radio broadcasting.

Part 73 of title 47 of the Code of Federal Regulations is amended as follows:

## PART 73—RADIO BROADCAST SERVICES

1. The authority citation for Part 73 continues to read as follows:

**Authority:** 47 U.S.C. 154, 303, 334 and 336.

**§ 73.202 [Amended]**

2. Section 73.202(b), the Table of FM Allotments under Texas, is amended by adding Channel 271A at Camp Wood.

Federal Communications Commission.

**John A. Karousos,**

*Assistant Chief, Audio Division, Media Bureau.*

[FR Doc. 02–20593 Filed 8–13–02; 8:45 am]

**BILLING CODE 6712–01–P**

## FEDERAL COMMUNICATIONS COMMISSION

### 47 CFR Part 73

**[DA 02–1875; MM Docket No. 02–25; RM–10361]**

### Radio Broadcasting Services; Beverly Hills and Spring Hill, FL

**AGENCY:** Federal Communications Commission.

**ACTION:** Final rule.

**SUMMARY:** In this document, the Commission reallots Channel 292C3 from Beverly Hills to Spring Hill, Florida, as the community's first local aural transmission service, and modifies WGUL–FM, Inc.'s license for Station WGUL–FM to reflect the change of community. *See* 67 FR 8219 (02/22/2002). Coordinates for Channel 292C3 at Spring Hill are: NL 28–36–00 and WL 82–33–45.

**DATES:** Effective September 16, 2002.

**FOR FURTHER INFORMATION CONTACT:** Victoria M. McCauley, Media Bureau, (202) 418–2180.

**SUPPLEMENTARY INFORMATION:** This is a synopsis of the Commission's Report and Order, MM Docket No. 02–25, adopted July 24, 2002, and released August 2, 2002. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Reference Center (Room 239), 445 12th Street, SW., Washington, DC. 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.*

**List of Subjects in 47 CFR Part 73**

Radio, Radio broadcasting.

Part 73 of Title 47 of the Code of Federal Regulations is amended as follows:

## PART 73—RADIO BROADCAST SERVICES

1. The authority citation for Part 73 continues to read as follows:

**Authority:** 47 U.S.C. 154, 303, 334, and 336.

2. Section 73.202(b), the Table of FM Allotments under Florida, is amended by adding Spring Hill, Channel 292C3, and removing Beverly Hills, Channel 292C3.

Federal Communications Commission.

**John A. Karousos,**

*Assistant Chief, Audio Division, Media Bureau.*

[FR Doc. 02–20596 Filed 8–13–02; 8:45 am]

**BILLING CODE 6712–01–P**

## FEDERAL COMMUNICATIONS COMMISSION

### 47 CFR Part 73

### Radio Broadcasting Services; Various Locations

**AGENCY:** Federal Communications Commission.

**ACTION:** Final rule.

**SUMMARY:** The Commission, on its own motion, editorially amends the Table of FM Allotments to specify the actual classes of channels allotted to various communities. The changes in channel classifications have been authorized in response to applications filed by licensees and permittees operating on these channels. This action is taken pursuant to *Revision of Section 73.3573(a)(1) of the Commission's Rules Concerning the Lower Classification of an FM Allotment*, 4 FCC Rcd 2413 (1989), and the *Amendment of the Commission's Rules to permit FM*

*Channel and Class Modifications [Upgrades] by Applications,* 8 FCC Rcd 4735 (1993).

**DATES:** Effective August 14, 2002.

**FOR FURTHER INFORMATION CONTACT:** Kathleen Scheuerle, Media Bureau, (202) 418–2180.

**SUPPLEMENTARY INFORMATION:** This is a summary of the Commission's Report and Order, adopted July 31, 2002, and released August 2, 2002. The full text of this Commission decision is available for 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. 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.*

**List of Subjects in 47 CFR Part 73**

Radio, Radio broadcasting.

Part 73 of title 47 of the Code of Federal Regulations is amended as follows:

## PART 73—RADIO BROADCAST SERVICES

1. The authority citation for part 73 continues to read as follows:

**Authority:** 47 U.S.C. 154, 303, 334 and 336.

**§ 73.202 [Amended]**

2. Section 73.202(b), the Table of FM Allotments under Hawaii, is amended by removing Channel 284C2 and adding Channel 284C at Lanai City.

3. Section 73.202(b), the Table of FM Allotments under Iowa, is amended by removing Channel 273C and adding Channel 273C0 at Des Moines.

4. Section 73.202(b), the Table of FM Allotments under Missouri, is amended by removing Channel 223A and adding Channel 223C3 at Poplar Bluff.

5. Section 73.202(b), the Table of FM Allotments under Tennessee, is amended by removing Channel 299C3 and adding Channel 299C2 at Henderson.

6. Section 73.202(b), the Table of FM Allotments under Texas, is amended by removing Channel 252A and adding Channel 252C3 at Pecos and by removing Channel 276C3 and adding Channel 276C2 at Pittsburg.

7. Section 73.202(b), the Table of FM Allotments under Wyoming, is amended by removing Channel 297C2 and adding Channel 297C1 at Kemmerer.

Federal Communications Commission.

**John A. Karousos,**

*Assistant Chief, Audio Division, Media Bureau.*

[FR Doc. 02–20597 Filed 8–13–02; 8:45 am]

**BILLING CODE 6712–01–P**

## DEPARTMENT OF THE INTERIOR

## Fish and Wildlife Service

## 50 CFR Part 17

**RIN 1018–AI19**

## Endangered and Threatened Wildlife and Plants; Determination of Endangered Status for the Tumbling Creek Cavesnail

**AGENCY:** Fish and Wildlife Service, Interior.

**ACTION:** Final rule.

**SUMMARY:** We, the Fish and Wildlife Service (Service), determine the Tumbling Creek cavesnail (*Antrobia culveri*) to be an endangered species under the Endangered Species Act of 1973, as amended (Act). This species is known to occur in one cave in Missouri. The distribution of this species in Tumbling Creek has decreased by 90 percent since 1974. Although cavesnail numbers fluctuated seasonally and annually between 1996 and 2000, the species was not found in the monitored section of the cave stream during six surveys in 2001 and two surveys in 2002. Small numbers of individuals continue to exist in other portions of the cave stream. Because the sudden population decline demonstrates a significant and imminent risk to the well-being of the Tumbling Creek cavesnail, we find that listing this species is necessary to provide Federal protection pursuant to the Act.

**DATES:** This final rule is effective August 14, 2002.

**ADDRESSES:** The complete file for this rule is available for inspection, by appointment, during normal business hours at the U.S. Fish and Wildlife Service, Columbia Field Office, 608 E. Cherry St., Room 200, Columbia, MO 65201–7712.

**FOR FURTHER INFORMATION CONTACT:** Paul McKenzie, Ph.D., Columbia Field Office (*see* **ADDRESSES**) (telephone: 573–876–1911, ext. 107; e-mail: *paul_mckenzie@fws.gov;* facsimile: 573–876–1914). Individuals who are hearing-impaired or speech-impaired may call the Federal Relay Service at 1–800–877–8337 for TTY assistance.

**SUPPLEMENTARY INFORMATION:**

**Background**

The Tumbling Creek cavesnail (*Antrobia culveri*) was described as a new species by Hubricht (1971) from specimens taken by David Culver, Thomas Aley, and Leslie Hubricht in 1969 and 1970. *Antrobia culveri* is the type species for the genus *Antrobia,* also described new to science in 1971 by Hubricht. Hershler and Hubricht (1988) examined specimens of *A. culveri* and confirmed the taxonomic placement of this species in the subfamily Littoridininae of the Gastropod family Hydrobiidae. They also noted the similarity of the genus *Antrobia* to, but distinguished it from, the genus *Fontigens,* which contains cave-adapted snails found in other caves and springs of the Ozark Plateau in Missouri and Arkansas. The Tumbling Creek cavesnail is a small, white, blind, aquatic snail. Hubricht (1971) provided the following measurements of the type specimen: height 2.3 millimeters (mm) (0.09 inches (in)); diameter 2.0 mm (0.08 in); aperture height 1.2 mm (0.05 in); aperture diameter 1.1 mm (0.04 in); with a small, conical, well-rounded, pale-yellow shell containing about 3.5 whorls (Hubricht 1971). The Tumbling Creek cavesnail is restricted to a single cave stream in Tumbling Creek Cave in Taney County, southwestern Missouri.

Greenlee (1974) provided the first information on the habitat of the species. He reported that the species was found primarily on ''3 inch gravel substrate'' (presumably meaning small stones or cobble of 3-inch (7.5 cm) diameter), with a few individuals observed using the recesses of a solid rock stream bottom. Greenlee's use of a Surber Sampler, however, may have biased his survey to search for rocks smaller than 25 cm (10 in) in diameter (Julian J. Lewis, J. Lewis & Associates, Clarksville, IN; *in litt.,* January 27, 2002). Greenlee (1974) did not note whether the snails used the upper or lower surface of the 3-inch gravel he observed them on, or whether the species was ever observed using larger rocks within the cave stream. Subsequent surveyors, however, have failed to document *A. culveri* using a solid rock bottom, and the species is usually observed on the undersurface of rocks and gravel of various sizes (Ashley unpub. data; McKenzie *in litt.*, September 16, 1996; Ashley and McKenzie, pers. obs.). Although Greenlee (1974) stated that the Tumbling Creek cavesnail was absent from areas of the stream that contained bat guano, subsequent observers (Ashley 2001a; Ashley and McKenzie, pers. obs.) have noted *A. culveri* in portions of

Tumbling Creek where bat guano occurs. Greenlee (1974) noted that the species appears to prefer areas of the stream that lack silt, but Ashley (2000) found no significant differences in snail populations between habitats having silt and those lacking silt. There is insufficient data currently available to determine if silt is detrimental to the Tumbling Creek cavesnail. Tom and Cathy Aley suggested (pers. comm., August 30, 2001) that silt deposition in recent years in the stream has ''cemented'' smaller rocks to the stream bottom making their undersurface unavailable to cavesnails. This hypothesis is supported by observations made by researchers while conducting cavesnail surveys (e.g., Ashley and McKenzie, pers. obs.).

Although little is known regarding the biology of this cavesnail, Greenlee (1974) postulated that the species feeds on aquatic microfauna. Because Tumbling Creek cavesnails have been concentrated in sections of Tumbling Creek Cave that are usually adjacent to large deposits of bat guano, it has been postulated that *Antrobia culveri* is indirectly dependent upon these deposits for food (Greenlee 1974). Other life history aspects of this species, including its reproductive behavior, are unknown. Although nothing is known about the longevity or movements of this species, some limited information is available on the frequency of shell sizes within the population across different seasons. Ashley (2000) examined shell length data collected between 1996 and 2000 and noted that the average length of *A. culveri* shells exhibited a slight peak during summer months but further noted that the difference was not statistically significant. Ashley (2000) also analyzed the frequency distribution of cavesnail shell lengths from fall data collected between 1997 and 2000 and noted a decrease in the frequency of smaller shells over that period. Ashley (2000) concluded that both fewer snails and fewer smaller snails in the younger age classes were observed in the more recent fall visits conducted from 1997 through 2000. This suggests that there has been a reduction in recruitment of younger age classes into the population between 1997 and 2000.

The fauna of Tumbling Creek Cave is highly diverse (Thomas Aley, Ozark Underground Laboratory (OUL), *in litt.* 1978; Cecil Andrus, USDI, *in litt.* 1980). In addition to one species included in the Missouri Department of Conservation's (MDC) *Checklist of Species of Conservation Concern* (Missouri Natural Heritage Program 2001) (*i.e.*, a cave millipede (*Scoterpes dendropus*)), *Antrobia culveri* is associated with at least three, and possibly as many as six, species that are new to science but have not yet been formally described: a millipede (*Chaetaspis* sp.), a terrestrial isopod (*Caucasonethes* sp.), an amphipod (*Stygobromus* sp.), a dipluran (*Plusiocampa* sp.), a phalangodid harvestman (*Phalangium* sp.), and a cave spider (*Islandiana* sp.). Tumbling Creek Cave also provides habitat for a large maternity colony of federally listed gray bats (*Myotis grisescens*), with a recent estimated breeding population of 12,400 in 1998 (Dr. William Elliott, MDC, in litt. October 9, 2001). Historically, the gray bat breeding population included an estimated 50,000 individuals (MDC 1992, Missouri Natural Heritage Program 2000). The Gray Bat Recovery Plan lists Tumbling Creek Cave as a ''Priority 1'' cave. Priority 1 gray bat caves have the highest level of biological significance for a gray bat maternity site (*i.e.*, a cave deemed to be ''absolutely essential'' in preventing the extinction of the endangered gray bat) (U.S. Fish and Wildlife Service 1982). There have also been historical observations of a very small hibernating population of the federally listed Indiana bat (*Myotis sodalis*). However, the Indiana bat has not been documented at the site since 1989 (Missouri Natural Heritage Program 2000).

Tumbling Creek Cave is owned by Tom and Cathy Aley of Protem, MO. Because of its rich cave fauna, the large maternity colony for the endangered gray bat, and its diverse physical features, Tumbling Creek Cave was designated as a National Natural Landmark and approved for inclusion on the National Registry of Natural Landmarks under the authority of the Historic Sites Act of 1935 (49 Stat. 666; 16 U.S.C. 461 *et seq.*) (Cecil Andrus, USDI, *in litt.*, 1980; 48 FR 8693). Tumbling Creek Cave and approximately 395 acres surrounding the cave were embodied in the designation, including about 140 surface acres owned by the Aleys and about 255 surface acres owned by two adjacent property owners.

**Status and Distribution**

*Antrobia culveri* is known only from Tumbling Creek Cave in Taney County, southwestern Missouri. In an extensive survey of publicly and privately owned Missouri caves, no additional populations of this cavesnail were discovered (Gardner 1986). Recent surveys conducted in nearby caves and springs by Dr. David Ashley of Missouri Western State College, St. Joseph, MO, have also failed to locate this species at any other sites (David Ashley, *in litt.* November 2001). The fact that no additional populations were found in springs in close proximity to Tumbling Creek Cave supports the long-held contention that Tumbling Creek cave is the only location where this species occurs.

*Antrobia culveri* was historically known from an estimated area of 1,016 square meters ($m^2$) (10,900 square feet ($ft^2$) or 0.25 acres) of Tumbling Creek along approximately 229 meters (m) (750 feet (ft)) of the stream in the middle one-third of the lower stream passage in Tumbling Creek Cave (Greenlee 1974). Based on a survey of approximately 630 $m^2$ (6,800 $ft^2$) of suitable habitat within the 457 m (1,500 ft) of human-accessible cave-stream habitat, Greenlee (1974) estimated the population of Tumbling Creek cavesnails at 15,118 individuals.

In 1995, we reviewed the status of the species, including the survey methodology originally established by Greenlee (1974), and determined that an inadequate description of the survey methods made it difficult to determine the number of plots taken. Our lack of knowledge on the number of plots sampled by Greenlee made it difficult to interpret his population estimates and impossible to duplicate his survey methods. Therefore, we concluded that a new and more rigorous statistical survey design would be necessary to establish population trends for the species. Following meetings with Dr. Pam Haverland of the U.S. Geological Survey, Columbia Environmental Research Center in Columbia, MO, and Mr. Tom Aley, President of Ozark Underground Laboratory (OUL) and owner of Tumbling Creek Cave, a sampling protocol was established within an approximate 75 m (247 ft) section of Tumbling Creek that was known to be inhabited by *Antrobia culveri* but that would minimize any potential impacts to the federally endangered gray and Indiana bats.

Following the establishment of sampling stations within Tumbling Creek Cave, and an initial September 1996 survey using those stations (McKenzie, *in litt.* 1996), we contracted Dr. David Ashley, of Missouri Western State College, St. Joseph, MO, to monitor population trends of the Tumbling Creek cavesnail. Ashley completed 19 separate monitoring trips between September 3, 1997, and March 23, 2002 (Ashley 2000, 2001a, 2001b, 2001c, 2002). Ashley (2000, 2001a, 2001b, 2001c, 2002) determined that population estimates of *Antrobia culveri* within the monitoring stations fluctuated both seasonally and annually, and ranged from a high of 1,166

individuals on September 3, 1997, to a low of 0 individuals on January 11, March 17, May 8, July 16, August 31, and November 2, 2001, and January 9 and March 23, 2002. Ashley concluded that a significant decrease in the numbers of cavesnails had occurred between September 9, 1996, and March 23, 2002 (Ashley 2002).

Although the 2001 and 2002 surveys failed to document the presence of any cavesnails within the established monitoring stations, 40 individuals were discovered upstream of the sampling stations in March 2001. During March 16–18, 2001, Ashley and others surveyed the entire human-accessible 457 m (1,500 ft) of Tumbling Creek, including a small tributary that has approximately 9 additional meters (30 ft) of accessible habitat. A total of 39 person-hours was expended in searching a total of 1,054 rocks in the 466 m (1,530 ft) of available habitat. A total of 39 cavesnails were located in a 14-m (45-ft) section of the stream upstream from the monitoring stations, and another cavesnail was found in the tributary (Ashley 2001a). Subsequent surveys in May, July, September, and November, 2001, and January, 2002, documented the presence of cavesnails only in this 14-m section upstream of the established sampling stations. The small tributary stream was not searched during those subsequent surveys. A more thorough search was not conducted in either the tributary or the area upstream from the sampling stations in order to minimize disturbance to cavesnails in those areas. Observations made between September 1997 and March 2002 suggest that the numbers of *Antrobia culveri* have declined significantly from estimates obtained by Greenlee (1974); however, differing sampling methods make it impossible to directly compare Ashley's estimates with those of Greenlee.

In addition to Greenlee's 1974 survey and the standardized surveys conducted between 1996 and 2002, other attempts have been made to monitor the species' status and derive estimates of its abundance. A June 1991 survey conducted by Tom Aley, Paul McKenzie (Service, Columbia, MO), and Dennis Figg (MDC, Jefferson City, MO) located 42 individuals after a 9 person-hour search (McKenzie, pers. obs.). A June 1993 survey conducted by Monty Holder (a high school biology instructor) of Sedalia, MO, and three assistants located 21 individuals during 6 person-hours of search effort (Tom Aley, *in litt.* 1993), but the number of plots sampled is unknown. On August 29, 1995, Paul McKenzie and Cathy Aley searched for the species and attempted to estimate the number of cavesnails discovered per 0.3 $m^2$ (1 $ft^2$) plot. This survey yielded 6 cavesnails in 22 plots or 0.27 cavesnails per plot (McKenzie, unpubl. data). This compares to an estimated 2.16 cavesnails per plot observed by Greenlee (1974) when equivalent plot sizes were calculated for analysis purposes. Although it is impossible to determine the exact number of plots sampled by Greenlee (1974), he did record the average number of snails per plot, and this can be compared to the same variable measured in 1995. A decrease from 2.16 cavesnails per plot to 0.27 cavesnails per plot would represent an approximate 88 percent decrease in the species' density over the 22-year period between 1974 and 1995.

**Previous Federal Action**

On January 6, 1989, the Service published an Animal Notice of Review (54 FR 54554–54579) which included the Tumbling Creek cavesnail as a category 2 candidate species for possible future listing as threatened or endangered. Category 2 candidates were those taxa for which information contained in the Service's files indicated that listing may be appropriate but for which additional data were needed to support a listing proposal. On November 21, 1991, the Service published an Animal Candidate Notice of Review (56 FR 58804–58836), which elevated the Tumbling Creek cavesnail to category 1 status. Category 1 candidates were those taxa for which the Service had on file sufficient information on biological vulnerability and threats to support preparation of listing proposals. In the subsequent February 28, 1996, Candidate Notice of Review (61 FR 7596–7613), we indicated that the category 2 candidate species list was being discontinued, and that henceforth the term ''candidate species'' would be applied only to those taxa that would have earlier fit the definition of the former category 1 candidate taxa, that is, those species for which we had on hand sufficient information to support a listing proposal. *Antrobia culveri* was retained as a candidate species in that notice.

In 1996, we initiated a 5-year set of standardized surveys designed to better assess and quantify the decline in the species' population that was apparent from the earlier data. In January 2001, Ashley (pers. comm. January 14, 2001) notified the Service that no cavesnails were observed within the established monitoring stations during the January 11 survey. He further reported that an analysis of 5 years of data collected between September 1996 and March 2001 indicated that the population of the species had exhibited an alarming decline (Ashley 2001b). Based on this information, the Service determined that it was necessary to more closely monitor the species by having surveys conducted once every two months. Surveys conducted every two months between March 2001 and March 2002 have yielded the same results—no cavesnails have been found within the established sampling section of Tumbling Creek (Ashley 2002).

Recognizing the need for prompt additional conservation actions for the species, on January 30, 2001, Region 3 of the Service recommended changing the listing priority number for the Tumbling Creek cavesnail from 7 to 1 based upon the mid-January monitoring that failed to locate any cavesnails (Service 2001). Region 3 also recommended pursuing an emergency listing of the species and simultaneously publishing a proposal for long-term listing as endangered under the Act as soon as funding became available. On October 30, 2001, we published an updated Candidate Species Notice of Review (66 FR 54808) that formally changed the listing priority number for *Antrobia culveri* from 7 to 1, reflecting our increased concern for the survival of the species.

On August 29, 2001, the U.S. Department of the Interior reached an agreement with several conservation organizations regarding a number of listing actions that had been delayed by court-ordered critical habitat designations and listing actions for other species. That agreement was subsequently approved by the U.S. District Court for the District of Columbia. Under the agreement, the Service and the organizations agreed to significantly extend the existing court-approved deadlines for the actions on the other species, thereby making funds available for a number of listing actions judged to be higher priority by the Service. Those higher priority listing actions included the emergency listing of the Tumbling Creek cavesnail.

On December 27, 2001 (66 FR 66803), we listed *Antrobia culveri* on an emergency basis for 240 days through August 26, 2002. On the same date (66 FR 66868), we published a proposal to list the Tumbling Creek cavesnail as an endangered species under the standard listing provisions of the Act, and solicited comments on the proposed rule. The comment period was opened for 60 days and closed February 25, 2002.

**Summary of Peer Review and Public Comments**

In the December 27, 2001, proposed rule, we requested all interested parties to submit factual reports or information that might contribute to the development of a final rule. We also provided a notice indicating that a request for a public hearing could be made by February 11, 2002. We contacted appropriate Federal and State agencies, county governments, scientific organizations, and interested parties and requested their comments. We published notices inviting public comment in the Springfield, MO, News Leader and the Branson, MO, Tri-Lakes Daily News. In accordance with our July 1, 1994, Interagency Policy on Peer Review (59 FR 34270), we requested the expert opinions of independent specialists regarding pertinent scientific or commercial data and assumptions relating to the supportive biological and ecological information in the proposed rule. The purpose of such review is to ensure that the listing decision is based on scientifically sound data, assumptions, and analyses, including input of appropriate experts and specialists.

We requested scientific peer review of our proposed endangered listing from four invertebrate zoologists who possess expertise on the cavesnail or other invertebrates, and also solicited comments from one research fisheries biologist who has expertise on the potential impacts of contaminants on aquatic invertebrates. We received a written response and comments from all five of these experts; we also received comments from five private land owners within the recharge area for Tumbling Creek Cave during the open comment period. No requests for a public hearing were received. All species experts and private landowners strongly supported the listing proposal and agreed that this species is in need of Federal protection as an endangered species. Four of the five peer reviewers commented that the data on changes in cavesnail numbers were very thorough and that there was clear scientific evidence for listing the species as endangered. The fifth peer reviewer did not comment on adequacy of the data.

*A. Technical and Editorial Comments*

Several technical and editorial comments and corrections were provided by two peer reviewers. Clarification of biological terminology, enhanced explanations of information cited from several references, and the inclusion of additional literature citations to strengthen Factors A through D, discussed below, were recommended. We have incorporated the majority of the recommended changes, as appropriate. In a few cases, suggested changes were not made if we determined that incorporating the change in text would not improve the clarity of the discussion.

*B. Suggestions Related to Recovery Actions*

Three peer reviewers and two private land owners suggested various recovery actions that could benefit the cavesnail or its habitat. We will prepare a recovery plan for the cavesnail following the publication of the final rule, and these comments will be considered for incorporation into the recovery plan at that time. They are not discussed in this document, because they are not germane to this listing decision.

*C. Specific Comments*

All peer reviewers commented on the possible reasons for the recent decline in cavesnail numbers. With the exception of the introduction of a few new suggestions discussed below, most of the reasons provided by the peer reviewers are identical to those outlined in the December 27, 2001, emergency rule. All peer reviewers reaffirmed the supposition that siltation from erosion problems, overgrazing, poor land management, deforestation, or the sudden appearance and population explosion of limpets probably contributed to the decline in the species. Other reasons presented by peer reviewers that were previously provided in the Service's emergency rule were: eutrophication or nutrient runoff from livestock operations within the recharge area; disease; depressed dissolved oxygen levels; and degraded water quality from various waterborne contaminants. Two private landowners also believed that silt deposited into Tumbling Creek cave was a major contributor to habitat loss of the species. Newly suggested reasons given by peer reviewers for the decline in cavesnail numbers that were not addressed in the emergency rule were: residual toxins in the surrounding substrate that could adversely affect the water quality of the cave stream and cause changes in water chemistry (*e.g.*, change in pH or imbalances in the anion/cation exchange).

Four of the five private landowners who provided comments stated their belief that the listing of Tumbling Creek cavesnail as an endangered species would not impact their property rights. The fifth landowner did not comment on this issue. Two respondents indicated that the declining population of *Antrobia culveri* served as a barometer on the quality of water important to area land owners and further noted that listing the species was important in preserving the rich biological diversity of the Ozarks on esthetic and ecological grounds. One peer reviewer and two land owners recommended that the entire recharge area of Tumbling Creek cave be designated as critical habitat. Comments related to the issue of critical habitat for this species are addressed below.

**Summary of Factors Affecting the Species**

After a thorough review and consideration of all information available, we determine that the Tumbling Creek cavesnail should be classified as an endangered species. We followed procedures found in section 4 of the Act (16 U.S.C. 1533) and regulations (50 CFR part 424) promulgated to implement the listing provisions of the Act. We may determine a species to be endangered or threatened due to one or more of the five factors described in section 4(a)(1) of the Act. These factors and their application to the Tumbling Creek cavesnail (*Antrobia culveri*) are as follows:

*A. The Present or Threatened Destruction, Modification, or Curtailment of Its Habitat or Range*

*Antrobia culveri* has exhibited a large decline in numbers since the first estimate was made by Greenlee (1974) (see Status and Distribution, above). Systematic sampling within various sections of Tumbling Creek was initiated in 1996 (McKenzie *in litt.* 1996). Placement of sampling quadrats was done by inspecting the area within each of the sampling sections and arbitrarily placing the sampling squares approximately equidistant along each section. Ashley reported a statistically significant decline in the snail population over the period between 1996 and the first quarter of 2002 (Ashley 2001c, 2002). Additionally, no cavesnails have been located at established monitoring stations during the last eight surveys (Ashley 2001a, 2001b, 2001c, 2002).

We also have documented a large reduction in the portion of the cave stream occupied by the cavesnail. *Antrobia culveri* was historically known from an estimated 229 m (750 ft) of Tumbling Creek (Greenlee 1974). The 229 m of occupied habitat in 1974 constituted 50 percent of the 457 m (1,500 ft) of human-accessible cave-stream habitat that is believed to be

suitable for the cavesnail. The entire accessible 457 m (1,500 ft) of Tumbling Creek, including a small tributary that has approximately 9 additional meters (30 ft) of accessible suitable habitat, was surveyed in March 2001. Cavesnails were found solely in one small (14-m) (45-ft) section of the stream and in the small tributary (Ashley 2001a). Observations between March and August 2001 suggest that *A. culveri* is now restricted to 23 m of available stream habitat or approximately 5 percent of the 457 m of accessible suitable habitat. These figures indicate that distribution of this species in Tumbling Creek Cave has decreased by 90 percent.

Species such as the Tumbling Creek cavesnail, which spend all of their life cycle in subterranean waters, are highly vulnerable to changes in the quality and quantity of that water. In turn, the quality and quantity of the subsurface water is highly dependent upon conditions and human activities on the land surface. Water feeds into losing streams and sinkholes that drain into underground karst conduits. Surface water moves into the subsurface system by a number of mechanisms, including sinkholes, percolation through sandy or gravelly soils and stream bottoms, and seepage and flowage into crevices. As water moves from the surface to the subsurface system, it carries the chemicals and particulate matter from the surface (Gines and Gines 1992). The land surface that feeds water into a particular cave stream is referred to as the ''recharge area'' for that cave stream. Because recharge areas may be large and may consist of all or parts of several surface watersheds, it is critically important to accurately determine the boundaries of the recharge area with reliable hydrogeological methods. Only when the recharge area is accurately delineated can water quality threats be successfully addressed (Aley and Aley 1991).

The recharge area that feeds water into Tumbling Creek Cave has been recently delineated by the cave owner, Mr. Thomas Aley of the OUL, who is also a recognized cave specialist and expert karst hydrogeologist (Aley and Aley 2001). Pending the results of additional recharge delineation studies currently being conducted by Aley on a tract of land recently purchased by him and Cathy Aley (Tom Aley, pers. comm., September 24, 2001), he estimated the recharge area to be approximately 2,349 hectares (5,804 acres or 9.07 square miles). Land ownership based on current data within the recharge area is: (1) Tom and Cathy Aley own approximately 1,550 acres, or 25 percent of the total; (2) employees of Ozark Underground Laboratory and other private individuals, who manage their property to protect water quality and benefit the species, own approximately 1,268 acres or 22 percent; (3) an estimated 1,300 acres or 23 percent is within Mark Twain National Forest; (4) the U.S. Army Corps of Engineers (CE) owns an estimated 100 acres or 2 percent; and (5) other private landowners, whose land use practices and knowledge of the cavesnail are currently unknown to us, own approximately 1,636 acres or 28 percent. Thus, within the delineated recharge area for Tumbling Creek Cave, roughly 4,168 acres or approximately 72 percent is either in public or private ownership by entities who can be expected to manage their land to benefit the species. This includes 920 acres recently purchased by Tom and Cathy Aley, or about 22 percent of the total conservation ownership. However, most of this recently purchased land was subject to land use practices (*e.g.*, overgrazing and removal of riparian vegetation) by the previous owner that resulted in heavy soil erosion that probably continues to contribute to deteriorating water quality in Tumbling Creek Cave. Remediation and restoration of these lands are planned and will require considerable funds, effort, and time.

The Tumbling Creek cavesnail is likely threatened by habitat degradation through diminished water quality from upstream locations within the unprotected or improperly managed areas within the cave's delineated recharge zone. The dramatic decrease in the population and area occupied by this species is probably attributable to degraded water quality from these sources. In recent years, there has been a noticeable increase in water turbidity in Tumbling Creek; the increased turbidity has probably had an adverse effect on the water quality in the cave's stream (Tom and Cathy Aley, pers. comm., August 30, 2001). Increased silt loads within Tumbling Creek could adversely affect the cavesnail by hampering reproduction and recruitment by suffocating juvenile cavesnails (Ashley 2000). Several authors (*e.g.*, Poulson 1996, Elliott 2000, Taylor *et al.* 2000) have noted that high sediment loads usually have a negative impact on aquatic species. Tom and Cathy Aley have also observed that clay particles within deposited silt have settled between gravel and rocks and cemented them together and to the stream bottom (Tom and Cathy Aley, pers. comm., August 2001). Such cementing decreases habitat available to cavesnails, especially interstitial areas, because the species is generally restricted to the undersurface of gravel and rocks. Coineau and Boutin (1992) demonstrated that interstitial habitats are critically important to the dispersal capabilities of animals with limited movements. Comacho (1992) suggested that the size, porosity, and compaction of sediment grains (*e.g.*, clay vs. sand) was a limiting factor in the availability of interstitial habitats to aquatic cave organisms. Interestingly, Ashley (2000) determined that some Tumbling Creek cavesnails use silt-covered substrates. This is different from the observations made by Greenlee (1974) who noted that cavesnails were not observed in areas of the stream where fine silt was deposited. Ashley's observations may be due to a reduction in the amount of silt-free substrates preferred by cavesnails which could force the species to use less favorable habitats. Although silt has been a component of Tumbling Creek since Greenlee's initial survey in 1974, it has apparently increased since that date (Tom and Cathy Aley, pers. comm., August 2001).

Silt could also be harmful to *Antrobia culveri* indirectly due to the interrelationship between various harmful bacteria or viruses and some sediment mediums. Taylor and Webb (2000) reported that the survival of some bacteria and viruses may increase when they become attached to the surface of silt and clay particles and organic matter. Additionally, they noted that such harmful bacteria as coliform and fecal coliform bacteria ''may persist and reach much higher concentrations in aquatic sediments (especially in the presence of organic nutrients) than in the water column.'' Consequently, an increase of silt into Tumbling Creek could exacerbate the potential problems from bacteria and viruses originating from livestock wastes entering Tumbling Creek. Additional research is needed to determine the degree of silt deposition within Tumbling Creek and if the deposition of silt into the cave is adversely impacting the species, especially smaller and younger individuals (Ashley 2000).

Potential sources of silt within the cave's recharge area have been identified on the two tracts recently purchased by Tom and Cathy Aley, including an earthen dam that burst, as well as severely degraded and eroded pastureland due to overgrazing. In the latter case, soil erosion has been exacerbated in the last six years by the removal of nearly all vegetation by bulldozing equipment within the riparian corridors of all semi-permanent

and intermittent streams on one of those parcels. Tree removal activities associated with pasture expansion have increased soil erosion and resulted in the subsequent movement of silt into the cave system (Aley, Ashley, and McKenzie, pers. obs.). Harvey (1980) concluded that ''accelerated erosion and sediment transport'' was a problem within drainage basins that have ''excessive slopes,'' and identified ''timber cutting and land clearing for raising livestock, extending urban sprawl, and highway building'' as potential sources of ''accelerated erosion.'' In addition to these sources, the construction of fire lanes associated with controlled burning on Forest Service property within the recharge area may increase the threat of soil erosion with a resulting decrease in water quality in Tumbling Creek.

Other factors within the recharge area of Tumbling Creek Cave that could contribute to the deterioration of the water quality of Tumbling Creek include: (1) Nutrient enrichment from livestock feedlots or from fertilizers used for crop production or pasture improvement within the recharge area that could reduce dissolved oxygen levels in Tumbling Creek or become toxic to aquatic organisms at high concentrations; (2) chemicals used for highway maintenance or from accidental spills; (3) contaminants from different types of trash or hazardous waste materials deposited into sinkholes, ravines, and depressions; and (4) contamination from hormones, antibiotics, disinfectants, or other chemicals found in human and livestock wastes (Koplin *et al.* 2002). Contaminants presumably from crop fertilizers were detected at levels high enough in cave streams within the Perryville Karst Region of southeastern Missouri to be detrimental to aquatic life (Vandike 1985; Burr *et al.* 2001). Contamination of groundwater has occurred due to spills associated with traffic accidents in the Mammoth Cave area of Kentucky (U.S. Department of Interior 1983; U.S. Fish and Wildlife Service 1988; Taylor *et al.* 2000). Because portions of Routes 160 and 125 occur within the recharge area for Tumbling Creek Cave, accidental spills resulting from traffic accidents could potentially occur. Taylor and Webb (2000) summarized the deleterious effects of various inorganic ions on the distribution and abundance of different aquatic cave isopods and amphipods. Taylor *et al.* (2000) suggested that several parameters, including depressed oxygen levels, improper pH levels, and the presence of metals, pesticides, and harmful bacteria may all contribute to the persistence or decline of aquatic cave organisms. Burr *et al.* (2001) reported that ''no less than one-half of sinkholes in Perry County, MO, contain anthropomorphic refuse, ranging from household cleansers and sewage to used pesticide and herbicide containers.'' Some unidentified point source pollution that was apparently dumped accidentally into Running Bull Cave in Perry County, MO, resulted in a mass mortality of cave-dwelling grotto sculpin (Burr *et al.* 2001). Eliott (2000) summarized the documented impact of various chemical pollutants into cave systems including sewage, contaminants from old batteries, nitric acid, leaks from petroleum products, brine pollution, herbicides, pesticides, solvents, fertilizers, milk, cream, tobacco waste products, and medical waste. Kolpin *et al.* (2002) sampled 139 streams across 30 States, including Missouri, and documented the presence of human and livestock antibiotics, human prescription and nonprescription drugs, steroid compounds including several biogenic and synthetic reproductive compounds, and 30 different organic wastewater contaminants in 80 percent of the streams sampled. Although there are no waste water treatment facilities within the recharge area for Tumbling Creek cave, livestock antibiotics, hormones, and chemical treatments for controlling insect pests could originate from livestock facilities that occur within the cave's recharge area. The extent to which any of these factors have contributed to the decline of the Tumbling Creek cavesnail remains to be determined. Refer to Factor E for further discussion of these potential threats.

*B. Overutilization for Commercial, Recreational, Scientific, or Educational Purposes*

Because access to Tumbling Creek Cave is controlled by the cave owners, all collection of and research on *Antrobia culveri* is strictly controlled. Consequently, there is no evidence, and very little likelihood, of overutilization of this species for commercial, recreational, scientific, or educational purposes. There is also no evidence that disturbance associated with conducting regular surveys is adversely affecting the species. Rocks that are examined for cavesnails are carefully replaced in the location from which they were removed, any specimens discovered are disturbed as little as possible and kept moist to reduce stress, and only a small percentage of the available habitat is sampled during each survey.

*C. Disease or Predation*

The direct effect of disease on the Tumbling Creek cavesnail is not known and such risks to the species have not been determined. Because the Tumbling Creek cavesnail is known to inhabit only a single location, disease must be considered a potential significant threat to the survival of the species. Certain species of salamanders have been shown to be adversely impacted by the bacterium *Acinetobacter* that flourished due to increasing levels of nitrogen associated with the overstocking of livestock (Worthylake and Hovingh 1989). Similarly, Lefcort *et al.* (1997) and Kiesecker and Blaustein (1997) found that amphibians exposed to high levels of silt are susceptible to infection by different species of water mold of the genus *Saprolegnia. Saprolegnia* spp. are widespread in natural waters and commonly grow on dead organic material (Wise *et al.* 1995). Speer (1995) stated that some species of *Saprolegnia* are parasitic on aquatic invertebrates such as rotifers, nematodes, diatoms, and arthropods. High nitrogen and silt levels from overgrazing or other agricultural or urban runoff may increase the cavesnail's susceptibility to disease and may act synergistically with other risk factors (e.g., competition from limpets, discussed below) to jeopardize the survival of the remaining individuals. Whether the Tumbling Creek cavesnail is being adversely affected by bacteria or water molds associated with increased loads of nitrogen or silt into Tumbling Creek is unknown but warrants further investigation.

During the December 6, 1997, survey, a few individuals of an unknown species of limpet (*Ferrissia* sp.) were discovered for the first time on the same substrates used by Antrobia culveri within the established monitoring stations (Ashley, pers. comm., September 10, 2001). Limpets were not observed again until the January 11, 2001, survey, after which their numbers began to increase. By the August 31, 2001, survey, limpet numbers had increased explosively, and the presence of many small limpets, as well as larger limpets with visible, developing embryos, indicated that reproduction was taking place (Ashley, pers. comm., September 10, 2001; McKenzie pers. obs.) The reasons that caused these organisms to appear and increase in numbers within Tumbling Creek are unknown; it is also unknown whether they compete with the cavesnails for food, breeding substrates, or other necessary resources. Dr. Julian J. Lewis documented that the disappearance of

the rare isopod crustacean *Caecidotea rotunda* coincided with the appearance of limpets in a cave in southern Indiana (J. Lewis, *in litt.,* January 27, 2002). Numerous investigations by David Culver and others (*e.g.*, Culver 1970, 1975) have demonstrated that interspecific competition between aquatic cave invertebrates may reduce the availability of important niche habitats. Other cave invertebrates (*e.g.,* a troglobitic isopod, *Caecidota antricola*.; a troglobitic amphipod, *Stygobromus* sp.; and a troglophilic amphipod, *Gammarus* sp.) coexist with *A. culveri,* often on the same rocks, but it is unknown if these species compete with the cavesnail in any way. Additional research is needed to determine if local environmental changes have provided a competitive advantage for one or more of these species over the Tumbling Creek cavesnail.

*D. The Inadequacy of Existing Regulatory Mechanisms*

The primary cause of the decline of the Tumbling Creek cavesnail is unknown but is believed to be associated with factors within the 2,349-hectare (5,804-acre) delineated recharge area that have adversely affected the water quality of Tumbling Creek. Federal, State, and local laws have not been sufficient to prevent past and ongoing impacts to areas within the cave's delineated recharge area. *Antrobia culveri* is listed as critically imperiled globally (G1) by The Nature Conservancy, as well as critically imperiled in the State (S1) on the *Missouri Species of Conservation Concern Checklist* (Missouri Natural Heritage Program 2001). The designation as G1/S1 on this checklist, however, provides no legal protection, but is simply utilized for planning and communication purposes (Missouri Natural Heritage Program 2001). Nonetheless, the species currently receives some protection under the *Wildlife Code of Missouri* (Wildlife Code) (Missouri Department of Conservation 2001) as a ''biological diversity element'' (Missouri Natural Heritage Program 2001). ''Biological diversity elements'' are protected under the following general prohibitions of chapter 4 of the Wildlife Code (3CSR10–4.110): ''(1) No bird, fish, amphibian, reptile, mammal or other form of wildlife, including their homes, dens, nests and eggs in Missouri shall be molested, pursued, taken, hunted, trapped, tagged, marked, enticed, poisoned, killed, transported, stored, served, bought, imported, exported or liberated to the wild in any manner, number, part, parcel or quantity, at any time, except as specifically permitted by these rules and any laws consistent with Article IV, sections 40–46 of the *Constitution of Missouri.* (2) Except as otherwise provided in this Code, wildlife may be taken only by holders of the prescribed permits and in accordance with prescribed methods. (3) No person, corporation, municipality, county, business or other public or private entity shall cause or allow any deleterious substance to be placed, run or drained into any of the waters of this State in quantities sufficient to injure, stupefy or kill fish or other wildlife which may inhabit such waters.''

Under the Section 6 Cooperative Agreement between MDC and the Service, if a species is listed as endangered under the Act, the Conservation Commission of Missouri shall list the species as State endangered. The protection of all species in Missouri is outlined in Chapter 4 of the Wildlife Code, and regulations pertaining to endangered species are listed in section 3CSR10–4.111. Under the Wildlife Code, citizens can possess (but not sell or purchase) up to five individuals of any species without a permit and when not specifically protected elsewhere in the code (3CSR10–9.110). However, when a species is listed as endangered, citizens cannot possess any individuals and cannot import, transport, purchase, or take the species without a scientific collecting or special use permit. Although the term ''refuge'' is not defined under the Wildlife Code, there is also a provision that enables MDC's Director to establish refuges not to exceed 1 square mile for not more than 60 days to provide essential protection to endangered species. Furthermore, the Wildlife Code states that a species' ''home'' is protected. The term ''home'' is not defined in this statute and may provide limited or no protection for the cavesnail's habitat. For instance, the creek where the cavesnail resides and the cave's recharge area would probably not be considered a home and thus receive no protection under the Wildlife Code (Bob White, MDC, Protection Division Chief, pers. comm., October 2, 2001).

The Federal Cave Resources Protection Act of 1988 (18 U.S.C. 4301–4309; 102 Stat. 4546) was passed to ''secure, protect, and preserve significant caves on Federal lands'' and to ''foster increased cooperation and exchange of information between governmental authorities and those who utilize caves located on Federal lands for scientific, educational, or recreational purposes.'' Although this statute and a final rule to implement the Federal Cave Resources Protection Act on Forest Service land (59 FR 31152; June 17, 1994) provide protection for caves located on property owned by the Forest Service, they do not provide protection for caves whose recharge areas are within Forest Service boundaries if the caves themselves are under private lands, as is the case with Tumbling Creek Cave.

Under Section 578.215 of the Missouri Cave Resources Act (Missouri Department of Conservation 2002), the following actions are prohibited: ''A person shall not purposely introduce into any cave, cave system, sinkhole, or subsurface waters of the state any substance that will or could violate any provision of the Missouri clean water law as set forth in chapter 204, RSMo (Revised Statutes of Missouri), or any water quality standard or effluent limitation promulgated pursuant thereto.'' Although this statute is intended to prevent harmful chemicals from being placed into a cave, it is rarely enforced, and an individual prosecuted for a violation of this measure can be convicted of no more than a Class A misdemeanor; therefore, it is largely ineffective at providing protection for aquatic animals within a cave stream (Bill Elliott, Cave Biologist, Missouri Department of Conservation, Jefferson City, MO, pers. comm., March 15, 2002).

The protection afforded *Antrobia culveri* from the statutes mentioned above is limited, does not provide adequate protections to its habitat, and includes no provisions to protect areas within the delineated recharge area for Tumbling Creek Cave. Therefore, we conclude the most likely threats to the species cannot be addressed by existing regulatory mechanisms.

*E. Other Natural or Manmade Factors Affecting Its Continued Existence*

Several other potential factors, including point and non-point pollution, threats from residential and commercial development, and recent changes to the hydrological cycle within the 2,349-hectare (5,804-acre) delineated recharge area supporting Tumbling Creek Cave may have negative effects on the species. It is possible that the recent decline in cavesnail numbers is attributable to some yet to be identified point or non-point source pollution within the cave's recharge area. Because the Tumbling Creek cavesnail occupies a permanent, flowing stream, it will likely come in contact with any deleterious chemical or other material that enters the cave's recharge system. Silt deposition has been identified as a potential problem, especially to younger

cohorts of the cavesnail's population, but additional research is needed to determine if other contaminants are potentially involved. (*See* Factor A above.)

Non-point source pollution may be a problem in a significant portion of the recharge area that feeds Tumbling Creek Cave. Potential sources of pollution include the drainage of barnyard and feedlot wastes and the discharge of treated sewage into sinkholes and losing streambeds within the cave's recharge area. The water quality of Tumbling Creek may also be threatened due to accidental spills into sinkholes or losing stream valleys feeding Tumbling Creek Cave from State and county highways passing through the recharge area. Such sources of pollution have been identified as potential problems for ground water in the Springfield-Salem Plateaus of southern Missouri (including the watershed that encompasses Tumbling Creek and its identified recharge zone) (Harvey 1980). The decline in numbers of the Tumbling Creek cavesnail may be due to one or several sources of pollution that have resulted in a deterioration of water quality within the recharge area for Tumbling Creek as outlined in Factor A. In comparing the quality of groundwater sites within the Ozark Plateaus (including southwestern Missouri) with other National Water-Quality Assessment Program (NAWQA) sites, Petersen *et al.* (1998) documented that: (1) Nitrate concentrations in parts of the Springfield Plateau aquifer were higher than in most other NAWQA drinking-water aquifers, and (2) volatile organic compounds were detected more frequently in drinking-water aquifers within the Ozark Plateaus than in most other drinking-water aquifers. Tumbling Creek Cave is within the NAWQA study boundaries; consequently, the cavesnail could be threatened from these contaminants. Peck (1998) concluded that all aquatic cave species were especially vulnerable to karst groundwater pollution. Elliott (2000) summarized numerous examples of cave systems being contaminated by a wide range of pollutants that are directly or indirectly dumped into cave streams and further suggested that reduced biotic diversity correlated with degraded water quality in three caves in Tennessee. Although no detailed water analyses have yet been performed on Tumbling Creek, an instrumentation package to measure water quality parameters will be installed in Tumbling Creek Cave during the summer of 2002.

Aley (pers. comm., Jan. 19, 2001) postulated that the decline in cavesnail numbers may actually be because of too much gray bat guano that could deplete oxygen levels in Tumbling Creek, especially during periods of reduced flows as occurred during 1999–2001. Vandike (1982) and Elliott (2000) reported on a massive die-off of the Salem cave crayfish (*Cambarus hubrichti*) and the southern cavefish (*Typhlichthys subterraneus*) when a large quantity of liquid fertilizer containing ammonium nitrate and urea accidentally spilled into a losing stream and significantly lowered dissolved oxygen levels in Meramec Spring, which is 21 km (13 mi) downstream from the spill. What importance gray bat guano plays in the life history requirements of the Tumbling Creek cavesnail is yet to be tested experimentally. The instrumentation package mentioned above will provide data on dissolved oxygen levels once it is installed.

Tumbling Creek Cave is approximately 45 km (28 mi) southeast of Branson, MO, which is one of the most rapidly expanding areas in the State due to tourism, outdoor recreation, and entertainment developments. If recent trends continue, it has been projected that the number of visitors attracted to this area would increase from an estimated level of 6 million in 1992 to 11 million by the year 2015. The accompanying growth in entertainment- and recreation-related activities will place even greater demands on this area of the State (Mullen and Keith 1992). Tumbling Creek Cave is about 4 km (2.5 mi) northwest of Bull Shoals Lake which is also undergoing additional real estate development. Consequently, it is likely that sections of the recharge zone for Tumbling Creek Cave will be adversely affected by real estate development and related construction and land management activities. Elliott (2000) provided multiple examples of how various land development activities have adversely impacted important karst resources in the eastern United States.

Another potential threat to the species results from the close hydrologic association of Tumbling Creek with nearby Bull Shoals Lake. Occasional high water levels in this CE reservoir are believed to cause water to backup into the cave stream, threatening roosting bats and the cavesnail (Aley, pers. comm., July 16, 2000). The CE is considering raising the conservation pool of the reservoir by 10 feet, which will likely increase the frequency and duration of the backup events in Tumbling Creek Cave. Lewis (1994) reported that the habitat of the subterranean hydrobiid snail *Antroselates spiralis* in Mammoth Cave, KY, was reduced significantly due to ponding of the adjacent Green River by a dam downstream of the cave. The back-flooding created a siltation problem that fragmented previously occupied areas into disjunct islands of habitat (J. Lewis *in litt.,* January 27, 2002).

Climatic changes, especially recent periods of drought, may also be a contributing factor to the decline of the cavesnail. The National Oceanic and Atmospheric Administration's (NOAA) Palmer Drought Severity Index provides a widely recognized and accepted standard measurement of moisture conditions (NOAA 2001). The Index varies roughly from −6.0 (extreme drought) to +6.0 (extremely wet), with −0.49 to 0.49 indicating near normal conditions. Since the 1974 survey by Greenlee, there have been 4 periods in Southwest Missouri where the Index was below normal for 6 months or longer and was below an Index value of -2.0 (moderate drought) for some part of that period. These events occurred in 2-year cycles: 1980–1981; 1991–1992; 1995–1996; and 1999–2000. The 1980–1981 drought was the most prolonged and severe, with the Index reaching −5.0 (extreme drought). We further analyzed a 6-year period between 1995 and 2000, which is the approximate period that Ashley conducted his cavesnail monitoring. The Index was below normal for 6 months or more for 4 of these 6 years. The years, number of months the Index was below normal, and the averages for the negative indices are: 1995, 6 months, average Index −1.54; 1996, 7 months, average Index −1.2; 1999, 6 months, average Index −1.29; 2000, 10 months, average Index −1.65. Preliminary data on NOAA's Web site indicate that below-normal moisture (negative Palmer Index) occurred in this region during the early part of 2001, but precipitation levels are now near normal.

According to these climatic data, in 2 recent periods (1995–1996 and 1999–2000) precipitation within the recharge area for Tumbling Creek Cave was below normal for an extended period. The direct or indirect impacts of these droughts on the cavesnail are unknown. Reduced flows in the cave stream, especially when combined with other threats, could hamper essential life history requirements (*e.g.,* reproduction, food availability, water temperature); decrease the flushing of silt, guano, and harmful contaminants from the stream; and create an environment more favorable for competitors (*e.g.,* limpets, isopods, and amphipods).

The small population size and endemism (*i.e.,* restricted to a single site) of *Antrobia culveri* makes it vulnerable to extinction due to genetic drift, inbreeding depression, and random or chance changes to the environment (Smith 1990) that can significantly impact cavesnail habitat. Inbreeding depression can result in death, decreased fertility, smaller body size, loss of vigor, reduced fitness, and various chromosome abnormalities (Smith 1990). Despite any evolutionary adaptations for rarity, habitat loss and degradation increase a species' vulnerability to extinction (Noss and Cooperrider 1994). Numerous authors (*e.g.,* Noss and Cooperrider 1994, Thomas 1994) have indicated that the probability of extinction increases with decreasing habitat availability. Although changes in the environment may cause populations to fluctuate naturally, small and low-density populations are more likely to fluctuate below a minimum viable population (*i.e.,* the minimum or threshold number of individuals needed in a population to persist in a viable state for a given interval; Gilpin and Soule 1986, Shaffer 1981, Shaffer and Samson 1985). Current threats to the habitat of the Tumbling Creek cavesnail may exacerbate potential problems associated with its low population numbers and increase the chances of this species going extinct.

**Conclusion**

Tumbling Creek cavesnail is known from a single cave in Taney County, southwestern Missouri. The distribution of this species has decreased in Tumbling Creek by 90 percent since 1974. Analysis of survey data collected at established sampling points between September 9, 1996, and March 23, 2002, indicates that numbers of the species have decreased significantly, and the cavesnail is vulnerable to extinction. This decline has continued to the point that cavesnails are no longer present in portions of Tumbling Creek where they had always been found prior to 2001 using the same monitoring methodology. The Tumbling Creek cavesnail is likely threatened by habitat degradation through diminished water quality from upstream locations within the unprotected or improperly managed areas within the cave's delineated recharge zone. The dramatic decrease in the population and area occupied by this species is probably attributable to degraded water quality from one or a number of the following sources: siltation from poor land management practices within the cave's recharge area; contamination from numerous chemicals associated with point or non-point source pollution; or imbalances in dissolved oxygen, pH, or cation/anion exchange. The species may also be threatened with competition from limpets or from changes in the cave's normal hydrological cycles due to recent droughts. Because the sudden population decline and high magnitude of threats demonstrates a significant and imminent risk to the well-being of the Tumbling Creek cavesnail, we find that listing this species as endangered is appropriate.

In making this determination, we have carefully assessed the best scientific and commercial information available regarding the past, present, and future threats faced by the Tumbling Creek cavesnail. From the discussion under Factor D of this section, it is clear that currently applicable Federal, State, and local laws, regulations, and ordinances, individually and collectively, do not provide adequate protection for the Tumbling Creek cavesnail or its habitat or assure that the species will continue to survive.

We believe that the survival of the Tumbling Creek cavesnail now depends on protecting the delineated recharge area of Tumbling Creek Cave from further degradation and restoring and rehabilitating areas within the recharge area to improve the water quality in Tumbling Creek. The small remaining population is vulnerable to extinction from ongoing threats, as well as from random natural or human-caused events unless sufficient habitat is protected, water quality improves, and the current small population greatly increases in size. The recent rapid population decline makes it clear that this cavesnail is on the brink of extinction. By listing the Tumbling Creek cavesnail as an endangered species, we believe the additional protection, funding, and recognition that immediately become available to the species will greatly increase the likelihood that extinction can be prevented and the species ultimately recovered.

We are making this rule effective immediately in order to ensure there is no gap in the protection provided by the Act to the Tumbling Creek cavesnail. The temporary protection that was provided by our emergency listing of the species on December 27, 2001, ends on August 26, 2002. This final rule results in no change to the temporary protection and regulatory authority that was provided by the emergency listing, so there is no overriding need for a delayed effective date in order to provide adequate time to notify individuals, agencies, and organizations of new regulations that may affect them.

**Critical Habitat**

Critical habitat is defined in section 3 of the Act as: (i) The specific areas within the geographical area occupied by a species, at the time it is listed in accordance with the Act, on which are found those physical or biological features (I) essential to the conservation of the species and (II) that may require special management considerations or protection; and (ii) specific areas outside the geographical area occupied by a species at the time it is listed, upon a determination that such areas are essential for the conservation of the species. ''Conservation'' means the use of all methods and procedures needed to bring the species to the point at which listing under the Act is no longer necessary.

Section 4(a)(3) of the Act, as amended, and implementing regulations (50 CFR 424.12) require that, to the maximum extent prudent and determinable, we designate critical habitat at the time the species is determined to be endangered or threatened. However, our budget for listing and critical habitat activities is currently insufficient to allow us to immediately complete all of the listing actions required by the Act. Listing the Tumbling Creek cavesnail without designation of critical habitat will allow us to concentrate our limited resources on other listing actions that must be addressed, while allowing us to invoke protections needed for the conservation of this species without further delay. This is consistent with section 4(b)(6)(C)(i) of the Act, which states that final listing decisions may be issued without critical habitat designations when it is essential that such determinations be promptly published. The legislative history of the 1982 Act amendments also emphasized this point: ''The Committee feels strongly, however, that, where biology relating to the status of the species is clear, it should not be denied the protection of the Act because of the inability of the Secretary to complete the work necessary to designate critical habitat. * * * The committee expects the agencies to make the strongest attempt possible to determine critical habitat within the time period designated for listing, but stresses that the listing of species is not to be delayed in any instance past the time period allocated for such listing if the biological data is clear but the habitat designation process is not complete.'' (H.R. Rep. No. 97–567 at 20 (1982)). If prudent and determinable, we will prepare a critical habitat proposal in the future at such time as our

available resources and other listing priorities under the Act will allow.

**Available Conservation Measures**

Conservation measures provided to species listed as endangered or threatened under the Act include recognition, recovery actions, requirements for Federal protection, and prohibitions against certain practices. Recognition through listing results in public awareness and conservation actions by Federal, Tribal, State, and local agencies, private organizations, and individuals. The Act provides for possible land acquisition and cooperation with the State and requires that recovery actions be carried out for all listed species. The protection required of Federal agencies and the prohibitions against certain activities involving listed species are discussed, in part, below.

Section 7(a) of the Act, as amended, requires Federal agencies to evaluate their actions with respect to any species that is proposed or listed as endangered or threatened, and with respect to its critical habitat, if any is being designated. Regulations implementing this interagency cooperation provision of the Act are codified at 50 CFR part 402. If a species is listed on an emergency basis, or is listed under a non-emergency listing proposal, section 7(a)(2) requires Federal agencies to ensure that activities they authorize, fund, or carry out are not likely to jeopardize the continued existence of such a species or to destroy or adversely modify its critical habitat. If a Federal agency action may adversely affect a listed species or adversely modify its designated critical habitat, the responsible Federal agency must initiate formal consultation with the Service. Section 7(a)(4) of the Act requires Federal agencies to confer with us on any action that is likely to jeopardize the continued existence of a proposed species or result in destruction or adverse modification of proposed critical habitat. Federal agency actions that may affect the Tumbling Creek cavesnail and may require consultation with the Service include, but are not limited to, those within the jurisdiction of the U.S. Forest Service, U.S. Army Corps of Engineers, Natural Resources Conservation Service, Environmental Protection Agency, and Federal Highway Administration.

The Act and its implementing regulations found at 50 CFR 17.21 set forth a series of general prohibitions and exceptions that apply to all endangered wildlife. These prohibitions, in part, make it illegal for any person subject to the jurisdiction of the United States to take (including harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect; or attempt any such conduct), import or export, ship in interstate or foreign commerce in the course of commercial activity, or sell or offer for sale in interstate or foreign commerce any listed species. It also is illegal to possess, sell, deliver, carry, transport, or ship any such wildlife that has been taken illegally. Certain exceptions apply to Service agents and those of State conservation agencies.

Permits may be issued to carry out otherwise prohibited activities involving endangered wildlife under certain circumstances. Regulations governing permits are codified at 50 CFR 17.22 and 17.23. For endangered species, such permits are available for scientific purposes, to enhance the propagation or survival of the species, and for incidental take in connection with otherwise lawful activities.

As published in the **Federal Register** on July 1, 1994 (59 FR 34272), it is the Service's policy to identify, to the maximum extent practicable at the time a species is listed, those activities that would or would not constitute a violation of section 9 of the Act. The intent of this policy is to increase public awareness of the effect of the listing on proposed and ongoing activities within a species' range.

We believe that, based on the best available information, the following actions are not likely to result in a violation of section 9, provided these actions are carried out in accordance with any existing regulations and permit requirements:

(1) Possession of a Tumbling Creek cavesnail legally acquired prior to the effective date of this rule;

(2) Actions that may affect the Tumbling Creek cavesnail that are authorized, funded, or carried out by a Federal agency, when the action is conducted in accordance with an incidental take statement issued by the Service under section 7 of the Act;

(3) Actions that may affect the Tumbling Creek cavesnail that are not authorized, funded, or carried out by a Federal agency, when the action is conducted in accordance with an incidental take permit issued by the Service under section 10(a)(1)(B) of the Act. Applicants design a Habitat Conservation Plan (HCP) and apply for an incidental take permit. These HCPs are developed for species listed under section 4 of the Act and are designed to minimize and mitigate impacts to the species to the greatest extent practicable; and

(4) Actions that may affect the Tumbling Creek cavesnail that are conducted in accordance with the conditions of a section 10(a)(1)(A) permit for scientific research or to enhance the propagation or survival of the species.

We believe that the following actions could result in a violation of section 9; however, possible violations are not limited to these actions alone:

(1) Unauthorized possession, collecting, trapping, capturing, killing, harassing, sale, delivery, or movement, including interstate and foreign commerce, or harming, or attempting any of these actions, of Tumbling Creek cavesnails without a permit (research activities where cavesnails are collected will require a permit under section 10(a)(1)(A) of the Endangered Species Act);

(2) Illegal discharges or dumping of toxic chemicals, silt, or other pollutants (point source and non-point source pollution) within the recharge area of Tumbling Creek Cave that alters or degrades the water quality of Tumbling Creek to the point that it results in death or injury to individuals of the species or results in degradation of cavesnail-occupied habitat;

(3) Intentional release of exotic species (including, but not limited to, fish and crayfish) into Tumbling Creek that adversely affect the cavesnail;

(4) Unlawful destruction or alteration of the species' occupied habitat (e.g., vandalism to Tumbling Creek); and

(5) Violation of any discharge or water withdrawal permit within Tumbling Creek.

We will review other activities not identified above on a case-by-case basis to determine whether they are likely to result in a violation of section 9 of the Act. We do not consider these lists to be exhaustive and provide them as information to the public.

Questions regarding whether specific activities will constitute a violation of section 9 should be directed to the Field Supervisor of the Columbia, Missouri Field Office (*see* **FOR FURTHER INFORMATION CONTACT**).

Requests for copies of the regulations regarding listed species and inquiries regarding prohibitions and permits may be addressed to the U.S. Fish and Wildlife Service, Endangered Species Permits, Bishop Whipple Federal Building, 1 Federal Dr., Fort Snelling, MN 55111–4056 (612/713–5343, facsimile 612/713–5292).

**National Environmental Policy Act**

The Service has determined that an Environmental Assessment, as defined under the authority of the National Environmental Policy Act of 1969, need not be prepared in connection with

regulations adopted pursuant to section 4(a) of the Endangered Species Act, as amended. The Service published a notice outlining our reasons for this determination in the **Federal Register** on October 25, 1983 (48 FR 49244).

**Paperwork Reduction Act**

This rule does not contain any collections of information that require additional Office of Management and Budget (OMB) approval under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* An information collection related to the rule pertaining to permits for endangered and threatened species has OMB approval and is assigned control number 1018–0094, which expires on July 31, 2004. This rule does not alter that information collection requirement. 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 control number. For additional information concerning permits and associated requirements for endangered wildlife, *see* 50 CFR 17.21 and 17.22.

**Effective Date**

This rule is effective upon publication. The Administrative Procedures Act provides Federal agencies a means under 5 U.S.C. (d)(3) for making rules effective less than 30 days following publication in the **Federal Register** for ''good cause.'' We believe that we have good cause for making this rule effective upon publication. The emergency listing rule for the Tumbling Creek cavesnail was published in the **Federal Register** on December 27, 2001 (66 FR 66803). That rule listed the Tumbling Creek cavesnail as endangered on an emergency basis for 240 days through August 26, 2002. We are now publishing a final rule to the proposed rule (66 FR 66868) that we published on the same day as the emergency listing rule. To continue to provide this species the protections of the Act originally provided under the emergency rule, we must make this final rule effective upon publication.

**References Cited**

A complete list of all references cited in this rulemaking is available upon request from the Field Supervisor, Columbia Field Office (*see* **ADDRESSES**).

**Author**

The primary author of this proposed rule is Paul M. McKenzie, Ph.D., U.S. Fish and Wildlife Service, Columbia Field Office (*see* **ADDRESSES**).

**List of Subjects in 50 CFR Part 17**

Endangered and threatened species, Exports, Imports, Reporting and recordkeeping requirements, Transportation.

**Regulation Promulgation**

For the reasons given in the preamble, we amend part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations, as set forth below:

## PART 17—[AMENDED]

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

**Authority:** 16 U.S.C. 1361–1407; 16 U.S.C. 1531–1544; 16 U.S.C. 4201–4245; Pub. L. 99–625, 100 Stat. 3500, unless otherwise noted.

2. Amend § 17.11(h) by adding the following, in alphabetical order under SNAILS, to the List of Endangered and Threatened Wildlife:

**§ 17.11 Endangered and threatened wildlife.**

* * * * *

(h) * * *

| Species | | Historic range | Vertebrate population where endangered or threatened | Status | When listed | Critical habitat | Special rules |
|---|---|---|---|---|---|---|---|
| Common name | Scientific name | | | | | | |
| * | * | * | * | * | * | * | |
| SNAILS | | | | | | | |
| * | * | * | * | * | * | * | |
| Cavesnail, Tumbling Creek | *Antrobia culveri* ..... | U.S.A. (MO) ..... | NA ..... | E | 731 | NA | NA |
| * | * | * | * | * | * | * | |

Dated: July 26, 2002.

**Steve Williams,**

*Director, Fish and Wildlife Service.*

[FR Doc. 02–20339 Filed 8–13–02; 8:45 am]

BILLING CODE 4310–55–P

## DEPARTMENT OF COMMERCE

## National Oceanic and Atmospheric Administration

## 50 CFR Part 660

**[Docket No. 020430101–2101–01; I.D. 080202E]**

## Fisheries Off West Coast States and in the Western Pacific; West Coast Salmon Fisheries; Inseason Action 7–Adjustment of the Commercial Fishery from the U.S.-Canada Border to Cape Falcon, OR

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

**ACTION:** Adjustment; request for comments.

**SUMMARY:** NMFS announces that the commercial fishery for all salmon except coho in the area from the U.S.–Canada Border to Cape Falcon, OR, was modified to reopen on July 26 and close at midnight, August 5, 2002, with a vessel limit of 500 chinook salmon for the 11–day open period. The Northwest Regional Administrator, NMFS (Regional Administrator), determined that available catch and effort data indicated that these management measures should be implemented to provide fishers greater access to the chinook and coho quotas. This action was necessary to conform to the 2002 management goals.

**DATES:** Adjustment in the area from the U.S.–Canada Border to Cape Falcon, OR effective 0001 hours local time (l.t.), July 26, 2002, through 2359 hours l.t. August 5, 2002, after which the fishery will remain closed until opened through an additional inseason action, which will be published in the **Federal Register** for the west coast salmon fisheries, or until the effective date of the year 2003 management measures. Comments will be accepted through August 29, 2002.

**ADDRESSES:** Comments on this action must be mailed or faxed to D. Robert Lohn, Regional Administrator, Northwest Region, NMFS, NOAA, 7600 Sand Point Way N.E., Bldg. 1, Seattle, WA 98115–0070, facsimile 206–526–6376; or Rod McInnis, Acting Regional Administrator, Southwest Region, NMFS, NOAA, 501 W. Ocean Blvd., Suite 4200, Long Beach, CA 90802–4132, facsimile 562–980–4018.

Comments will not be accepted if submitted via e-mail or the Internet. Information relevant to this document is available for public review during business hours at the Office of the Regional Administrator, Northwest Region, NMFS.

**FOR FURTHER INFORMATION CONTACT:** Christopher Wright, 206–526–6140.

**SUPPLEMENTARY INFORMATION:** The Regional Administrator modified the season for the commercial fishery in the area from the U.S.–Canada Border to Cape Falcon, OR to reopen on July 26 and close at midnight, August 5, 2002, with a vessel limit of 500 chinook salmon for the 11–day open period. Information provided on July 25 regarding the available catch and effort data indicated that these management measures should be implemented to allow fishers to fully access the chinook and coho quotas. Modification of fishing seasons are authorized by regulations at 50 CFR 660.409(b)(1)(i).

In the 2002 annual management measures for ocean salmon fisheries (67 FR 30616, May 7, 2002), NMFS announced that the commercial fishery for all salmon except coho in the area from the U.S.-Canada Border to Cape Falcon, OR would open July 1 and run through the earlier of September 8 or a 32,500–chinook quota, except for a selective fishery for marked coho scheduled at the end of the season with a 5,000–marked coho quota.

The fishery in the area from the U.S.-Canada Border to Cape Falcon, OR has been modified twice by inseason action. The first inseason action opened the fishery as scheduled on July 1, but modified it to close at midnight, July 8, 2002, with the provision that no vessel may possess, land, or deliver more than 250 chinook for the entire 8–day open period (67 FR 47334, July 18, 2002). The second inseason action reopened the area on July 12 and closed it at midnight, July 22, 2002, with the provision that no vessel may possess, land, or deliver more than 400 chinook for the entire 11–day open period (67 FR 49876, August 1, 2002). These modifications to the fishing season were adopted to avoid closing the fishery early due to reaching the chinook quota, thus precluding the opportunity to catch available marked hatchery coho salmon later in the season.

On July 25, 2002, the Regional Administrator consulted with representatives of the Pacific Fishery Management Council, Washington Department of Fish and Wildlife, and Oregon Department of Fish and Wildlife (ODFW) by conference call. Information related to catch to date, the chinook catch rate, and effort data indicated that it was likely that the chinook quota would be reached prematurely unless adequately controlled, potentially foreclosing opportunity of fishers to conduct the selective fishery for marked coho later in the season. As a result, the states of Washington and Oregon recommended, and the Regional Administrator concurred, that the commercial fishery in the area from the U.S.–Canada Border to Cape Falcon, OR would reopen on July 26 and close at midnight, August 5, 2002, with the provision that no vessel may possess, land, or deliver more than 500 chinook for the entire 11–day open period. All other restrictions that apply to this fishery remain in effect as announced in the 2002 annual management measures. The State of Oregon added a landing restriction for this fishery in their regulations requiring that fishers fishing north of Cape Falcon, and intending to land salmon south of Cape Falcon, notify the ODFW before they leave the area at the following phone number (541) 867–0300, Ext. 252. In addition, the parties agreed to reevaluate the fishery on August 8, and assess the possibility of further openings in the fishery.

The Regional Administrator determined that the best available information indicated that the catch and effort data, and projections, supported the above inseason action recommended by the states. The states manage the fisheries in state waters adjacent to the areas of the U.S. exclusive economic zone in accordance with this Federal action. As provided by the inseason notice procedures of 50 CFR 660.411, actual notice to fishers of the above described action was given prior to the effective date by telephone hotline numbers 206–526–6667 and 800–662–9825, and by U.S. Coast Guard Notice to Mariners broadcasts on Channel 16 VHF-FM and 2182 kHz.

This action does not apply to other fisheries that may be operating in other areas.

## Classification

The Assistant Administrator for Fisheries, NOAA (AA), finds that good cause exists for this notification to be issued without affording prior notice and opportunity for public comment under 5 U.S.C. 553(b)(B), or delaying the effectiveness of this rule for 30 days under 5 U.S.C. 553(d)(3), because such notification and delay would be impracticable and contrary to the public interest. As previously noted, actual notice of this action was provided to fishers through telephone hotline and radio notification. This action complies with the requirements of the annual management measures for ocean salmon fisheries (67 FR 30616, May 7, 2002) and the West Coast Salmon Plan. Prior notice and opportunity for public comment was impracticable because NMFS and the state agencies have insufficient time to provide for prior notice and the opportunity for public comment between the time the fishery catch and effort data are collected to determine the extent of the fisheries and the time the limits to which the fishery must be adjusted to reduce harvest rates in the fishery must be in place. Moreover, such prior notice and the opportunity for public comment is contrary to the public interest because it does not allow commercial fishermen appropriately controlled access to the available fish at the time they are available.

The AA finds good cause to waive the 30–day delay in effectiveness required under 5 U.S.C. 553(d)(3). A delay in effectiveness of this action would not allow commercial fishermen appropriately controlled access to the available fish at the time they are available.

This action is authorized by 50 CFR 660.409 and 660.411 and is exempt from review under Executive Order 12866.

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

Dated: August 7, 2002.

**Virginia M. Fay,**

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

[FR Doc. 02–20653 Filed 8–13–02; 8:45 am]

**BILLING CODE 3510–22–S**

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

### 50 CFR Part 660

**[Docket No. 020430101–2101–01; I.D. 080202C]**

### Fisheries Off West Coast States and in the Western Pacific; West Coast Salmon Fisheries; Inseason Action 5 - Adjustment of the Recreational Fishery from the U.S.-Canada Border to Cape Falcon, OR

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

**ACTION:** Adjustment; request for comments.

**SUMMARY:** NMFS announces that the recreational fishery for all salmon in the area from the U.S.-Canada Border to Cape Falcon, OR, was modified to establish a chinook salmon minimum size limit of 28 inches (71.1 cm) total length for the area from the U.S.-Canada Border to Leadbetter Point, WA, and 26 inches (66.0 cm) total length for the area from Leadbetter Point to Cape Falcon, starting on Sunday, July 21. The Northwest Regional Administrator, NMFS (Regional Administrator), determined that available catch and effort data indicated that these management measures should be implemented to provide greater access to the chinook and coho quotas. This action was necessary to conform to the 2002 management goals.

**DATES:** Adjustment in the area from the U.S.-Canada Border to Cape Falcon, OR, effective 0001 hours local time (l.t.), July 21, 2002, through 2359 hours l.t., September 30, 2002, or until the effective date of the year 2003 management measures. Comments will be accepted through August 29, 2002.

**ADDRESSES:** Comments on this action must be mailed to D. Robert Lohn, Regional Administrator, Northwest Region, NMFS, NOAA, 7600 Sand Point Way N.E., Bldg. 1, Seattle, WA 98115–0070; or faxed to 206–526–6376; or Rod McInnis, Acting Regional Administrator, Southwest Region, NMFS, NOAA, 501 W. Ocean Blvd., Suite 4200, Long Beach, CA 90802–4132; or faxed to 562–980–4018. Comments will not be accepted if submitted via e-mail or the Internet. Information relevant to this document is available for public review during business hours at the Office of the Regional Administrator, Northwest Region, NMFS.

**FOR FURTHER INFORMATION CONTACT:** Christopher Wright, 206–526–6140.

**SUPPLEMENTARY INFORMATION:** The Regional Administrator modified the season for the recreational fishery in the area from the U.S.-Canada Border to Cape Falcon, OR, to establish a chinook minimum size limit of 28 inches (71.1 cm) total length from the U.S.-Canada Border to Leadbetter Point, WA, and 26 inches (66.0 cm) total length from Leadbetter Point to Cape Falcon, starting on Sunday, July 21, 2002. Information provided on July 18 regarding the available catch and effort data indicated that these management measures should be implemented to provide recreational fishers extended access to the chinook and coho quotas. Modification of fishing seasons is authorized by regulations at 50 CFR 660.409(b)(1)(i).

In the 2002 annual management measures for ocean salmon fisheries (67 FR 30616, May 7, 2002), NMFS announced a minimum size limit of 24 inches (61.0 cm) total length for chinook for the recreational fishery in the area from the U.S.-Canada Border to Cape Falcon, OR and its four sub-areas, Neah Bay, La Push, Westport, and Columbia River.

On July 18, 2002, the Regional Administrator consulted with representatives of the Pacific Fishery Management Council, Washington Department of Fish and Wildlife, and Oregon Department of Fish and Wildlife by conference call. Information related to catch to date, the chinook catch rate, and effort data indicated that it was likely that the chinook quota would be reached prematurely unless adequately controlled, potentially foreclosing the opportunity for fishers to harvest marked coho, which arrive in greater numbers later in the season. As a result, the States of Washington and Oregon recommended, and the Regional Administrator concurred, that the recreational fishery in the area from the U.S.-Canada Border to Cape Falcon required a modification of the chinook size limit to slow the catch rate for chinook. Effective Sunday, July 21, the minimum size limit for chinook for the Neah Bay, La Push, and Westport sub-areas was increased from 24 inches (61.0 cm) to 28 inches (71.1 cm) total length, and for the Columbia River sub-area from 24 inches (61.0 cm) to 26 inches (66.0 cm) total length. All other restrictions that apply to this fishery remain in effect as announced in the 2002 annual management measures.

The Regional Administrator determined that the best available information indicated that the catch and effort data, and projections, supported the above inseason action recommended by the states. The states manage the fisheries in state waters adjacent to the areas of the U.S. exclusive economic zone in accordance with this Federal action. As provided by the inseason notice procedures of 50 CFR 660.411, actual notice to fishers of the above described action was given prior to the effective date by telephone hotline numbers 206–526–6667 and 800–662–9825, and by U.S. Coast Guard Notice to Mariners broadcasts on Channel 16 VHF-FM and 2182 kHz.

This action does not apply to other fisheries that may be operating in other areas.

### Classification

The Assistant Administrator for Fisheries, NOAA (AA), finds that good cause exists for this notification to be issued without affording prior notice and opportunity for public comment under 5 U.S.C. 553(b)(B), or delaying the effectiveness of this rule for 30 days under 5 U.S.C. 553(d)(3), because such notification and delay would be impracticable and contrary to the public interest. As previously noted, actual notice of this action was provided to fishers through telephone hotline and radio notification. This action complies with the requirements of the annual management measures for ocean salmon fisheries (67 FR 30616, May 7, 2002) and the West Coast Salmon Plan. Prior notice and opportunity for public comment was impracticable because NMFS and the state agencies have insufficient time to provide for prior notice and the opportunity for public comment between the time the fishery catch and effort data are collected to determine the extent of the fisheries, and the time the limits to which the fishery must be adjusted to reduce harvest rates in the fishery must be in place. Moreover, such prior notice and opportunity for public comment is contrary to the public interest because it does not allow fishers appropriately controlled access to the available fish at the time they are available.

Moreover, the AA finds good cause to waive the 30–day delay in effectiveness required under 5 U.S.C. 553(d)(3). A delay in effectiveness of this action would not allow fishers appropriately controlled access to the available fish at the time they are available.

This action is authorized by 50 CFR 660.409 and 660.411 and is exempt from review under Executive Order 12866.

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

Dated: August 7, 2002.

**Virginia M. Fay,**

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

[FR Doc. 02–20656 Filed 8–13–02; 8:45 am]

**BILLING CODE 3510–22–S**

## DEPARTMENT OF COMMERCE

## National Oceanic and Atmospheric Administration

## 50 CFR Part 660

**[Docket No. 020430101–2101–01; I.D. 080202D]**

## Fisheries Off West Coast States and in the Western Pacific; West Coast Salmon Fisheries; Inseason Action 6 - Closure of the Commercial Fishery from Horse Mountain to Point Arena (Fort Bragg)

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

**ACTION:** Closure; request for comments.

**SUMMARY:** NMFS announces that the commercial fishery for all salmon except coho in the Fort Bragg area was closed at midnight on July 23, 2002. The Northwest Regional Administrator, NMFS (Regional Administrator), determined that the quota of 10,000 chinook salmon had been reached. This action was necessary to conform to the 2002 management goals.

**DATES:** Closure in the area from Horse Mountain to Point Arena, CA effective 2359 hours local time (l.t.), July 23, 2002, until 0001 hours l.t., August 1, 2002. Comments will be accepted through August 29, 2002.

**ADDRESSES:** Comments on this action must be mailed or faxed to D. Robert Lohn, Regional Administrator, Northwest Region, NMFS, NOAA, 7600 Sand Point Way N.E., Bldg. 1, Seattle, WA 98115–0070, facsimile 206–526–6376; or Rod McInnis, Acting Regional Administrator, Southwest Region, NMFS, NOAA, 501 W. Ocean Blvd., Suite 4200, Long Beach, CA 90802–4132, facsimile 562–980–4018. Comments will not be accepted if submitted via e-mail or the Internet. Information relevant to this document is available for public review during business hours at the Office of the Regional Administrator, Northwest Region, NMFS.

**FOR FURTHER INFORMATION CONTACT:** Christopher Wright, 206–526–6140.

**SUPPLEMENTARY INFORMATION:** The Regional Administrator closed the commercial fishery in the Fort Bragg area effective at midnight on Tuesday, July 23, 2002. Information provided on July 23 estimated that the quota of 10,000 chinook salmon had been reached. Automatic season closures based on quotas are authorized by regulations at 50 CFR 660.409(a)(1).

In the 2002 annual management measures for ocean salmon fisheries (67 FR 30616, May 7, 2002), NMFS announced that the commercial fishery for all salmon except coho in the Fort Bragg area would open July 20 through the earlier of July 30 or a 10,000–chinook quota. The fishery would then reopen on August 1 through August 30, and again from September 1 through September 30.

On July 23, 2002, the Regional Administrator consulted with representatives of the Pacific Fishery Management Council and California Department Fish and Game (CDFG) by conference call. Information related to catch to date, the chinook catch rate, and effort data indicated that it was likely that the quota had been reached. As a result, the State of California recommended, and the Regional Administrator concurred, that the commercial fishery in the Fort Bragg area close effective at midnight on Tuesday, July 23, 2002. All other regulations that apply to this fishery remain in effect as announced in the 2002 annual management measures and subsequent inseason actions.

The Regional Administrator determined that the best available information indicated that the catch and effort data and projections supported the above inseason action recommended by the CDFG. The states manage the fisheries in state waters adjacent to the areas of the U.S. exclusive economic zone in accordance with this Federal action. As provided by the inseason notice procedures of 50 CFR 660.411, actual notice to fishers of the above described action was given prior to the effective date by telephone hotline numbers 206–526–6667 and 800–662–9825, and by U.S. Coast Guard Notice to Mariners broadcasts on Channel 16 VHF-FM and 2182 kHz.

This action does not apply to other fisheries that may be operating in other areas.

### Classification

The Assistant Administrator for Fisheries, NOAA (AA), finds that good cause exists for this notification to be issued without affording prior notice and opportunity for public comment under 5 U.S.C. 553(b)(B), or delaying the effectiveness of this rule for 30 days under 5 U.S.C. 553(d)(3), because such notification and delay would be impracticable and contrary to the public interest. As previously noted, actual notice of this action was provided to fishers through telephone hotline and radio notification. This action complies with the requirements of the annual management measures for ocean salmon fisheries (67 FR 30616, May 7, 2002) and the West Coast Salmon Plan. Prior notice and opportunity for public comment is impracticable because NMFS and the state agencies have insufficient time to allow for prior notice and the opportunity for public comment between the time the fishery catch and effort data are collected to determine the extent of the fisheries, and the time the fishery closure must be implemented to avoid exceeding the quota. Moreover, such prior notice and the opportunity for public comment is contrary to the public interest because not closing the fishery upon attainment of the quota would allow the quota to be exceeded, resulting in fewer spawning fish and reduced yield of the stocks. The 30–day delay in effectiveness required under U.S.C. 553(d)(3) is also hereby waived due to the immediate need to stop a fishery upon attainment of a quota.

This action is authorized by 50 CFR 660.409 and 660.411 and is exempt from review under Executive Order 12866.

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

Dated: August 7, 2002.

**Virginia M. Fay,**

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

[FR Doc. 02–20661 Filed 8–13–02; 8:45 am]

**BILLING CODE 3510–22–S**

# Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

## DEPARTMENT OF AGRICULTURE

### Animal and Plant Health Inspection Service

### 7 CFR Part 319

**[Docket No. 02–032–1]**

### Environmental Impact Statement for the Importation of Wood Packaging Material

**AGENCY:** Animal and Plant Health Inspection Service, USDA.

**ACTION:** Notice of intent to prepare an environmental impact statement, scope of study, and notice of public meetings.

**SUMMARY:** We are advising the public that the Animal and Plant Health Inspection Service intends to prepare an environmental impact statement in connection with regulations we are considering regarding the importation of wood packaging material. This notice identifies potential alternatives and issues that we plan to examine in the environmental impact statement, requests public comment to further delineate the scope of the alternatives and issues, and provides notice of public meetings.

**DATES:** We will consider all comments that we receive on or before September 13, 2002. We will also consider comments made at public hearings that will be held in Washington, DC, on September 3, 2002, beginning at 10 a.m., and in Long Beach, CA, on September 5, 2002, beginning at 1 p.m. and again at 7 p.m. (two sessions).

**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. 02–032–1, 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. 02–032–1. 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. 02–032–1'' on the subject line.

The September 3, 2002, public hearing will be held at the USDA South Building, Jefferson Auditorium, 14th Street and Independence Avenue SW., Washington, DC. The September 5, 2002, public hearing will be held at the Hilton of Long Beach, 701 West Ocean Blvd., Long Beach, CA.

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:** Mr. Harold Smith, Environmental Protection Officer, Environmental Services, PPD, APHIS, 4700 River Road, Unit 149, Riverdale, MD 20737–1238; (301) 734–6742.

**SUPPLEMENTARY INFORMATION:**

The Animal and Plant Health Inspection Service is planning to amend its regulations on the importation of logs, lumber, and other unmanufactured wood articles to decrease the risk of wood packaging material (*e.g.*, crates, dunnage, wooden spools, pallets, and packing blocks) introducing exotic plant pests into the United States. Under the provisions of the National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321 *et seq.*), we are required to consider the potential environmental effects of our proposed actions and alternatives. The purpose of this notice is to inform the public of our intent to prepare an environmental impact statement (EIS), to advise the public of the schedule for two public meetings, and to solicit public comments on the scope of the environmental issues to be examined in the EIS.

The regulations in 7 CFR 319.40–1 through 319.40–11 (referred to below as the regulations) are intended to mitigate the plant pest risk presented by the importation of logs, lumber, and other unmanufactured wood articles, including wood packaging material (WPM). Introductions into the United States of exotic plant pests such as the pine shoot beetle and the Asian longhorned beetle have been linked to the importation of WPM. Recently, the emerald ash borer has been found in five counties in Michigan. These and other plant pests that could be carried by imported WPM pose a serious threat to U.S. agriculture and to natural, cultivated, and urban forests.

In 1998, we took regulatory action to require that WPM from China be heat treated, fumigated, or treated with preservatives prior to arrival in the United States. This action has decreased interceptions of pests associated with WPM from China. However, since then, a number of factors, including increased international trade, additional interceptions of serious exotic plant pests in WPM from other countries, and the adoption by the International Plant Protection Convention (IPPC) of international standards to mitigate pest risk from WPM, have demonstrated the need for the United States to take further measures to mitigate the pest risk from WPM from other countries.

In addition to establishing the necessary framework for protecting U.S. agriculture and forests, we must give full consideration to harmonizing our regulations with the new international standards (the ''International Standards for Phytosanitary Measures—Guidelines for Regulating Wood Packaging Materials in International Trade,'' Publication 15 of the Secretariat of the IPPC of the Food and Agriculture Organization of the United Nations, Rome, Italy, 2002).

The continually increasing risk of invasive exotic plant pest species imparts a degree of urgency to our development of regulations to mitigate risk from the importation of WPM. Therefore, our rulemaking and environmental processes are being undertaken at an accelerated rate. This is entirely consistent with regulations implementing NEPA (40 CFR 1501.8(b)). We anticipate that the proposed rule we publish will provide advance notice to industry of specific regulatory

requirements that may be made final and implemented within 30 days of the publication of a final rule.

We are requesting public comment to help us identify and/or confirm potential alternatives and environmental issues that should be examined in the EIS. We have identified five broad alternatives that we plan to consider in the EIS, as follows:

• Take no action. This would be characterized as no change in the existing regulations that apply to the importation of WPM (while not contributing to the further mitigation of risk, the analysis of the no action alternative provides a baseline and is required by NEPA and its implementing regulations);

• Apply the same requirements concerning WPM from China to WPM from the rest of the world (*i.e.*, require WPM imported from any part of the world to be heat treated, fumigated, or treated with preservatives prior to arrival in the United States);

• Implement a comprehensive risk reduction program (more expansive than the regulations currently applying to China or provided for under the new international standards). This would be categorized as a broad risk mitigation strategy that involves various options such as increased inspection, heat treatment, fumigation, wood preservatives, irradiation, controlled atmosphere, selective prohibition, and disposal;

• Adopt the new international standards and apply their methods (heat treatment at 56 °C for 30 minutes, fumigation with methyl bromide, and marking of WPM) to all countries; and

• Require the use of substitute materials that are not hosts of plant pests or diseases (*e.g.,* metal, rubber, or fiberglass).

We will examine the potential effects on the human environment of each alternative. We also are interested in comments that identify other issues that should be examined in the EIS. Potential issues could include new treatment methods, logistical considerations, environmental regulations and constraints, and harmonization of regulatory efforts.

Comments regarding the proposed scope of the EIS are welcome and will be considered fully. When the draft EIS is completed, a notice announcing its availability and an invitation to comment on it will be published in the **Federal Register**.

Done in Washington, DC, this 8th day of August 2002.

**Peter Fernandez,**

*Acting Administrator, Animal and Plant Health Inspection Service.*

[FR Doc. 02–20523 Filed 8–13–02; 8:45 am]

**BILLING CODE 3410–34–P**

## DEPARTMENT OF TRANSPORTATION

## Federal Aviation Administration

## 14 CFR Part 39

**[Docket No. 2002–CE–07–AD]**

**RIN 2120–AA64**

## Airworthiness Directives; Raytheon Aircraft Company Beech Models 36, A36, A36TC, B36TC, 58, and 58A Airplanes

**AGENCY:** Federal Aviation Administration, DOT.

**ACTION:** Notice of proposed rulemaking (NPRM).

**SUMMARY:** This document proposes to supersede Airworthiness Directive (AD) 2000–26–16, which applies to certain Raytheon Aircraft Company (Raytheon) Beech Models A36, B36TC, and 58 airplanes. AD 2000–26–16 currently requires you to inspect for missing rivets on the right hand side of the fuselage and, if necessary, install rivets. AD 2000–26–16 resulted from Raytheon identifying several instances of missing rivets on these airplanes. AD 2000–26–16 incorporated an incorrect listing of serial numbers for the affected model airplanes and omitted certain airplane models from the applicability section of AD 2000–26–16. This proposed AD would retain the actions required in AD 2000–26–16 and correct the applicability section. The actions specified by this proposed AD are intended to detect and correct missing rivets in the right hand fuselage panel assembly in the area above the right wing and below the cabin door threshold. These rivets must be present for the fuselage to carry the ultimate load and prevent critical structural failure with loss of airplane control.

**DATES:** The Federal Aviation Administration (FAA) must receive any comments on this proposed rule on or before October 18, 2002.

**ADDRESSES:** Submit comments to FAA, Central Region, Office of the Regional Counsel, Attention: Rules Docket No. 2002–CE–07–AD, 901 Locust, Room 506, Kansas City, Missouri 64106. You may view any comments at this location between 8 a.m. and 4 p.m., Monday through Friday, except Federal holidays. You may also send comments electronically to the following address: 9-ACE-7-Docket@faa.gov. Comments sent electronically must contain ''Docket No. 2002–CE–07–AD'' in the subject line. If you send comments electronically as attached electronic files, the files must be formatted in Microsoft Word 97 for Windows or ASCII text.

You may get service information that applies to this proposed AD from Raytheon Aircraft Company, 9709 E. Central, Wichita, Kansas 67201–0085; telephone: (800) 429–5372 or (316) 676–3140. You may also view this information at the Rules Docket at the address above.

**FOR FURTHER INFORMATION CONTACT:** T.N. Baktha, Aerospace Engineer, FAA, Wichita Aircraft Certification Office, 1801 Airport Road, Mid-Continent Airport, Wichita, Kansas 67209; telephone: (316) 946–4155; facsimile: (316) 946–4407.

**SUPPLEMENTARY INFORMATION:**

### Comments Invited

*How Do I Comment on This Proposed AD?*

The FAA invites comments on this proposed rule. You may submit whatever written data, views, or arguments you choose. You need to include the rule's docket number and submit your comments to the address specified under the caption **ADDRESSES**. We will consider all comments received on or before the closing date. We may amend this proposed rule in light of comments received. Factual information that supports your ideas and suggestions is extremely helpful in evaluating the effectiveness of this proposed AD action and determining whether we need to take additional rulemaking action.

*Are There Any Specific Portions of This Proposed AD I Should Pay Attention To?*

The FAA specifically invites comments on the overall regulatory, economic, environmental, and energy aspects of this proposed rule that might suggest a need to modify the rule. You may view all comments we receive before and after the closing date of the rule in the Rules Docket. We will file a report in the Rules Docket that summarizes each contact we have with the public that concerns the substantive parts of this proposed AD.

*How Can I Be Sure FAA Receives My Comment?*

If you want FAA to acknowledge the receipt of your mailed comments, you must include a self-addressed, stamped

postcard. On the postcard, write ''Comments to Docket No. 2002–CE–07–AD.'' We will date stamp and mail the postcard back to you.

**Discussion**

*Has FAA Taken Any Action to This Point?*

Raytheon production and inspection personnel identified several instances of missing rivets on Models A36, B36TC, and 58 airplanes. The missing rivets are the result of a quality control problem. This condition caused us to issue AD 2000–26–16, Amendment 39–12066 (66 FR 1253, January 8, 2001). AD 2000–26–16 requires you to inspect for missing rivets on the right hand fuselage and if necessary, install rivets.

*What Has Happened Since AD 2000–26–16 To Initiate This Action?*

Raytheon notified FAA that the airplane models and serial numbers listed in Raytheon Mandatory Service Bulletin SB 53–3341, Rev. 1, Revised: May, 2000, and the applicability section of AD 2000–26–16 are incorrect. The serial number designations did not correctly refer to the applicable airplane models. We are correcting this in this document.

*The FAA's Determination and an Explanation of the Provisions of This Proposed AD What Has FAA Decided?*

After examining the circumstances and reviewing all available information related to the incidents described above, we have determined that:

—The unsafe condition referenced in this document exists or could develop on other Raytheon Beech Models 36, A36, A36TC, B36TC, 58, and 58A airplanes of the same type design;

—The applicability of AD 2000–26–16 should be changed as discussed earlier; and

—AD action should be taken in order to correct this unsafe condition.

*What Would This Proposed AD Require?*

This proposed AD would supersede AD 2000–26–16 with a new AD that would retain the actions required in AD 2000–26–16 and add certain airplane models to the applicability section of this proposed AD.

**Cost Impact**

*How Many Airplanes Would This Proposed AD Impact?*

We estimate that this proposed AD affects 3632 airplanes in the U.S. registry.

*What Would Be the Cost Impact of This Proposed AD on Owners/Operators of the Affected Airplanes?*

We estimate the following costs to accomplish the proposed inspection:

| Labor cost | Parts cost | Total cost per airplane | Total cost on U.S. operators |
|---|---|---|---|
| 1 workhour × $60 per hour = $60 | No parts required for the inspection. | $60 per airplane | $60 × 3632 = $217,920. |

We estimate the following costs to accomplish the modification if necessary:

| Labor cost | Parts cost | Total cost per airplane |
|---|---|---|
| 4 workhours × $60 per hour = $240 | $100 per airplane | $340 per airplane. |

*What Is the Difference Between the Cost Impact of This Proposed AD and the Cost Impact of AD 2000–26–16?*

The only difference between this proposed AD and AD 2000–26–16 is the correction to the applicability. No additional actions are being proposed. The FAA has determined that this proposed AD action does not increase the cost impact over that already required by AD 2000–26–16.

**Regulatory Impact**

*Would This Proposed AD Impact Various Entities?*

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 proposed rule would not have federalism implications under Executive Order 13132.

*Would This Proposed AD Involve a Significant Rule or Regulatory Action?*

For the reasons discussed above, I certify that this proposed 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) 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 has been placed 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, under 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. FAA amends § 39.13 by removing Airworthiness Directive (AD) 2000–26–16, Amendment 39–12066 (66 FR 1253, January 8, 2001), and by adding a new AD to read as follows:

**Raytheon Aircraft Company:** Docket No. 2002–CE–07AD; Supersedes AD 2000–26–16, Amendment 39–12066.

(a) *What airplanes are affected by this AD?* This AD affects the following airplane models and serial numbers that are certificated in any category:

| Model | Serial Nos. |
|---|---|
| (1) Group 1: | |
| A36 | E–185 through E–3231 and E–3233. |
| B36TC | EA–242 and EA–273 through EA–635. |
| 58 | TH–1 through TH–1811 and TH–1813 through TH–1897. |
| (2) Group 2: | |
| 36 | E–1 through E–184. |
| A36TC | EA–1 through EA–241 and EA–243 through EA–272. |
| 58A | TH–1 through TH–1811 and TH–1813 through TH–1897. |

(b) *Who must comply with this AD?* Anyone who wishes to operate any of the airplanes identified in paragraph (a) of this AD must comply with this AD.

(c) *What problem does this AD address?* The actions specified by this AD are intended to detect and correct missing rivets in the right hand fuselage panel assembly in the area above the right wing and below the cabin door threshold. These rivets must be present for the fuselage to carry the ultimate load and prevent critical structural failure with loss of control of the airplane.

(d) *What actions must I accomplish to address this problem?* To address this problem, you must accomplish the following, unless already accomplished:

| Actions | Compliance | Procedures |
|---|---|---|
| (1) For Group airplanes: inspect for up to 9 missing rivets between fuselage station (F.S.) 83.00 and F.S. 91.00 at water line (W.L.) 90.3. | Within the next 100 hours time-in-service (TIS) after February 16, 2001 (the effective date of AD 200–26–16). | In accordance with the ACCOMPLISHMENT INSTRUCTIONS paragraph of Raytheon Mandatory Service Bulletin SB 53–3341. Revision 1, Revised: May 2000, and the Bonanza Series Maintenance Manual or Baron Model 58 Series Maintenance Manual. |
| (2) For Group 2 airplanes: inspector for up to 9 missing rivets between fuselage station (F.S.) 83.00 and F.S. 91.00 at water line (W.L.) 90.3. | Within the next 100 hours time-in-service after the effective date of this AD. | In accordance with the ACCOMPLISHMENT INSTRUCTIONS paragraph of Raytheon Mandatory Service Bulletin SB 53–3341, Revision 1, Revised: May 2000, and the Bonanza Series Maintenance Manual. |
| (3) For all affected airplanes: if you find rivets are missing, install these rivets. | Before further flight after the inspection ..... | In accordance with the ACCOMPLISHMENT INSTRUCTIONS paragraph of Raytheon Mandatory Service Bulletin SB 53–3341I Revision 1, Revised: May 200, and the Bonanza Series Maintenance Manual or Baron Model 58 Series Maintenance Manual. |

(e) *Can I comply with this AD in any other way?*

(1) You may use an alternative method of compliance or adjust the compliance time if:

(i) Your alternative method of compliance provides an equivalent level of safety; and

(ii) The Manager, Wichita Aircraft Certification Office (ACO), approves your alternative. Submit your request through an FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Wichita ACO.

(2) Alternative methods of compliance approved in accordance with AD 2000–26–16, which is superseded by this AD, are approved as alternative methods of compliance with this AD.

**Note:** This AD applies to each airplane identified in paragraph (a) of this AD, 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 (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 you have not eliminated the unsafe condition, specific actions you propose to address it.

(f) *Where can I get information about any already-approved alternative methods of compliance?* Contact T.N. Baktha, Aerospace Engineer, FAA, Wichita Aircraft Certification Office, 1801 Airport Road, Mid-Continent Airport, Wichita, Kansas 67209; telephone: (316) 946–4155; facsimile: (316) 946–4407.

(g) *What if I need to fly the airplane to another location to comply with this AD?* The FAA can issue a special flight permit under sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate your airplane to a location where you can accomplish the requirements of this AD.

(h) *How do I get copies of the documents referenced in this AD?* You may get copies of the documents referenced in this AD from Raytheon Aircraft Company, P.O. Box 85, Wichita, Kansas 67201–0085; telephone: (800) 429–5372 or (316) 676–3140. You may view these documents at FAA, Central Region, Office of the Regional Counsel, 901 Locust, Room 506, Kansas City, Missouri 64106.

(i) *Does this AD action affect any existing AD actions?* This amendment supersedes AD 2000–26–16, Amendment 39–12066.

Issued in Kansas City, Missouri, on August 6, 2002.

**Michael Gallagher,**

*Manager, Small Airplane Directorate, Aircraft Certification Service.*

[FR Doc. 02–20519 Filed 8–13–02; 8:45 am]

**BILLING CODE 4910–13–P**

## DEPARTMENT OF TRANSPORTATION

## Federal Aviation Administration

## 14 CFR Part 39

**[Docket No. 2001–SW–34–AD]**

**RIN 2120–AA64**

## Airworthiness Directives; Eurocopter France Model SA–365N, SA–365N1, AS–365N2, and AS 365 N3 Helicopters

**AGENCY:** Federal Aviation Administration, DOT.

**ACTION:** Notice of proposed rulemaking (NPRM).

**SUMMARY:** This document proposes adopting a new airworthiness directive (AD) for Eurocopter France (ECF) Model SA–365N, SA–365N1, AS–365N2, and AS 365 N3 helicopters. This proposal would require inspecting the 9-degree frame (frame) for the correct edge distance of the two attachment holes for the reinforced latch support and for a crack and repairing the frame if necessary. This proposal is prompted by the detection of a fatigue crack on the left-hand (LH) side of the frame during maintenance. The actions specified by this proposed AD are intended to prevent failure of the frame due to a crack at the latch support, loss of a passenger door, damage to the rotor system, and subsequent loss of control of the helicopter.

**DATES:** Comments must be received on or before October 15, 2002.

**ADDRESSES:** Submit comments in triplicate to the Federal Aviation Administration (FAA), Office of the Regional Counsel, Southwest Region, Attention: Rules Docket No. 2001–SW–34–AD, 2601 Meacham Blvd., Room 663, Fort Worth, Texas 76137. You may also send comments electronically to the Rules Docket at the following address: *9-asw-adcomments@faa.gov.* Comments may be inspected at the Office of the Regional Counsel between 9 a.m. and 3 p.m., Monday through Friday, except Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** Jim Grigg, Aviation Safety Engineer, FAA, Rotorcraft Directorate, Rotorcraft Standards Staff, Fort Worth, Texas 76193–0110, telephone (817) 222–5490, fax (817) 222–5961.

**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 should 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 document may be changed in light of the comments received.

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 mailed comments submitted in response to this proposal must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. 2001–SW–34–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, Office of the Regional Counsel, Southwest Region, Attention: Rules Docket No. 2001–SW–34–AD, 2601 Meacham Blvd., Room 663, Fort Worth, Texas 76137.

**Discussion**

The Direction Generale De L'Aviation Civile (DGAC), the airworthiness authority for France, notified the FAA that an unsafe condition may exist on ECF Model SA–365N, SA–365N1, AS–365N2, and AS 365 N3 helicopters incorporating MOD 0753B31. The DGAC advises of the discovery of a crack on the left-hand side of the frame.

ECF has issued AS 365 Alert Service Bulletin No. 53.00.42, dated January 31, 2001, which specifies measuring the edge distance of the attachment holes for the reinforced latch support of the frame, inspecting for a crack, and installing a repair on the frame or stop-drilling the crack, and monitoring the crack for continued growth. The DGAC classified this service bulletin as mandatory and issued AD No. 2001–060–052(A), dated February 21, 2001, to ensure the continued airworthiness of these helicopters in France.

These helicopter models are manufactured in France and are type certificated for operation in the United States under the provisions of 14 CFR 21.29 and the applicable bilateral agreement. Pursuant to the applicable bilateral 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.

This unsafe condition is likely to exist or develop on other ECF model helicopters of the same type design registered in the United States. Therefore, the proposed AD would require, within 50 hours time-in-service, inspecting the frame at the two attachment holes for the latch support for the correct edge distance and for a crack and repairing the frame if necessary. The actions would be required to be accomplished in accordance with the service bulletin described previously.

The FAA estimates that 45 helicopters of U.S. registry would be affected by this proposed AD, that it would take approximately 3 work hours to visually inspect all helicopters and 8 work hours to repair an estimated 10 helicopters to correct edge distance only and 12 work hours to repair edge distance and cracks for an estimated 5 helicopters, and that the average labor rate is $60 per work hour. Required parts would cost approximately $200 assuming a repair is necessary for 15 helicopters. Based on these figures, the total cost impact of the proposed AD on U.S. operators is estimated to be $19,500.

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 a new airworthiness directive to read as follows:

**Eurocopter France:** Docket No. 2001–SW–34–AD.

*Applicability:* Model SA–365N, SA–365N1, AS–365N2, and AS 365 N3 helicopters, with MOD 0753B31 installed, certificated in any category.

**Note 1:** This AD applies to each helicopter 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 helicopters 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 failure of the frame due to a crack at the latch support, loss of a passenger door, damage to the rotor system, and subsequent loss of control of the helicopter, accomplish the following:

(a) Within 50 hours time-in-service, inspect each 9-degree frame (frame) by measuring the edge distance at the two 5.2 mm (0.205 inch)

diameter attachment holes for the latch support for the passenger door in accordance with the Accomplishment Instructions, paragraph 2.B.1., of Eurocopter France AS 365 Alert Service Bulletin 53.00.42, dated January 31, 2001 (ASB). Inspect the area around the attachment holes for a crack.

(1) If the edge distance of both attachment holes is equal to or more than 8 mm (0.315 inch) and no crack is present, no action is required by this AD.

(2) If the edge distance is less than 8 mm and no crack is present, before further flight, install a reinforcing plate in accordance with the Accomplishment Instructions paragraph 2.B.2. of the ASB. Accomplishing the requirements of paragraph 2.B.2. of the ASB constitutes terminating action for the requirements of this AD.

(3) If there is a crack, before further flight, stop-drill the crack with a 3-millimeter diameter hole and repair the frame in accordance with the Accomplishment Instructions, paragraph 2.B.3 of the ASB. Accomplishing the requirements of paragraph 2.B.3. of the ASB constitutes terminating action for the requirements of this AD.

(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, Regulations Group, Rotorcraft Directorate, FAA. Operators shall submit their requests through an FAA Principal Maintenance Inspector, who may concur or comment and then send it to the Manager, Regulations Group.

**Note 2:** Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Regulations Group.

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

**Note 3:** The subject of this AD is addressed in Direction Generale De L'Aviation Civile (France) AD No. 2001–060–052(A), dated February 21, 2001.

Issued in Fort Worth, Texas, on August 5, 2002.

**David A. Downey,**

*Manager, Rotorcraft Directorate, Aircraft Certification Service.*

[FR Doc. 02–20518 Filed 8–13–02; 8:45 am]

**BILLING CODE 4910–13–P**

## DEPARTMENT OF TRANSPORTATION

## Federal Aviation Administration

## 14 CFR Part 39

**[Docket No. 2002–SW–26–AD]**

**RIN 2120–AA64**

## Airworthiness Directives; Eurocopter France Model EC 155B Helicopters

**AGENCY:** Federal Aviation Administration, DOT.

**ACTION:** Notice of proposed rulemaking (NPRM).

**SUMMARY:** This document proposes adopting a new airworthiness directive (AD) for Eurocopter France (ECF) Model EC 155B helicopters. This proposal would require inspecting and adjusting, if necessary, the position of the locking pins on each pilot, co-pilot, and passenger-hinged and sliding door (door) initially and each time a door is replaced. This proposal is prompted by two reports of inadvertent opening of the passenger-hinged doors in flight due to improper adjustment of the door-locking mechanism. The actions specified by this proposed AD are intended to prevent loss of a door in flight, contact with the main rotor or tail rotor, and subsequent loss of helicopter control.

**DATES:** Comments must be received on or before October 15, 2002.

**ADDRESSES:** Submit comments in triplicate to the Federal Aviation Administration (FAA), Office of the Regional Counsel, Southwest Region, Attention: Rules Docket No. 2002–SW–26–AD, 2601 Meacham Blvd., Room 663, Fort Worth, Texas 76137. You may also send comments electronically to the Rules Docket at the following address: *9-asw-adcomments@faa.gov.* Comments may be inspected at the Office of the Regional Counsel between 9 a.m. and 3 p.m., Monday through Friday, except Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** Richard Monschke, Aviation Safety Engineer, FAA, Rotorcraft Directorate, Rotorcraft Standards Staff, Fort Worth, Texas 76193–0110, telephone (817) 222–5116, fax (817) 222–5961.

**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 should 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 will be considered before taking action on the proposed rule. The proposals contained in this document may be changed in light of the comments received.

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 mailed comments submitted in response to this proposal must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. 2002–SW–26–AD.'' The postcard will be date stamped and returned to the commenter.

### Discussion

The Direction Generale De L'Aviation Civile (DGAC), the airworthiness authority for France, notified the FAA that an unsafe condition may exist on ECF Model EC 155B helicopters. The DGAC advises of two reports of the passenger-hinged doors opening in flight. The investigation revealed noncompliant installation and adjustment of the door-locking mechanism, which can result in the door unlocking and a risk of losing the door in flight.

ECF has issued Alert Telex 52–A008, dated March 11, 2002, which specifies checking and adjusting the position of each door's locking pins to prevent the door opening in flight. The DGAC classified this service bulletin as mandatory and issued AD No. 2002–186–005(A), dated April 3, 2002, to ensure the continued airworthiness of these helicopters in France.

This helicopter model is manufactured in France and is type certificated for operation in the United States under the provisions of 14 CFR 21.29 and the applicable bilateral agreement. Pursuant to the applicable bilateral 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.

This unsafe condition is likely to exist or develop on other helicopters of the same type design registered in the United States. Therefore, the proposed AD would require inspecting and, if necessary, adjusting the door-locking mechanism initially and each time a door is replaced. Replacing a door is not expected during the life of the rotorcraft except in extremely rare instances where a door may be damaged from an outside source. The actions would be required to be accomplished in accordance with the service bulletin

described previously except compliance with the caution and reporting requirements are not mandatory. In addition, the FAA considers shimming by the addition of washers as a permanent repair.

The FAA estimates that 2 helicopters of U.S. registry would be affected by this proposed AD, that it would take approximately 4 work hours per helicopter to accomplish the proposed actions, and that the average labor rate is $60 per work hour. Based on these figures, the total cost impact of the proposed AD on U.S. operators is estimated to be $480.

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 a new airworthiness directive to read as follows:

**Eurocopter France:** Docket No. 2002–SW–26–AD.

*Applicability:* Model EC 155B helicopters, certificated in any category.

**Note 1:** This AD applies to each helicopter 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 helicopters 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 within 25 hours time-in-service, unless accomplished previously, and each time a pilot, co-pilot, or passenger hinged or sliding (door) is replaced.

To prevent loss of a door in flight and subsequent loss of helicopter control, accomplish the following:

(a) Inspect and adjust, if necessary, the position of each door's locking pins in accordance with the Accomplishment Instructions, paragraph 2., of Eurocopter France Alert Telex No. 52-A008, dated March 11, 2002 (Telex), except you are not required to comply with the caution and with the reporting requirements of the Telex, and you may consider shimming by washers a permanent repair.

(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, Regulations Group, Rotorcraft Directorate, FAA. Operators shall submit their requests through an FAA Principal Maintenance Inspector, who may concur or comment and then send it to the Manager, Regulations Group.

**Note 2:** Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Regulations Group.

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

**Note 3:** The subject of this AD is addressed in Direction Generale De L'Aviation Civile (France) AD 2002–186–005(A), dated April 3, 2002.

Issued in Fort Worth, Texas, on August 5, 2002.

**David A. Downey,**

*Manager, Rotorcraft Directorate, Aircraft Certification Service.*

[FR Doc. 02–20517 Filed 8–13–02; 8:45 am]

BILLING CODE 4910–13–P

## DEPARTMENT OF TRANSPORTATION

## Federal Aviation Administration

## 14 CFR Part 39

**[Docket No. 99–CE–71–AD]**

**RIN 2120–AA64**

## Airworthiness Directives; MORAVAN a.s. Models Z–143L and Z–242L Airplanes

**AGENCY:** Federal Aviation Administration, DOT.

**ACTION:** Notice of proposed rulemaking (NPRM).

**SUMMARY:** This document proposes to adopt a new airworthiness directive (AD) that would apply to certain MORAVAN a.s. (Moravan) Models Z–143L and Z–242L airplanes. This proposed AD would require you to modify the engine secondary vent line. This proposed AD is the result of mandatory continuing airworthiness information (MCAI) issued by the airworthiness authority for the Czech Republic. The actions specified by this proposed AD are intended to prevent the engine crankcase ventilation lines from freezing during flight in cold weather (winter) conditions, which could result in oil leaking from the engine. Such a condition could lead to engine failure.

**DATES:** The Federal Aviation Administration (FAA) must receive any comments on this proposed rule on or before September 20, 2002.

**ADDRESSES:** Submit comments to FAA, Central Region, Office of the Regional Counsel, Attention: Rules Docket No. 99–CE–71–AD, 901 Locust, Room 506, Kansas City, Missouri 64106. You may view any comments at this location between 8 a.m. and 4 p.m., Monday through Friday, except Federal holidays. You may also send comments electronically to the following address: *9-ACE-7-Docket@faa.gov.* Comments sent electronically must contain ''Docket No. 99–CE–71–AD'' in the subject line. If you send comments electronically as attached electronic files, the files must be formatted in Microsoft Word 97 for Windows or ASCII text.

You may get service information that applies to this proposed AD from Moravan, Inc., 765 81 Otrokovice, Czech Republic; telephone: +420 67 767 3940; facsimile: +420 67 792 2103. You may also view this information at the Rules Docket at the address above.

**FOR FURTHER INFORMATION CONTACT:** Doug Rudolph, Aerospace Engineer, FAA, Small Airplane Directorate, 901

Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329–4059; facsimile: (816) 329–4090.

**SUPPLEMENTARY INFORMATION:**

**Comments Invited**

*How Do I Comment on This Proposed AD?*

The FAA invites comments on this proposed rule. You may submit whatever written data, views, or arguments you choose. You need to include the rule's docket number and submit your comments to the address specified under the caption **ADDRESSES.** We will consider all comments received on or before the closing date. We may amend this proposed rule in light of comments received. Factual information that supports your ideas and suggestions is extremely helpful in evaluating the effectiveness of this proposed AD action and determining whether we need to take additional rulemaking action.

*Are There Any Specific Portions of This Proposed AD I Should Pay Attention to?*

The FAA specifically invites comments on the overall regulatory, economic, environmental, and energy aspects of this proposed rule that might suggest a need to modify the rule. You may view all comments we receive before and after the closing date of the rule in the Rules Docket. We will file a report in the Rules Docket that summarizes each contact we have with the public that concerns the substantive parts of this proposed AD.

*How Can I Be Sure FAA Receives My Comment?*

If you want FAA to acknowledge the receipt of your mailed comments, you must include a self-addressed, stamped postcard. On the postcard, write ''Comments to Docket No. 99–CE–71–AD.'' We will date stamp and mail the postcard back to you.

**Discussion**

*What Events Have Caused This Proposed AD?*

The Civil Aviation Authority (CAA), which is the airworthiness authority for the Czech Republic, notified FAA that an unsafe condition may exist on certain Moravan Models Z–143L and Z–242L airplanes. The CAA reports that during a production delivery flight of a Model Z–242L airplane, smoke accumulated in the cockpit of the airplane, and engine oil pressure dropped significantly. As a result of this situation, the pilot was forced to make an emergency landing.

Investigation analysis revealed that the engine crankcase ventilation lines became frozen while flying in low ambient air temperature (winter) conditions. When the engine crankcase ventilation lines freeze, the front crankcase seal ring slips out, which allows oil to leak from the engine.

*What Are the Consequences if the Condition Is Not Corrected?*

This condition, if not corrected, could result in the engine crankcase ventilation lines freezing during flight in cold weather (winter) conditions. Such a condition could lead to engine failure.

*Is There Service Information That Applies to This Subject?*

Moravan has issued Mandatory Service Bulletin Z 242L/19a—Rev. 3, Z 143L/20a, dated April 30, 1999.

*What Are the Provisions of This Service Information?*

The service bulletin includes procedures for modifying the engine vent lines.

*What Action Did the CAA Take?*

The CAA classified this service bulletin as mandatory and issued Czech Republic AD Number CAA–AD–042/1999, dated August 18, 1999, in order to ensure the continued airworthiness of these airplanes in the Czech Republic.

*Was This in Accordance With the Bilateral Airworthiness Agreement?*

These airplane models are manufactured in the Czech Republic 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 CAA has kept FAA informed of the situation described above.

**The FAA's Determination and an Explanation of the Provisions of This Proposed AD**

*What Has FAA Decided?*

The FAA has examined the findings of the CAA; reviewed all available information, including the service information referenced above; and determined that:

—The unsafe condition referenced in this document exists or could develop on other Moravan Models Z–143L and Z–242L airplanes of the same type design that are on the U.S. registry;

—The actions specified in the previously-referenced service information should be accomplished on the affected airplanes; and

—AD action should be taken in order to correct this unsafe condition.

*What Would This Proposed AD Require?*

This proposed AD would require you to incorporate the actions in the previously-referenced service bulletin.

**Cost Impact**

*How Many Airplanes Would This Proposed AD Impact?*

We estimate that this proposed AD affects 39 airplanes in the U.S. registry.

*What Would Be the Cost Impact of This Proposed AD on Owners/Operators of the Affected Airplanes?*

We estimate the following costs to accomplish the proposed modification:

| Labor cost | Parts cost | Total cost per airplane | Total cost on U.S. operators |
|---|---|---|---|
| 1 workhour × $60 per hour = $60 | No parts required | $60 | $60 × 39 = $2,340. |

**Regulatory Impact**

*Would This Proposed AD Impact Various Entities?*

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 proposed rule would not have federalism implications under Executive Order 13132.

*Would This Proposed AD Involve a Significant Rule or Regulatory Action?*

For the reasons discussed above, I certify that this proposed 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) 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 has been placed 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, under 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. FAA amends § 39.13 by adding a new airworthiness directive (AD) to read as follows:

**Moravan A.S.:** Docket No. 99–CE–71–AD

(a) *What airplanes are affected by this AD?* This AD affects the following airplane models and serial numbers that are certificated in any category:

| Model | Serial Nos. |
|---|---|
| Z–143L ..... | All serial numbers up to and including 0029, except 0025 and 0027. |
| Z–242L ..... | All serial numbers up to and including 0733. |

(b) *Who must comply with this AD?* Anyone who wishes to operate any of the airplanes identified in paragraph (a) of this AD must comply with this AD.

(c) *What problem does this AD address?* The actions specified by this AD are intended to prevent the engine crankcase ventilation lines from freezing during flight in cold weather (winter) conditions, which could result in oil leaking from the engine. Such a condition could lead to engine failure.

(d) *What actions must I accomplish to address this problem?* To address this problem, you must accomplish the following:

| Actions | Compliance | Procedures |
|---|---|---|
| Modify the engine vent lines ..... | Within the next 100 hours time-in-service after the effective date of this AD. | In accordance with Moravan Mandatory Service Bulletin Z 242L/19a—Rev. 3, Z vent service after the 143L/20a, dated April 30, 1999. |

(e) *Can I comply with this AD in any other way?* You may use an alternative method of compliance or adjust the compliance time if:

(1) Your alternative method of compliance provides an equivalent level of safety; and

(2) The Manager, Small Airplane Directorate, approves your alternative. Submit your request through an FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Small Airplane Directorate.

**Note 1:** This AD applies to each airplane identified in paragraph (a) of this AD, 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 (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 you have not eliminated the unsafe condition, specific actions you propose to address it.

(f) *Where can I get information about any already-approved alternative methods of compliance?* Contact Doug Rudolph, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329–4059; facsimile: (816) 329–4090.

(g) *What if I need to fly the airplane to another location to comply with this AD?* The FAA can issue a special flight permit under sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate your airplane to a location where you can accomplish the requirements of this AD.

(h) *How do I get copies of the documents referenced in this AD?* You may get copies of the documents referenced in this AD from Moravan, Inc., 765 81 Otrokovice, Czech Republic; telephone: +420 67 767 3940; facsimile: +420 67 792 2103. You may view these documents at FAA, Central Region, Office of the Regional Counsel, 901 Locust, Room 506, Kansas City, Missouri 64106.

**Note 2:** The subject of this AD is addressed in Czech Republic AD Number CAA–AD–042/1999, August 18, 1999.

Issued in Kansas City, Missouri, on August 7, 2002.

**Michael Gallagher,**

*Manager, Small Airplane Directorate, Aircraft Certification Service.*

[FR Doc. 02–20516 Filed 8–13–02; 8:45 am]

**BILLING CODE 4910–13–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### 21 CFR Part 872

**[Docket No. 02N–0305]**

### Dental Devices; Classification of the Dental Sonography Device and the Jaw Tracking Device

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is proposing to classify the dental sonography device into class I, when it is used to monitor temporomandibular joint sounds, and into class II, when it is used to interpret temporomandibular joint sounds for the diagnosis of temporomandibular joint disorders and associated orofacial pain. FDA is also proposing to classify the jaw tracking device into class I, when it is used to monitor mandibular jaw positions relative to the maxilla, and into class II, when it is used to interpret mandibular jaw positions relative to the maxilla, for the diagnosis of temporomandibular joint disorders and associated orofacial pain. FDA is publishing the recommendations of the Dental Products Advisory Panel (the panel) regarding the classification of these devices in this document. After considering public comments on the proposed classification, FDA will publish a final regulation classifying these devices. This action is being taken to establish sufficient regulatory controls that will provide reasonable assurance of the safety and effectiveness of these devices. Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice of availability of a draft guidance document that would serve as the special control for the class II devices if this proposal becomes final.

**DATES:** Submit written or electronic comments by November 12, 2002.

**ADDRESSES:** Submit written or electronic 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:** Mary S. Runner, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–827–5283.

**SUPPLEMENTARY INFORMATION:**

## I. Background

The Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 301 *et seq.*), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Public Law 94–295), the Safe Medical Devices Act of 1990 (Public Law 101–629), and the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Public Law 105–115), established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360c) established three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Under section 513 of the act, devices that were in commercial distribution before May 28, 1976 (the date of enactment of the 1976 amendments), generally referred to as preamendments devices, are classified after FDA has: (1) Received a recommendation from a device classification panel (an FDA advisory committee); (2) published the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. FDA has classified most preamendments devices under these procedures.

A device that was not in commercial distribution before May 28, 1976, generally referred to as a postamendments device, is classified automatically by statute (section 513(f) of the act) into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval, unless and until: (1) The device is reclassified into class I or II; (2) FDA issues an order classifying the device into class I or II in accordance with new section 513(f)(2) of the act, as amended by FDAMA; or (3) FDA issues an order finding the device to be substantially equivalent, under section 513(i) of the act, to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously offered devices by means of the premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and 21 CFR part 807 of the regulations.

A preamendments device that has been classified into class III may be marketed, by means of the premarket notification procedures, without submission of a premarket approval application (PMA) until FDA issues a final regulation under section 515(b) of the act (21 U.S.C. 360e(b)) requiring premarket approval.

FDAMA added a new section 510(l) to the act. New section 510(l) of the act provides that a class I device is exempt from the premarket notification requirements under section 510(k) of the act, unless the device is intended for a use which is of substantial importance in preventing impairment of human health or it presents a potential unreasonable risk of illness or injury. Hereafter, these are referred to as ''reserved criteria.'' Such an exemption permits manufacturers to introduce into commercial distribution generic types of devices without first submitting a premarket notification to FDA. FDA believes that certain changes to devices within a generic type that is generally exempt may make the device intended for a use which is of substantial importance in preventing impairment of human health or may make the device present a potential unreasonable risk of illness or injury. Accordingly, devices changed in this manner would fall within the reserved criteria under section 510(l) of the act and would require premarket notification. For example, FDA considers a class I device to be subject to premarket notification requirements if the device operates using a different fundamental scientific technology than that used by a legally marketed device in that generic type.

FDAMA also added a new section 510(m) to the act. New section 510(m) of the act provides that a class II device may be exempted from the premarket notification requirements under section 510(k) of the act, if the agency determines that premarket notification is not necessary to assure the safety and effectiveness of the device.

## II. Recommendation of the Panel

In the **Federal Register** of August 12, 1987 (52 FR 30082), FDA published a final rule classifying dental devices. At that time, FDA was not aware that the dental sonography device and the jaw tracking device were preamendments devices, and inadvertently omitted classifying them.

Consistent with the act and the regulations, at a public meeting, held on August 4, 1998, FDA consulted with the panel, an FDA advisory committee, regarding the classification of these devices.

### *A. Identification*

FDA is proposing the following device identifications based on the panel's recommendation and the agency's review:

1. The class I dental sonography device is an electrically powered device, intended to be used to monitor temporomandibular joint sounds. The device is used to detect and record sounds made by the temporomandibular joint.

2. The class II dental sonography device is an electrically powered device, intended to interpret temporomandibular joint sounds for the diagnosis of temporomandibular joint disorders and associated orofacial pain. The device detects, records, displays, and stores sounds made by the temporomandibular joint during jaw movement. The device interprets these sounds to generate meaningful output, either directly or by connection to a personal computer. The device may be a part of a system of devices, contributing joint sound information to be considered with data from other diagnostic components.

3. The class I jaw tracking device is a nonpowered or electrically powered device used to monitor mandibular jaw positions relative to the maxilla. The device measures and records anatomical distances and angles in three-dimensional space, to determine the relative position of the mandible with respect to the location and position of the maxilla, while at rest and during jaw movement.

4. The class II jaw tracking device is an electrically powered device, intended to interpret mandibular jaw positions relative to the maxilla, for the diagnosis of temporomandibular joint disorders and associated orofacial pain. The device measures and records anatomical distances and angles to determine the relative position of the mandible in three dimensional space, with respect to the location and position of the maxilla, while at rest and during jaw movement. The device records, displays, and stores information about joint position. The device interprets jaw position to generate meaningful output, directly or by connection to a personal computer. The device may be a part of a system of devices, contributing jaw position information to be considered with data from other diagnostic components.

*B. Recommended Classification of the Panel*

During a public meeting, held on August 4, 1998, the panel made the classification recommendations (Ref. 1) for the dental sonography device and the jaw tracking device. The panel recommended that these devices be classified into class I (general controls), and that the devices should be subject to premarket notification. The panel also recommended that these devices be restricted to sale by, or on the order of a licensed dentist or physician (§ 801.109 (21 CFR 801.109)).

*C. Summary of Reasons for Recommendation*

The panel concluded that safety and effectiveness of the dental sonography device and the jaw tracking device can reasonably be assured by general controls. Specifically, the panel believed that safety and effectiveness of both devices can be reasonably assured by registration and listing (section 510 of the act); general requirements concerning reports (21 CFR 820.180) and complaint files (21 CFR 820.198); and good manufacturing practices requirements (section 520(f) of the act (21 U.S.C. 360j(f).) The panel also recommended that these devices be restricted to sale by, or on the order of a licensed dentist or physician (§ 801.109).

*D. Summary of the Data Upon Which the Recommendation Was Based*

The panel believes that these devices have provided dental practitioners adjunctive diagnostic information, as a part of the treatment of temporomandibular joint disorders, for over 23 years. When used with other dental devices and clinical techniques, these devices help the clinician to diagnose symptoms related to malfunction of the temporomandibular joint and associated musculature.

After reviewing the literature provided to panel members by FDA (Refs. 2 to 34); information provided by device manufacturers; several panel members' personal knowledge of and clinical experience with the devices; and in consideration of the consensus derived from the open panel discussion, the panel gave the following reasons in support of its recommendation to classify these devices into class I: (1) The devices provide adjunctive information in the form of temporomandibular joint sounds and relative jaw position, not otherwise available to the clinician; (2) no invasive procedures are required; (3) no energy is applied to craniofacial structures; and (4) the devices have been used for many years without documented medical devices reports or other published incident reports.

*E. Risks to Health*

The panel identified the following risks to health associated with the dental sonography device and the jaw tracking device:

1. Electrical Interference

Electrical interference generated by these devices may affect diagnostic and therapeutic medical devices, such as certain types of cardiac pacemakers. Manufacturers should validate the isolation of electrical circuitry of these devices from other medical devices.

2. Improper Treatment

There is no general consensus or established standard of care regarding interpretation of the output of these devices. Therefore, a misdiagnosis of a condition or abnormality may result in improper or unnecessary therapeutic intervention. The outputs of these devices are adjunctive to other diagnostic and therapeutic modalities.

**III. Proposed Classification**

FDA concurs that the dental sonography device and the jaw tracking device intended to be used for monitoring sounds made by the temporomandibular joint and mandibular jaw positions relative to the maxilla, respectively, should be classified into class I (general controls). General controls would provide reasonable assurance of safety and effectiveness of these devices for these intended uses. FDA, however, believes that the dental sonography device and jaw tracking device intended to interpret temporomandibular joint sounds and mandibular jaw positions for the diagnosis of temporomandibular joint disorders and associated orofacial pain should be classified into class II (special controls). Premarket notifications for dental sonography and jaw tracking devices with these intended uses should include clinical data to demonstrate performance, as well as labeling instructing the user on proper technique, interpretation of the device outputs, and appropriate warnings and precautions. FDA tentatively concurs with the panel's recommendation that these devices should be restricted to sale by or on the order of a licensed dentist or physician (§ 801.109).

FDA disagrees with the panel that the class I devices should require premarket notification because they meet the reserved criteria of new section 510(1) of the act. FDA believes that the intended uses of monitoring sounds emanated from the temporomandibular joint and mandibular jaw positions should be exempt from premarket notification. These devices for these intended uses are not of substantial importance in preventing impairment of human health, nor do they present an unreasonable risk of illness or injury.

FDA, however, is proposing that the jaw tracking device and the dental sonography device when used to interpret temporomandibular joint position or sounds for the diagnosis of temporomandibular joint disorder and associated orofacial pain be class II. As noted previously, section 510(m) of the act provides that a class II device may be exempted from the premarket notification requirements under section 510(k) of the act, if the agency determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. FDA tentatively concludes that premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the jaw tracking device and the dental sonography device when used to interpret temporomandibular joint position or sounds for the diagnosis of temporomandibular joint disorder and associated orofacial pain.

**IV. Special Controls**

FDA has included the special controls that it believes are necessary to provide reasonable assurance of the safety and effectiveness of the devices proposed for class II in the draft guidance document entitled ''Class II Special Controls Guidance Document: Dental Sonography and Jaw Tracking Devices; Guidance for Industry and FDA Reviewers.'' FDA intends this guidance to serve as the special control for these devices, if FDA classifies them in class II. Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice of availability of the draft guidance document. The draft guidance document sets forth recommendations on 510(k) submissions for the class II devices on device characterization, intended use and indications for use, preclinical and bench testing, device comparison, instructions for use, clinical information, and software validation. The draft guidance document would address the risk of electrical interference by assuring that the 510(k) includes preclinical and bench testing concerning this risk and by assuring that the device labeling includes adequate information for the user to minimize the risk of electrical interference. The guidance document

would address the risk of improper treatment by assuring that the 510(k) includes clinical information on this risks, by assuring that the labeling includes adequate information for the health professional using the device, and by assuring that the manufacturer has properly validated the software. If adopted, following the effective date of a final rule classifying the device, any firm submitting a 510(k) premarket nitification for the device would need to address the issues covered in the special control guidance. However, the firm would need to show only that its device meets the recommendations of the guidance or in some other way provides equivalent assurances of safety and effectiveness.

## V. Environmental Impact

The agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

## VI. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1501 *et seq.*). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this proposed rule is consistent with the regulatory philosophy and principles identified in the Executive order. In addition, the proposed rule is not a significant regulatory action as defined by the Executive order and so is not subject to review under the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. The class I devices are already subject to the general controls provisions of the act. If FDA finalizes this rule, it would impose no new requirements on manufacturers of class I devices. Manufacturers of class II jaw tracking and dental sonography devices currently are required to submit premarket notifications. The guidance document reflects existing FDA practice in the review of these premarket notifications. FDA expects that manufacturers of cleared class II jaw tracking and dental sonography devices will not have to take any additional action in response to this rule, if FDA finalizes this rule. This rule will help expedite the review process for any new manufacturers of these devices. The agency therefore certifies that this proposed rule, if issued, will not have a significant economic impact on a substantial number of small entities. In addition, this proposed rule will not impose costs of $100 million or more on either the private sector or State, local, and tribal governments in the aggregate, and therefore a summary statement or analysis under section 202(a) of the Unfunded Mandates Reform Act of 1995 is not required.

## VII. Paperwork Reduction Act of 1995

FDA tentatively concludes that this rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

## VIII. Proposed Implementation Plan

FDA proposes that any final rule that may issue based on this proposal become effective 30 days after its date of publication in the **Federal Register**.

## IX. Comments

You may submit written or electronic comments regarding this proposal to the Dockets Management Branch (see **ADDRESSES**) by November 12, 2002. You should submit two copies of any comments. Individuals may submit one copy. You must identify comments with the docket number found in brackets in the heading of this document. You may see any comments that FDA receives in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

## X. References

The following references have been placed 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.

1. Dental Products Panel Meeting, Transcript and Meeting Minutes, August 4, 1998.

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16. Lederman, K. H., ''Patients With Restored Occlusions. Part I: TMJ Dysfunction Determined by a Pantographic Reproducibility Index,'' *The Journal of Prosthetic Dentistry*, 47: 198–205, 1982.

17. Levitt, S. R. and M. W. McKinney, ''Appropriate Use of Predictive Values in Clinical Decision Making and Evaluating Diagnostic Tests for TMD,'' *Journal of Orofacial Pain*, 8: 298–308, 1994.

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**List of Subjects in 21 CFR Part 872**

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, FDA is proposing to amend 21 CFR part 872 as follows:

## PART 872—DENTAL DEVICES

1. The authority citation for 21 CFR part 872 continues to read as follows:

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

2. Section 872.2050 is added to subpart B to read as follows:

### § 872.2050 Dental sonography device.

(a) *Dental sonography device for monitoring*—(1) *Identification.* A dental sonography device for monitoring is an electrically powered device, intended to be used to monitor temporomandibular joint sounds. The device detects and records sounds made by the temporomandibular joint.

(2) *Classification.* Class I. The device is exempt from the premarket notification provisions of subpart E of part 807 of this chapter.

(b) *Dental sonography device for interpretation and diagnosis*—(1) *Identification.* A dental sonography device for interpretation and diagnosis is an electrically powered device, intended to interpret temporomandibular joint sounds for the diagnosis of temporomandibular joint disorders and associated orofacial pain. The device detects, records, displays, and stores sounds made by the temporomandibular joint during jaw movement. The device interprets these sounds to generate meaningful output, either directly or by connection to a personal computer. The device may be part of a system of devices, contributing joint sound information to be considered with data from other diagnostic components.

(2) *Classification.* Class II (special controls). The special control for this device is FDA's guidance document entitled ''Class II Special Controls Guidance Document: Dental Sonography and Jaw Tracking Devices; Guidance for Industry and FDA Reviewers.''

3. Section 872.2060 is added to subpart B to read as follows:

### § 872.2060 Jaw tracking device.

(a) *Jaw tracking device for monitoring mandibular jaw positions relative to the maxilla*—(1) *Identification.* A jaw tracking device for monitoring mandibular jaw positions relative to maxilla is a nonpowered or electrically powered device that measures and records anatomical distances and angles in three dimensional space, to determine the relative position of the mandible with respect to the location and position of the maxilla, while at rest and during jaw movement.

(2) *Classification.* Class I (general controls). The device is exempt from the premarket notification provisions of subpart E of part 807 of this chapter.

(b) *Jaw tracking device for interpretation of temporomandibular joint position for the diagnosis of temporomandibular joint disorders and associated orofacial pain*—(1) *Identification.* A jaw tracking device for interpretation of temporomandibular joint position for the diagnosis of temporomandibular joint disorders and associated orofacial pain is a nonpowered or electrically powered device that measures and records anatomical distances and angles to determine the relative position of the mandible in three dimensional space, with respect to the location and position of the maxilla, while at rest and during jaw movement. The device records, displays, and stores information about jaw position. The device interprets jaw position to generate meaningful output, either directly or by connection to a personal computer. The device may be a part of a system of devices, contributing jaw position information to be considered with data from other diagnostic components.

(2) *Classification.* Class II (special controls). The special control for this device is FDA's guidance document entitled ''Class II Special Controls Guidance Document: Dental Sonography and Jaw Tracking Devices; Guidance for Industry and FDA Reviewers.''

Dated: August 1, 2002.

**Linda S. Kahan,**

*Deputy Director, Center for Devices and Radiological Health.*

[FR Doc. 02–20499 Filed 8–13–02; 8:45 am]

BILLING CODE 4160–01–S

**DEPARTMENT OF TRANSPORTATION**

**Coast Guard**

**33 CFR Parts 2, 26, 62, 64, 95, 100, 120, and 165**

**46 CFR Parts 7 and 28**

**[USCG 2001–9044]**

**RIN 2115–AG13**

## Territorial Seas, Navigable Waters, and Jurisdiction

**AGENCY:** Coast Guard, DOT.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** This proposed rule would conform the Coast Guard's definitions of jurisdictional terms to existing law. We propose these updates so that our regulatory definitions will reflect statutory changes and Presidential proclamations affecting our jurisdiction. These changes would clarify how the Coast Guard interprets its jurisdiction to enforce treaties, laws, and regulations of the United States.

**DATES:** Comments and related materials must reach the Docket Management Facility on or before November 12, 2002.

**ADDRESSES:** To make sure that your comments and related materials are not entered more than once in the docket, please submit them by only one of the following means:

(1) By mail to the Docket Management Facility (USCG–2001–9044), U.S. Department of Transportation, room PL–401, 400 Seventh Street SW., Washington, DC 20590–0001.

(2) By hand delivery to room PL–401 on the Plaza level of the Nassif Building, 400 Seventh Street SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202–366–9329.

(3) By fax to the Docket Management Facility at 202–493–2251.

(4) By electronic means through the Web Site for the Docket Management System at *http://dms.dot.gov*.

The Docket Management Facility maintains the public docket for this rulemaking. Comments and materials received from the public, as well as documents mentioned in this preamble as being available in the docket, will become part of this docket and will be available for inspection or copying at room PL–401 on the Plaza level of the Nassif Building, 400 Seventh Street SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. You may also find this docket on the Internet at *http://dms.dot.gov.*

**FOR FURTHER INFORMATION CONTACT:** If you have questions on this proposed rule, call Alex Weller, Office of Maritime and International Law, U.S. Coast Guard, telephone 202–267–0097. If you have questions on viewing or submitting materials to the docket, call Dorothy Beard, Chief, Dockets, Department of Transportation, telephone 202–366–5149.

**SUPPLEMENTARY INFORMATION:**

### Request for Comments

We encourage you to participate in this rulemaking by submitting comments and related materials. If you do, please include your name and address, identify the docket number for this rulemaking (USCG–2001–9044), indicate the specific section of this document to which each comment applies, and give the reason for each comment. You may submit your comments and materials by mail, hand delivery, fax, or electronic means to the Docket Management Facility at the address under **ADDRESSES**; but please submit your comments and materials by only one means. If you submit them by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit them by mail and would like to know that they reached the Facility, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and materials received during the comment period. We may change this proposed rule in view of them.

### Public Meeting

We do not plan to hold a public meeting. But you may submit a request for one to the Docket Management Facility at the address under **ADDRESSES** explaining why one would be beneficial. If we determine that one would aid this rulemaking, we will hold one at a time and place announced by a later notice in the **Federal Register**.

### Background and Purpose

Part 2 of title 33 of the Code of Federal Regulations (33 CFR part 2) contains definitions of jurisdictional terms. The Coast Guard uses these definitions to enforce treaties, laws, and regulations of the United States. Most of the definitions in this part have not been amended since they were written in 1975. Since 1975, however, statutes and other legal authorities on which these jurisdictional terms were based have changed.

### Discussion of Proposed Rule

We propose to update the jurisdictional terms in 33 CFR part 2 and related jurisdictional terms in other parts of the Code of Federal Regulations so that their meaning conforms to existing law. Our proposed rule would also clarify how the Coast Guard interprets its jurisdiction with reference to these terms.

The following are the jurisdictional terms we propose to update:

*Territorial sea baseline.* In proposed § 2.20, the only change we propose for this definition is to include a reference to the 1982 United Nations Convention on the Law of the Sea (UNCLOS)(21 I.L.M. 1261) as a reference for how the baselines are determined.

*Territorial sea.* As originally drafted and amended in 1975, 33 CFR 2.05–5 defined the extent of the U.S. territorial sea seaward of the baseline as 3 nautical miles. This was the consistent position of the United States up to that time, both internationally and for domestic law purposes.

On December 27, 1988, by Presidential Proclamation 5928 (103 Stat. 2981; 54 FR 777, January 9, 1989), the breadth of the U.S. territorial sea was declared to be 12 nautical miles from the baseline, but only for international law purposes. Presidential Proclamation 5928 specifically stated it was not intended to and did not change existing federal or state domestic laws or regulations.

Certain statutes set the breadth of the United States' ''territorial sea'' as 3 nautical miles for purposes of the statute. Section 502(8) of the Clean Water Act (33 U.S.C. 1362 (8)) is an example of one of these statutes.

Other statutes authorize the United States to make domestic law applicable in the expanded territorial sea, the area between 3 and 12 nautical miles seaward of the baseline. The Ports and Waterways Safety Act (33 U.S.C. 1221 *et seq.*) is an example of one of these statutes.

Proposed § 2.22(a)(1) lists the purposes, with respect to the United States, for which the 12 nautical mile wide territorial sea is used. These include the statutes within Title 46 U.S.C. subtitle II and the Ports and Waterways Safety Act (PWSA), as amended (33 U.S.C. 1221 *et seq.*) and any regulations issued under the authority of these statutes. They also include the criminal jurisdiction of the United States pursuant to Title 18 U.S.C., and the special maritime and territorial jurisdiction of the United States under 18 U.S.C. 7. Proposed § 2.22(a)(1)(v) states that any statute,

treaty, or regulation we interpret as referring to the expanded territorial sea (out to 12 nautical miles) would fall under the proposed § 2.22(a)(1) territorial sea definition. For those purposes not specified in (a)(1), proposed paragraph (a)(2) defines territorial sea as being 3 nautical miles wide.

For Coast Guard regulations promulgated under two or more statutes, our proposed definition in § 2.22(a)(3) sets forth the standard for their territorial sea limit. If one or more of the statutes authorizes regulatory activity out to 12 nautical miles and one or more of the other statutes does not, the Coast Guard may apply the 12 nautical mile territorial sea definition in § 2.22(a)(1) to the regulation.

The proposed definition of ''territorial sea'' in § 2.22(b) recognizes and describes the effect of Presidential Proclamation 5928 on international law.

*Internal Waters.* The definition of ''internal waters'' in proposed § 2.24 has not been changed substantively from the current definition, however, for ease of understanding and because, in certain respects, the definition of ''inland waters'' has changed, the two terms, which are currently in the same section (33 CFR 2.05–20), have been placed in separate sections.

*Inland Waters.* In proposed § 2.26, we have changed the definition of ''inland waters'' by eliminating the specific reference to the definition of that term in certain statutes, including the Inland Navigation Rules Act. We did this in part because the definition of inland waters in the Inland Navigation Rules Act has been changed from that which appears in 33 CFR 2.05–20(b), and no purpose would be served by simply repeating the new definition in the regulation.

Further, there is no purpose served by separately listing each statute that contains a definition of inland waters that is different than this general definition. If a definition of inland waters appears in a statute or other regulation, for example, the Inland Navigational Rules Act of 1980 (33 U.S.C. chapter 34, specifically 33 U.S.C. 2003(o)) and 46 CFR 10.103, the rule of construction in proposed § 2.5 would apply, so that the specific definition in the statute concerned controls over the inland waters general definition in proposed § 2.26.

*Contiguous Zone.* In proposed § 2.28(a), we have defined the ''contiguous zone'' for purposes of the Federal Water Pollution Control Act, 33 U.S.C. 1251 *et seq.*, because that statute contains a delimited definition, which is more restrictive than the President's Proclamation 7219 of September 2, 1999 (113 Stat. 2138; 64 FR 48701, September 8, 1999, as corrected by 64 FR 49844, September 14, 1999). We have also included a definition in proposed § 2.28(b) that conforms to Presidential Proclamation 7219 for all other purposes.

Two regulations, 46 CFR 7.105 and 46 CFR 28.50, that define the boundary lines in the Gulf of Mexico pursuant to the authority in 33 U.S.C. 151, contain references to the 12-nautical-mile contiguous zone as currently defined in 33 CFR 2.05–15. Those regulations would be amended to conform to the proposed definition of the ''territorial sea'' in 33 CFR 2.22(a)(1).

*Exclusive Economic Zone.* In proposed § 2.30 we revise the definition of the ''Exclusive Economic Zone'' (''EEZ'') to conform to that found in the 1982 United Nations Convention on the Law of the Sea (UNCLOS). Certain laws contain specific definitions of the EEZ that differ from the general definition contained in this regulation. In those instances, the rule of construction contained in proposed § 2.5 would apply. No substantive change is intended; the revision is intended to clarify the definition.

*High Seas.* In proposed § 2.32 we have reorganized and clarified the definitions of ''high seas'' as used in the various statutes. We have also deleted the discussion of the Coast Guard authority under 14 U.S.C. 89, contained in footnote 1 to 33 CFR 2.05–1(a) because we consider it to be unnecessary to an understanding of the territorial application of the laws and regulations the Coast Guard administers and enforces.

We have also clarified that the waters of the Exclusive Economic Zone are not considered high seas for international law purposes, although UNCLOS makes clear that high seas freedoms of navigation exist in the EEZ. Our proposed definition recognizes this principle.

Finally, we have differentiated between the various breadths of the territorial seas defined in proposed § 2.22, to recognize that territorial seas have different breadths for purposes of different laws. The different breadths of the territorial seas impacts the corresponding location of the high seas for implementation of the particular statute.

*Waters subject to tidal influence, waters subject to the ebb and flow of the tide, and mean high water.* In proposed § 2.34, we have made only editorial changes to definitions of these terms currently found in 33 CFR 2.05–27.

*Navigable Waters.* ''Navigable waters of the United States'' and ''navigable waters'' are defined with reference to the different statutes that use those terms and contain specific definitions. The most notable example of this is the Federal Water Pollution Control Act (FWPCA). The legislative history of the FWPCA, as well as judicial decisions, which have interpreted these terms in that Act—until the U.S. Supreme Court's decision in *Solid Waste Agency of Northern Cook County* v. *U.S. Army Corps of Engineers,* 531 U.S. 159 (2001) (SWANCC)—had adopted the broadest possible definition of navigable waters of the United States consistent with the U.S. Constitution in order to further the purposes of the FWPCA.

The Coast Guard's current definition, 33 CFR 2.05–25, incorporated this concept. In SWANCC, however, the Supreme Court interpreted the term ''waters of the United States'' and ''navigable waters'' as used in the FWPCA more narrowly, and invalidated an assertion of jurisdiction under the FWPCA over isolated, non-navigable waters where jurisdiction was based solely on the use of those waters as breeding and feeding grounds by migratory birds. Accordingly, we propose to replace the broad definition in the current regulation, 33 CFR 2.05–25, with one that is consistent with SWANCC.

Our definition in proposed § 2.36 (b) of navigable ''waters of the United States'' and ''navigable waters'' for purposes of laws other than the FWPCA is consistent with our proposed paragraph 2.22 (a) that defines territorial sea. Our § 2.36 definition also includes waters over which State governments and the Federal government exercise concurrent jurisdiction.

We have prepared the following table to help you compare our proposed regulations with existing regulations.

TABLE 1.—33 CFR PART 2 DISTRIBUTION AND DERIVATION TABLE

| If the regulation is in the current 33 CFR part 2 . . . | You will find it in the NPRM at proposed . . . | If you are looking at the proposed NPRM cite . . . | It is derived from the current 33 CFR . . . |
|---|---|---|---|
| 2.01–1 | 2.1 | 2.1 | 2.01–1. |
| — | 2.5 | 2.5. | |
| 2.05–10 | 2.20 | 2.20 | 2.05–10. |
| 2.05–5 | 2.22 | 2.22 | 2.05–5. |
| 2.05–20 | 2.24 and 2.26 | 2.24 | 2.05–20. |
| — | — | 2.26 | 2.05–20. |
| 2.05–15 | 2.28 | 2.28 | 2.05–15. |
| 2.05–35 | 2.30 | 2.30 | 2.05–35. |
| 2.05–1 | 2.32 | 2.32 | 2.05–1. |
| 2.05–27 | 2.34 | 2.34 | 2.05–27. |
| 2.05–25 | 2.36 | 2.36 | 2.05–25. |
| 2.05–30 | 2.38 | 2.38 | 2.05–30. |
| 2.10–1 | 2.40 | 2.40 | 2.10–1. |
| 2.10–5 | 2.45 | 2.45 | 2.10–5 and 2.10–10. |
| 2.10–10 | 2.45. | | |

Finally, we have included a visual aid depicting the terms defined in this part (see figure 2.1 in proposed § 2.1).

**Regulatory Evaluation**

This proposed 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 Transportation (DOT)(44 FR 11040, February 26, 1979).

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 DOT is unnecessary because we are conforming our jurisdictional definitions to current statutes and presidential proclamations.

**Small Entities**

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered whether this proposed 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.

We are merely conforming our regulatory definitions to statutory authority and presidential proclamations, therefore, the Coast Guard certifies under 5 U.S.C. 605(b) that this proposed rule would not have a significant economic impact on a substantial number of small entities. If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule would have a significant economic impact on it, please submit a comment to the Docket Management Facility at the address under **ADDRESSES**. In your comment, explain why you think it qualifies and how and to what extent this rule would economically affect it.

**Assistance for Small Entities**

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104–121), we want to assist small entities in understanding this proposed rule so that they can better evaluate its effects on them and participate in the rulemaking. If the proposed rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please call (202–267–0097) or write (*see* **ADDRESSES**) Alex Weller.

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 proposed rule would call 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 proposed rule under that order and have determined that it does not have implications for federalism under that Order.

**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 million or more in any one year. Though this proposed rule would not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

**Taking of Private Property**

This proposed rule would 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 proposed 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 proposed rule under Executive Order 13045,

Protection of Children from Environmental Health Risks and Safety Risks. This proposed rule is not an economically significant rule and would not create an environmental risk to health or safety that might disproportionately affect children.

**Indian Tribal Governments**

This proposed rule does not have tribal implications, under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it would not have a substantial direct effect on one or more Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. We invite your comments on how this proposed rule might impact tribal governments, even if that impact may not constitute a ''tribal implication'' under the Order.

**Energy Effects**

We have analyzed this proposed 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. It has not been designated by the Administrator of the Office of Information and Regulatory Affairs as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

**Environment**

We have considered the environmental impact of this proposed rule and concluded that under figure 2–1, paragraph (34)(a), of Commandant Instruction M16475.lD, this rule is categorically excluded from further environmental documentation. Some of the proposed changes are mandated by statute and should be categorically excluded.

Where a statute does not mandate a change, we will revise the existing language to maintain the status quo for geographical scope. These changes should also be categorically excluded. The Coast Guard believes that merely updating the regulations to reflect movement of the boundary of the territorial sea from 3 nautical miles to 12 nautical miles from shore will not have any impact on the environment. A ''Categorical Exclusion Determination'' is available in the docket where indicated under **ADDRESSES.**

**List of Subjects**

*33 CFR Part 2*

Administrative practice and procedure, Law enforcement.

*33 CFR Part 26*

Communications equipment, Marine safety, Radio, Telephone, Vessels.

*33 CFR Part 62*

Navigation (water).

*33 CFR Part 64*

Navigation (water), Reporting and recordkeeping requirements.

*33 CFR Part 95*

Alcohol abuse, Drug abuse, Marine safety, Penalties.

*33 CFR Part 100*

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

*33 CFR Part 120*

Passenger vessels, Reporting and recordkeeping requirements, Security measures.

*33 CFR Part 165*

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

*46 CFR Part 7*

Law Enforcement, Vessels.

*46 CFR Part 28*

Fire prevention, Fishing vessels, Marine safety, Occupational safety and health, Reporting and recordkeeping requirements, Seamen.

For the reasons discussed in the preamble, the Coast Guard proposes to amend 33 CFR parts 2, 26, 62, 64, 95, 100, 120, and 165 and 46 CFR parts 7 and 28 as follows:

**Title 33—Navigation and Navigable Waters**

## PART 2—JURISDICTION

1. Revise part 2 to read as follows:

## PART 2—JURISDICTION

### Subpart A—General

Sec.



**Subpart B—Jurisdictional Terms**



**Subpart C—Availability of Jurisdictional Decisions**



**Authority:** 14 U.S.C. 633, 80 Stat. 931 (49 U.S.C. 108); 49 CFR 1.4(b), 1.46(b).

## PART 2—JURISDICTION

### Subpart A—General

#### § 2.1 Purpose.

(a) The purpose of this part is to define terms the Coast Guard uses in regulations, policies, and procedures, to determine whether it has jurisdiction on certain waters in cases where specific jurisdictional definitions are not otherwise provided.

(b) Figure 2.1 is a visual aid depicting the terms defined in this part.

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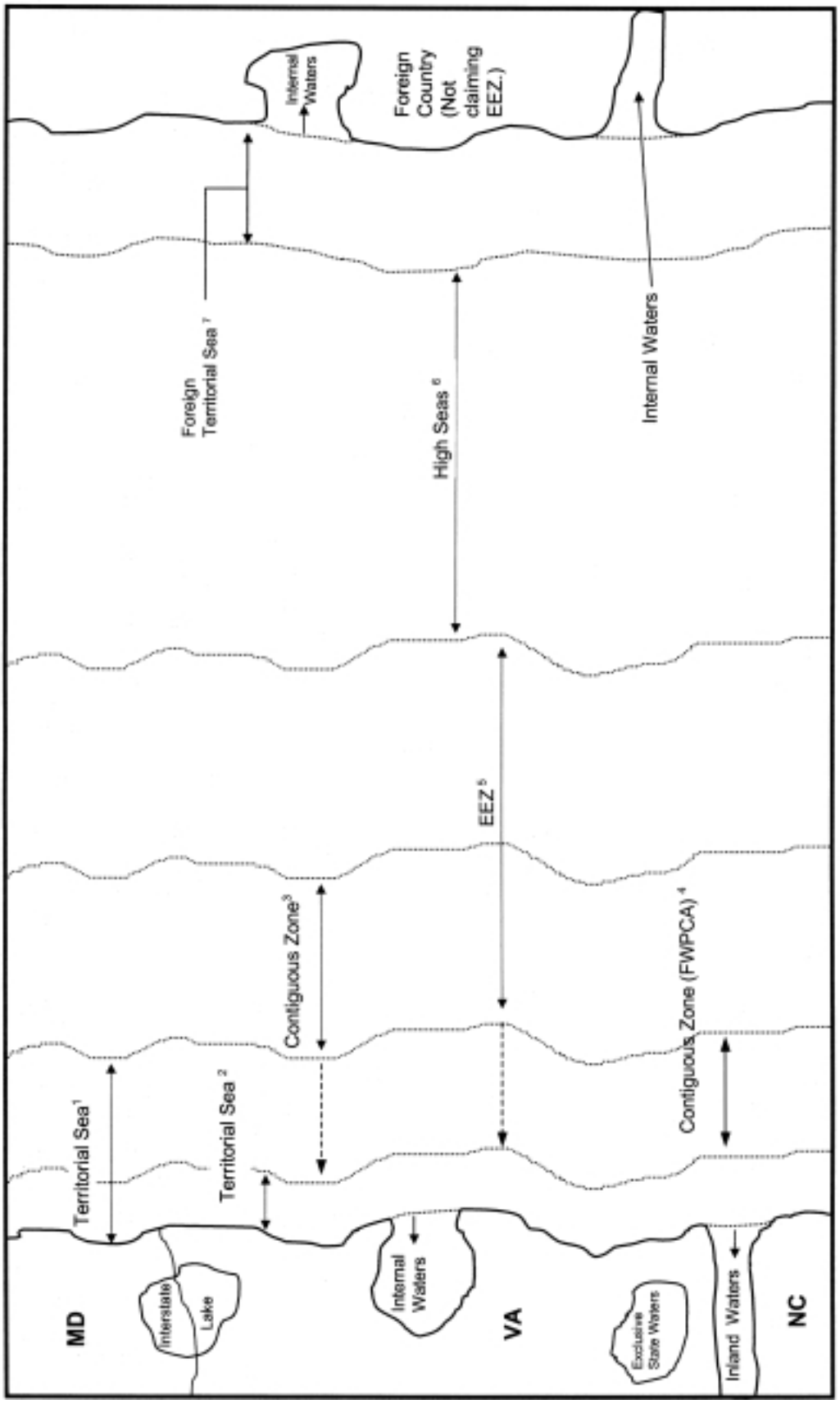
## FIGURE 2.1. JURISDICTIONAL AREAS




[1] Territorial sea for purposes identified in §2.22(a)(1).
[2] Territorial sea for purposes identified in §2.22(a)(2).
[3] Contiguous zone as described in §2.28(b), varies with territorial sea width for particular purpose involved.
[4] Contiguous zone as described in §2.28(a), for Federal Water Pollution Control Act purposes.
[5] Exclusive Economic Zone (EEZ) is measured from the seaward limit of the territorial sea, as variously defined in §2.22(a), to a distance of 200 nautical miles from the baseline. The inner (shoreward) boundary of the EEZ will vary for particular purposes..
[6] High seas as defined in §2.32(c). When a nation has not proclaimed an EEZ, the high seas begin at the seaward edge of the territorial sea
[7] The U.S. recognizes territorial sea claims of other nations up to a maximum distance of 12 nautical miles from the baseline.

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**§ 2.5 Specific definitions control.**

In cases where a particular statute, regulation, policy or procedure provides a specific jurisdictional definition that differs from the definitions contained in this part, the former definition controls.

**Note to § 2.5:** For example, the definition of ''inland waters'' in the Inland Navigational Rules Act of 1980 (33 U.S.C. 2003 (o)) would control the interpretation of inland navigation rules created under that Act and the ''inland waters'' definition in 46 CFR 10.103 would control regulations in 46 CFR part 10.

## Subpart B—Jurisdictional Terms

**§ 2.20 Territorial sea baseline.**

*Territorial sea baseline* means the line defining the shoreward extent of the territorial sea of the United States drawn according to the principles, as recognized by the United States, of the Convention on the Territorial Sea and the Contiguous Zone, 15 U.S.T. 1606, and the 1982 United Nations Convention on the Law of the Sea (UNCLOS), 21 I.L.M. 1261. Normally, the territorial sea baseline is the mean low water line along the coast of the United States. Note to § 2.20: Charts depicting the territorial sea baseline are available for examination in accordance with § 1.10–5 of this chapter.

**§ 2.22 Territorial sea.**

(a) With respect to the United States, the following apply—

(1) *Territorial sea* means the waters, 12 nautical miles wide, adjacent to the coast of the United States and seaward of the territorial sea baseline, for—

(i) Statutes included within subtitle II, title 46, U.S.C., and the Ports And Waterways Safety Act, as amended (33 U.S.C. 1221 *et seq.*), and any regulations issued under the authority of these statutes.

(ii) Purposes of criminal jurisdiction pursuant to title 18, United States Code.

(iii) The special maritime and territorial jurisdiction as defined in 18 U.S.C. 7.

(iv) Interpreting international law.

(v) Any other treaty, statute, or regulation, or amendment thereto, interpreted by the Coast Guard as incorporating the definition of territorial sea in paragraph (a)(1) of this section.

(2) Unless otherwise specified in paragraph (a)(1) of this section, *territorial sea* means the waters, 3 nautical miles wide, adjacent to the coast of the United States and seaward of the territorial sea baseline.

(3) In cases where regulations are promulgated under the authority of statutes covered by both paragraphs (a)(1) and (a)(2) of this section, the Coast Guard may use the definition of territorial sea in paragraph (a)(1) of this section.

(b) With respect to any other nation, *territorial sea* means the waters adjacent to its coast that have a width and baseline recognized by the United States.

**§ 2.24 Internal waters.**

(a) With respect to the United States, *internal waters* means the waters shoreward of the territorial sea baseline.

(b) With respect to any other nation, *internal waters* means the waters shoreward of its territorial sea baseline, as recognized by the United States.

**§ 2.26 Inland waters.**

*Inland waters* means the waters shoreward of the territorial sea baseline.

**§ 2.28 Contiguous zone.**

(a) For the purposes of the Federal Water Pollution Control Act (33 U.S.C. 1251 *et seq.*), *contiguous zone* means the zone, 9 nautical miles wide, adjacent to and seaward of the territorial sea, as defined in § 2.22(a)(2), that was declared to exist in Department of State Public Notice 358 of June 1, 1972 (37 FR 11906, June 15, 1972) and that extends from 3 nautical miles to 12 nautical miles as measured from the territorial sea baseline.

(b) For all other purposes, *contiguous zone* means all waters within the area adjacent to and seaward of the territorial sea, as defined in § 2.22(a), and extending to 24 nautical miles from the territorial sea baseline, but in no case extending within the territorial sea of another nation, as declared in Presidential Proclamation 7219 of September 2, 1999 (113 Stat. 2138).

**§ 2.30 Exclusive Economic Zone.**

(a) With respect to the United States, the Commonwealth of Puerto Rico, the Commonwealth of the Northern Mariana Islands (to the extent consistent with the Covenant and the United Nations Trusteeship Agreement); and United States' overseas possessions and territories,

*Exclusive Economic Zone* means the zone seaward of and adjacent to the territorial sea, as defined in § 2.22(a), including the contiguous zone, and extending 200 nautical miles from the territorial sea baseline, except where otherwise limited by treaty or other agreement recognized by the United States.

(b) For the purposes of interpretation of international law consistent with the 1982 United Nations Convention on the Law of the Sea, and with respect to other nations, *Exclusive Economic Zone* means the waters seaward and adjacent to the territorial sea, not extending beyond 200 nautical miles from the territorial sea baseline, as recognized by the United States.

**§ 2.32 High seas.**

(a) For the purposes of the special maritime and territorial jurisdiction of the United States as defined in 18 U.S.C. 7, *high seas* means the Great Lakes and all waters seaward of the territorial sea baseline.

(b) For the purposes of section 2 of the Act of February 19, 1895, as amended (33 U.S.C. 151) and the Inland Navigational Rules Act of 1980 (33 U.S.C chapter 34), *high seas* means the waters seaward of any lines established under these statutes, including the lines described in part 80 of this chapter and 46 CFR part 7.

(c) For the purposes of interpretation of international law, consistent with the United Nations Convention on the Law of the Sea, *high seas* means all waters that are neither the Exclusive Economic Zone, territorial sea (as defined in § 2.22) nor internal waters of the United States or any other nation.

(d) For all other purposes, *high seas* means all waters that are neither territorial seas (as defined in § 2.22) nor internal waters of the United States or any other nation.

**§ 2.34 Waters subject to tidal influence; waters subject to the ebb and flow of the tide; mean high water.**

*Waters subject to tidal influence* and *waters subject to the ebb and flow of the tide* are waters below mean high water. These terms do not include waters above mean high water caused by flood flows, storms, high winds, seismic waves, or other non-lunar phenomena.

*Mean high water* is the average of the height of the diurnal high water at a particular location measured over a lunar cycle of 19 years.

**§ 2.36 Navigable waters of the United States, navigable waters, and territorial waters.**

(a) For the purposes of sections 311 and 312 of the Federal Water Pollution Control Act (FWPCA), as amended (33 U.S.C. 1321 and 1322),and the Oil Pollution Act of 1990 (33 U.S.C. 2701 *et seq.*), *navigable waters of the United States* and *navigable waters,* mean—

(1) Territorial sea as defined in § 2.22(a)(2) of this chapter;

(2) Internal waters of the United States, as described in paragraphs (b)(2) and (b)(3) of this section and all waters of the United States adjacent or tributary thereto;

(3) Waters subject to the jurisdiction of the United States, as defined in § 2.38 (b); and

(4) All other waters included within the definitions of ''navigable waters'' and ''territorial seas'' in 33 U.S.C. 1362 (7) and (8) and 33 U.S.C. 2701 (21) and (35).

(b) For all other purposes, except where Congress has designated them not to be navigable waters of the United States, *navigable waters of the United States, navigable waters,* and *territorial waters* mean —

(1) Territorial sea of the United States as defined in § 2.22(a) of this chapter;

(2) Internal waters of the United States that are subject to tidal influence; and

(3) Internal waters that are not subject to tidal influence and—

(i) That are or have been used, or are or have been susceptible for use, by themselves or in connection with other waters, as highways for substantial interstate or foreign commerce, notwithstanding natural or man-made obstructions that require portage; or

(ii) That a governmental or non-governmental body having expertise in waterway improvement determines to be capable of improvement at a reasonable cost (a favorable balance between cost and need) to provide, by themselves or in connection with other waters, highways for substantial interstate or foreign commerce.

**§ 2.38 Waters subject to the jurisdiction of the United States; waters over which the United States has jurisdiction.**

*Waters subject to the jurisdiction of the United States* and *waters over which the United States has jurisdiction* mean the following waters—

(a) Navigable waters of the United States, as defined in § 2.36(b).

(b) Waters, other than those under paragraph (a) of this section, that are located on lands for which the United States has acquired title or controls and—

(1) Has accepted jurisdiction according to 40 U.S.C. 255; or

(2) Has retained concurrent or exclusive jurisdiction from the date that the State in which the lands are located entered the Union.

(c) Waters made subject to the jurisdiction of the United States by operation of the international agreements and statutes relating to the former Trust Territory of the Pacific Islands, and waters within the territories and possessions of the United States.

## Subpart C—Availability of Jurisdictional Decisions

**§ 2.40 Maintenance of decisions.**

(a) From time to time, the Coast Guard makes navigability determinations of specific waterways, or portions of thereof, in order to determine its jurisdiction on those waterways. Copies of these determinations are maintained by the District Commander in whose district the waterway is located.

(b) If the district includes portions of the territorial sea, charts reflecting Coast Guard decisions as to the location of the territorial sea baseline for the purposes of Coast Guard jurisdiction are maintained by the District Commander in whose district the waterway is located.

**§ 2.45 Decisions subject to change or modification and availability of lists and charts.**

The determinations referred to in § 2.40 are subject to change or modification. The determinations are made for Coast Guard use at the request of Coast Guard officials. Determinations made or subsequently changed are available to the public under § 1.10–5(b) of this chapter. Inquiries concerning whether a determination has been made for specific waters, for the purposes of Coast Guard jurisdiction, should be directed to the District Commander of the district in which the waters are located.

## PART 26—VESSEL BRIDGE-TO-BRIDGE RADIOTELEPHONE REGULATIONS

2. The authority citation for part 26 continues to read as follows:

**Authority:** 14 U.S.C. 2, 33 U.S.C. 1201–1208; 49 CFR 1.45(b), 1.46; Rule 1. International Regulations for the Prevention of Collisions at Sea.

3. In § 26.02, add, in alphabetical order, the definition of ''territorial sea'' to read as follows:

**§ 26.02 Definitions.**

* * * * *

*Territorial sea* means all waters as defined in § 2.22(a)(2) of this chapter.

* * * * *

## PART 62—UNITED STATES AIDS TO NAVIGATION SYSTEM

4. The authority citation for part 62 continues to read as follows:

**Authority:** 14 U.S.C. 85; 33 U.S.C. 1233; 43 U.S.C. 1333; 49 CFR 1.46.

5. In § 62.3, revise paragraph (g) to read as follows:

**§ 62.3 Definition of terms.**

* * * * *

(g) *Navigable waters of the United States*. The term navigable waters of the United States is defined in § 2.36(b) of this chapter.

* * * * *

## PART 64—MARKING OF STRUCTURES, SUNKEN VESSELS AND OTHER OBSTRUCTIONS

6. The authority citation for part 64 continues to read as follows:

**Authority:** 14 U.S.C. 633; 33 U.S.C. 409, 1231; 42 U.S.C. 9118; 43 U.S.C. 1333; 49 CFR 1.46.

7. In § 64.06, add, in alphabetical order, a definition of ''navigable waters of the United States'' to read as follows:

**§ 64.06 Definition of terms.**

* * * * *

*Navigable waters of the United States* means those waters described in § 2.36(b) of this chapter, specifically including the waters described in § 2.22(a)(2) of this chapter.

* * * * *

## PART 95—OPERATING A VESSEL WHILE UNDER THE INFLUENCE OF ALCOHOL OR A DANGEROUS DRUG

8. The authority citation for part 95 continues to read as follows:

**Authority:** 33 U.S.C. 2071; 46 U.S.C. 2302; 49 CFR 1.46.

9. In § 95.010, add, in alphabetical order, a definition of ''waters subject to the jurisdiction of the United States'' to read as follows:

**§ 95.010 Definition of terms as used in this part.**

* * * * *

*Waters subject to the jurisdiction of the United States* means those waters described in § 2.38 of this chapter.

## PART 100—MARINE EVENTS

10. The authority citation for part 100 continues to read as follows:

**Authority:** 33 U.S.C. 1233; 49 CFR 1.46.

11. In § 100.05, add paragraph (e) to read as follows:

**§ 100.05 Definition of terms used in this part.**

* * * * *

(e) *Navigable waters of the United States* means those waters described in § 2.36(b) of this chapter, specifically including the waters described in § 2.22(a)(2) of this chapter.

## PART 120—SECURITY OF PASSENGER VESSELS

12. The authority citation for part 120 continues to read as follows:

**Authority:** 33 U.S.C. 1231; 49 CFR 1.46.

13. In § 120.110, revise the definitions of ''high seas'' to read as follows:

### § 120.110 Definitions.

* * * * *

*High seas* means the waters defined in § 2.32 (d) of this chapter.

* * * * *

## PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

14. 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; 49 CFR 1.46.

15. Add § 165.9 to read as follows:

### § 165.9 Geographic application of limited and controlled access areas and regulated navigation areas.

(a) *General.* The geographic application of the limited and controlled access areas and regulated navigation areas in this part are determined based on the statutory authority under which each is created.

(b) *Safety zones and regulated navigation areas.* These zones and areas are created under the authority of the Ports and Waterways Safety Act, 33 U.S.C. 1221 *et seq.* Safety zones established under 33 U.S.C. 1226 and regulated navigation areas may be established in waters of the United States as defined in § 2.38 of this chapter including the territorial sea to a seaward limit of 12 nautical miles from the baseline.

(c) *Security zones.* These zones have two sources of authority—the Ports and Waterways Safety Act, 33 U.S.C. 1226, and the Magnuson Act, 50 U.S.C. 191. Security zones established under 33 U.S.C. 1226 may be established in waters of the United States as defined in § 2.38 of this chapter including the territorial sea to a seaward limit of 12 nautical miles from the baseline. Security zones established under the Magnuson Act, 50 U.S.C. 191, may be established in waters subject to the jurisdiction of the United States as defined in § 2.38 of this chapter, including the territorial sea out to a seaward limit of 3 n.m. from the baseline. Security zones established under the Ports and Waterways Safety Act and the Magunson Act may be established in waters subject to the jurisdiction of the United States as defined in § 2.38 of this chapter, including the territorial sea to a seaward limit of 3 n.m. from the baseline.

(d) *Naval vessel protection zones.* These zones are issued under the authority of 14 U.S.C. 91 and 633 and may be established in waters subject to the jurisdiction of the United States as defined in § 2.38 of this chapter, including the territorial sea to a seaward limit of 3 n.m. from the baseline.

**Title 46—Shipping**

## PART 7—BOUNDARY LINES

16. The authority citation for part 7 continues to read as follows:

**Authority:** 14 U.S.C. 633; 33 U.S.C. 151; 49 CFR 1.46.

17. Revise § 7.105 to read as follows:

### § 7.105 Marquesas Keys, FL to Rio Grande, TX.

A line drawn from Marquesas Keys, Florida at approximate position latitude 24°47.5′ N, longitude 82°11.2′ W; along the 12-mile line which marks the seaward limits of the territorial sea (as defined in 33 CFR 2.22 (a)(1)) to Rio Grande, Texas at approximate position latitude 25°58.6′ N, longitude 96°55.5′ W.

## PART 28—REQUIREMENTS FOR COMMERCIAL FISHING INDUSTRY VESSELS

18. The authority citation for part 28 continues to read as follows:

**Authority:** 46 U.S.C. 3316, 4502, 4505, 4506, 6104, 10603; 49 CFR 1.46.

19. In § 28.50, revise the definitions of ''boundary lines'' and ''coastline'', to read as follows:

### § 28.50 Definition of terms used in this part.

* * * * *

*Boundary lines* means the lines described in part 7 of this chapter. In general, they follow the trend of the seaward high water shorelines and cross entrances to small bays, inlets, and rivers. In some areas, they are along the 12-mile line that marks the seaward limits of the territorial sea and, in other areas, they come ashore.

* * * * *

*Coastline* means the territorial sea baseline as defined in 33 CFR 2.20.

* * * * *

Dated: August 6, 2002.

**Calvin M. Lederer,**

*Acting Chief Counsel, U.S. Coast Guard.*

[FR Doc. 02–20481 Filed 8–13–02; 8:45 am]

BILLING CODE 4910–15–P

## ENVIRONMENTAL PROTECTION AGENCY

## 40 CFR Part 52

**[TN–238–200112; FRL–7258–9]**

## Approval and Promulgation of Implementation Plans: Tennessee: Nitrogen Oxides Budget and Allowance Trading Program

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed conditional approval.

**SUMMARY:** EPA is proposing to conditionally approve a State Implementation Plan (SIP) revision submitted by the State of Tennessee on November 7, 2000, with additional material submitted on January 11, 2001, and October 4, 2001. This revision responds to the EPA's regulation entitled, ''Finding of Significant Contribution and Rulemaking for Certain States in the Ozone Transport Assessment Group Region for Purposes of Reducing Regional Transport of Ozone,'' otherwise known as the ''$NO_X$ SIP Call.'' This revision establishes and requires a nitrogen oxides ($NO_X$) allowance trading program for large electric generating and industrial units, and reductions for cement kilns, beginning in 2004. The intended effect of this SIP revision is to reduce emissions of $NO_X$ in order to help attain the national ambient air quality standard for ozone. EPA is proposing to approve Tennessee's $NO_X$ Reduction and Trading Program, with one exception, because it meets the requirements of the Phase I $NO_X$ SIP Call that will significantly reduce ozone transport in the eastern United States. The exception refers to Section 96.40 State trading program budget. Tennessee revised the model rule to allow for the allocation of additional allowances to $NO_X$ budget units that have been generated through $NO_X$ emission reductions from industrial, mobile, and area source sectors. However, Tennessee's rule provides for approval of the allocation of additional allowances solely by the permitting authority, without approval by EPA. Therefore, EPA is proposing to approve Tennessee's $NO_X$ Reduction and Trading Program with the condition that Tennessee correct the deficiencies in Section 96.40 State trading program budget by replacing or revising the unapprovable language.

**DATES:** Written comments must be received on or before September 13, 2002.

**ADDRESSES:** All comments should be addressed to: Steven M. Scofield at the EPA, Region 4 Air Planning Branch, 61 Forsyth Street, SW, Atlanta, Georgia 30303–8960.

Copies of documents relative to this action are available at the following addresses for inspection during normal business hours: Environmental Protection Agency, Region 4, Air Planning Branch, 61 Forsyth Street, SW, Atlanta, Georgia 30303–8960. Tennessee Department of Environment and Conservation, L & C Annex, 401 Church Street, Nashville, Tennessee 37243.

**FOR FURTHER INFORMATION CONTACT:** Steven M. Scofield, Regulatory Development Section, Air Planning Branch, Air, Pesticides and Toxics Management Division, Region 4, Environmental Protection Agency, Atlanta Federal Center, 61 Forsyth Street, SW, Atlanta, Georgia 30303–8960. The telephone number is (404) 562–9034. Mr. Scofield can also be reached via electronic mail at *scofield.steve@epa.gov.*

**SUPPLEMENTARY INFORMATION:** On November 7, 2000, the Tennessee Department of Environment and Conservation (TDEC) submitted a draft $NO_X$ emission control rule to the EPA for pre-adoption review, requesting parallel processing to the development of the rule at the State level and included a schedule for development and adoption of the rule by the State. On January 11, 2001, TDEC submitted adopted revisions to its SIP to meet the requirements of the Phase I $NO_X$ SIP Call. After adoption by the Tennessee Air Pollution Control Board, all rule revisions in Tennessee must be sent to the Secretary of State. Rule revisions become State-effective upon certification by the Secretary of State. Tennessee submitted State-effective rule revisions on October 4, 2001. The revisions comply with the requirements of the Phase I $NO_X$ SIP Call with one exception regarding deficiencies in Section 96.40 State trading program budget. Included in this document are new rules 1200–3–27–.04 STANDARDS FOR CEMENT KILNS and 1200–3–27–.06 $NO_X$ BUDGET TRADING PROGRAM FOR STATE IMPLEMENTATION PLANS (40 CFR part 96). The information in this proposal is organized as follows:



## I. EPA's Action

### *A. What Action Is EPA Proposing Today?*

EPA is proposing to conditionally approve revisions to Tennessee's SIP concerning the adoption of its $NO_X$ Reduction and Trading Program, submitted for parallel processing on November 7, 2000, with additional material submitted on January 11, 2001, and State-effective rules submitted on October 4, 2001.

### *B. Why Is EPA Proposing This Action?*

EPA is proposing this action because Tennessee's $NO_X$ Reduction and Trading Program regulations meet the requirements of the Phase I $NO_X$ SIP Call with one exception. The exception refers to deficiencies in Section 96.40 State trading program budget. Tennessee revised the model rule to allow for the allocation of additional allowances to $NO_X$ budget units that have been generated through $NO_X$ emission reductions from industrial, mobile, and area source sectors. However, Tennessee's rule provides for approval of the allocation of additional allowances solely by the permitting authority, without approval by EPA. In a letter dated June 25, 2002, EPA informed Tennessee of the deficiencies in Section 96.40 and how the State could correct these deficiencies. In the letter EPA also required the State to commit to correct the deficiencies within 12 months. Therefore, EPA is proposing to approve Tennessee's $NO_X$ Reduction and Trading Program, including a rule for cement kilns, with the condition that Tennessee correct the deficiencies in Section 96.40 State trading program budget.

### *C. What Are the $NO_X$ SIP Call General Requirements?*

On October 27, 1998, EPA published a final rule entitled, ''Finding of Significant Contribution and Rulemaking for Certain States in the Ozone Transport Assessment Group Region for Purposes of Reducing Regional Transport of Ozone,'' otherwise known as the ''$NO_X$ SIP Call.'' See 63 FR 57356. The $NO_X$ SIP Call requires 22 States and the District of Columbia to meet statewide $NO_X$ emission budgets during the five month period from May 1 through September 30 in order to reduce the amount of ground level ozone that is transported across the eastern United States.

EPA identified $NO_X$ emission reductions by source category that could be achieved by using cost-effective measures. The source categories included were electric generating units (EGUs) and non-electric generating units (non-EGUs), internal combustion engines, and cement kilns. EPA determined state-wide $NO_X$ emission budgets based on the implementation of these cost-effective controls for each affected jurisdiction to be met by the year 2007. Internal combustion engines are not addressed by Tennessee in this response to Phase I, but will be in Phase II. In the $NO_X$ SIP Call notice, EPA suggested that imposing statewide $NO_X$ emissions caps on large fossil-fuel fired industrial boilers and EGUs would provide a highly cost-effective means for states to meet their $NO_X$ budgets. In fact, the state-specific budgets were set assuming an emission rate of 0.15 pounds $NO_X$ per million British thermal units (lb. $NO_X$/mmBtu) at EGUs, multiplied by the projected heat input (mmBtu) from burning the quantity of fuel needed to meet the 2007 forecast for electricity demand. See 63 FR 57407. The calculation of the 2007 EGU emissions assumed that an emissions trading program would be part of an EGU control program. The $NO_X$ SIP Call state budgets also assumed on average a 30 percent $NO_X$ reduction from cement kilns, and a 60 percent reduction from industrial boilers and combustion. The non-EGU control assumptions were applied at units where the heat input capacities were greater than 250 mmBtu per hour, or in cases where heat input data were not available or appropriate, at units with actual emissions greater than one ton per day. However, the $NO_X$ SIP Call allowed states the flexibility to decide which source categories to regulate in order to meet the statewide budgets.

To assist the states in their efforts to meet the SIP Call, the $NO_X$ SIP Call final rulemaking notice included a model $NO_X$ allowance trading regulation, called ''$NO_X$ Budget Trading Program for State Implementation Plans,'' (40 CFR part 96), that could be used by states to develop their regulations. The $NO_X$ SIP Call notice explained that if states developed an allowance trading regulation consistent with the EPA model rule, they could participate in a regional allowance trading program that

would be administered by the EPA. *See* 63 FR 57458–57459.

There were several periods during which EPA received comments on various aspects of the $NO_X$ SIP Call emissions inventories. On March 2, 2000, EPA published additional technical amendments to the $NO_X$ SIP Call in the **Federal Register** (65 FR 11222). On March 3, 2000, the D.C. Circuit issued its decision on the $NO_X$ SIP Call ruling in favor of EPA on all the major issues. Michigan v. EPA, 213 F.3d 663 (D.C. Cir. 2000). The DC Circuit Court denied petitioners' requests for rehearing or rehearing en banc on July 22, 2000. However, the Circuit Court remanded four specific elements to EPA for further action: The definition of electric generating unit, the level of control for stationary internal combustion engines, the geographic extent of the $NO_X$ SIP Call for Georgia and Missouri, and the inclusion of Wisconsin. On March 5, 2001, the U.S. Supreme Court declined to hear an appeal by various utilities, industry groups and a number of upwind states from the D.C. Circuit's ruling on EPA's $NO_X$ SIP Call rule.

EPA published a proposal that addresses the remanded portion of the $NO_X$ SIP Call Rule on February 22, 2002 (67 FR 8396). Any additional emissions reductions required as a result of a final rulemaking on that proposal will be reflected in the second phase portion (Phase II) of the State's emission budget. On April 11, 2000, in response to the Court's decision, EPA notified Tennessee of the maximum amount of $NO_X$ emissions allowed for the State during the ozone season. This emission budget reflected adjustments to Tennessee's $NO_X$ emission budget to reflect the Court's decision regarding internal combustion engines and cogeneration facilities. Although the Court did not order EPA to modify Tennessee's budget, the EPA believes these adjustments are consistent with the Court's decision.

*D. What Is EPA's $NO_X$ Budget and Allowance Trading Program?*

EPA's model $NO_X$ budget and allowance trading rule, 40 CFR part 96, sets forth a $NO_X$ emissions trading program for large EGUs and non-EGUs. A state can voluntarily choose to adopt EPA's model rule in order to allow sources within its borders to participate in regional allowance trading. The October 27, 1998, **Federal Register** notice contains a full description of the EPA's model $NO_X$ budget trading program. *See* 63 FR 57514–57538 and 40 CFR part 96.

Air emissions trading, in general, uses market forces to reduce the overall cost of compliance for pollution sources, such as power plants, while maintaining emission reductions and environmental benefits. One type of market-based program is an emissions budget and allowance trading program, commonly referred to as a ''cap and trade'' program.

In an emissions budget and allowance trading program, the state or EPA sets a regulatory limit, or emissions budget, in mass emissions from a specific group of sources. The budget limits the total number of allowances for each source covered by the program during a particular control period. When the budget is set at a level lower than the current emissions, the effect is to reduce the total amount of emissions during the control period. After setting the budget, the state or EPA then assigns, or allocates, allowances to the participating entities up to the level of the budget. Each allowance authorizes the emission of a quantity of pollutant, *e.g.,* one ton of airborne $NO_X$.

At the end of the control period, each source must demonstrate that its actual emissions during the control period were less than or equal to the number of available allowances it holds. Sources that reduce their emissions below their allocated allowance level may sell their extra allowances. Sources that emit more than the amount of their allocated allowance level may buy allowances from the sources with extra reductions. In this way, the budget is met in the most cost-effective manner.

*E. What Guidance Did EPA Use To Evaluate Tennessee's Submittal?*

The final $NO_X$ SIP Call rule included a model $NO_X$ budget trading program regulation. See 40 CFR part 96. EPA used the model rule and 40 CFR 51.121–51.122 to evaluate Tennessee's $NO_X$ reduction and trading program.

*F. What Is the Result of EPA's Evaluation of Tennessee's Program?*

EPA has evaluated Tennessee's October 4, 2001, SIP submittal and finds it approvable with conditions. The Tennessee $NO_X$ reduction and trading program is consistent with EPA's guidance and meets the requirements of the Phase I $NO_X$ SIP Call with one exception regarding deficiencies in Section 96.40 State trading program budget. EPA finds the $NO_X$ control measures in Tennessee's $NO_X$ reduction and trading program, including the cement kiln rule, approvable.

The October 4, 2001, submittal will strengthen Tennessee's SIP for reducing ground level ozone by providing $NO_X$ reductions beginning in 2004. Also, EPA finds that the submittal contained the information necessary to demonstrate that Tennessee has the legal authority to implement and enforce the control measures, and to demonstrate their appropriate distribution of the compliance supplement pool. Furthermore, EPA proposes to find that the submittal demonstrates that the compliance dates and schedules, and the monitoring, recordkeeping and emission reporting requirements will be met.

## II. Tennessee's Control of $NO_X$ Emissions

*A. When Did Tennessee Submit the SIP Revision to EPA in Response to the $NO_X$ SIP Call?*

On November 7, 2000, the Tennessee Department of Environment and Conservation submitted a draft $NO_X$ emission control rule to the EPA for pre-adoption review, requesting parallel processing to the development of the rule at the State level and included a schedule for development and adoption of the rule by the State. On January 11, 2001, TDEC submitted adopted revisions to its SIP to meet the requirements of the Phase I $NO_X$ SIP Call. After adoption by the Tennessee Air Pollution Control Board, all rule revisions in Tennessee must be sent to the Secretary of State. Rule revisions become State-effective upon certification by the Secretary of State. Tennessee submitted State-effective rule revisions on October 4, 2001.

*B. What Is Tennessee's $NO_X$ Budget Trading Program?*

Tennessee's rule, as in the model rule, allows the large EGUs, boilers and turbines to participate in the multi-state cap and trade program. Cement kilns are not included in the trading program, but will be required to install low $NO_X$ burners, mid-kiln system firings or technology that achieves the same emission decreases. Tennessee's SIP revision to meet the requirements of the $NO_X$ SIP Call consists of new rules 1200–3–27–.04 STANDARDS FOR CEMENT KILNS and 1200–3–27–.06 $NO_X$ BUDGET TRADING PROGRAM FOR STATE IMPLEMENTATION PLANS (40 CFR 96). The regulations under 1200–3–27–.06 affect EGUs and non-EGUs. Rule 1200–3–27–.06 $NO_X$ BUDGET TRADING PROGRAM FOR STATE IMPLEMENTATION PLANS (40 CFR 96) added 10 new subparts: Subpart A—$NO_X$ Budget Trading Program General Provisions; Subpart B—Authorized Account Representative for $NO_X$ Budget Sources; Subpart C—

Permits; Subpart D—Compliance Certification; Subpart E—$NO_X$ Allowance Allocations; Subpart F—$NO_X$ Allowance Tracking System; Subpart G—$NO_X$ Allowance Transfers; Subpart H—Monitoring and Reporting; Subpart I—Individual Unit Opt-ins; and Subpart J—Mobile and Area Sources [Reserved].

Tennessee's $NO_X$ Budget Trading Program establishes and requires a $NO_X$ allowance trading program for large EGUs and non-EGUs. The regulations under 1200–3–27–.06 establish a $NO_X$ cap and allowance trading program for the ozone control seasons beginning May 31, 2004.

The State of Tennessee voluntarily chose to follow EPA's model $NO_X$ budget and allowance trading rule, 40 CFR part 96, that sets forth a $NO_X$ emissions trading program for large EGUs and non-EGUs. Tennessee's $NO_X$ Budget Trading Program is based upon EPA's model rule, therefore, Tennessee sources are allowed to participate in the interstate $NO_X$ allowance trading program that EPA will administer for the participating states. The State of Tennessee has adopted regulations that are substantively identical to 40 CFR part 96, with the exceptions of the allocation period and the State trading program budget. Tennessee chose to use a 15-year allocation period (2004–2018) for $NO_X$ allowance allocations, with the $NO_X$ allowance allocations, in accordance with Sec. 96.42, being submitted by April 1, 2016 (15 years after initial allocation), and April 1st of each year thereafter, to the Administrator for the control period in the year that is three years after the year of the applicable deadline. Tennessee's $NO_X$ allocations do not exceed the values allowed to meet the State cap. Therefore, pursuant to 40 CFR 51.121(p)(1), Tennessee's SIP revision is approvable as satisfying the State's $NO_X$ emission reduction obligations. Under 1200–3–27–.06, Tennessee allocates $NO_X$ allowances to the EGU and non-EGU units that are affected by these requirements. The $NO_X$ trading program applies to all Phase I units that are fossil fuel-fired EGUs with a nameplate capacity greater than 25 MW or more and selling any amount of electricity to the grid, or that are fossil fuel-fired non-EGUs that have a heat input capacity equal to or greater than 250 mmBtu per hour. Each $NO_X$ allowance permits a source to emit one ton of $NO_X$ during the seasonal control period. $NO_X$ allowances may be bought or sold. Unused $NO_X$ allowances may also be banked for future use, with certain limitations.

Tennessee also chose to revise Section 96.40 (State trading program budget) from the model rule at 1200–3–27–.06(1)(f) to allow for the allocation of additional allowances to $NO_X$ budget units that have been generated through $NO_X$ emission reductions from industrial, mobile, and area source sectors. However, Tennessee's rule provides for approval of the allocation of additional allowances solely by the permitting authority, without approval by EPA. Therefore, EPA is proposing to approve Tennessee's $NO_X$ Reduction and Trading Program with the condition that Tennessee correct the deficiencies in Section 96.40 State trading program budget by removing or making specific revisions to the unapprovable language. By letter dated June 25, 2002, EPA explained in detail the problems with this language and stated that the language should be deleted or replaced with specified, revised language.

Source owners will monitor their $NO_X$ emissions by using systems that meet the requirements of 40 CFR part 75, subpart H, and report resulting data to EPA electronically. Each budget source complies with the program by demonstrating at the end of each control period that actual emissions do not exceed the amount of allowances held for that period. However, regardless of the number of allowances a source holds, it cannot emit at levels that would violate other federal or state limits, for example, reasonably available control technology (RACT), new source performance standards, or Title IV (the Federal Acid Rain program).

Tennessee's Rule 1200–3–27–.04 STANDARDS FOR CEMENT KILNS establishes requirements for cement manufacturing facilities, however, these sources are subject to $NO_X$ reduction requirements but do not participate in the $NO_X$ trading program. Cement kilns are not included in the trading program, but will be required to install low $NO_X$ burners, mid-kiln system firings or technology that achieves the same emission decreases. Tennessee's submittal does not rely on any additional reductions beyond the anticipated Federal measures in the mobile and area source categories. However, Tennessee revised the model rule to allow for the allocation of additional allowances to $NO_X$ budget units that have been generated through $NO_X$ emission reductions from industrial, mobile, and area source sectors in the future. It is expected that Tennessee will revise this provision to be consistent with EPA requirements. Therefore, Tennessee may comply in the future using measures beyond the measures anticipated by the Federal rule.

Tennessee's submittal demonstrates that the Phase I $NO_X$ emission budgets established by EPA will be met as follows:

| Source category | EPA 2007 $NO_X$ budget emissions (tons/season) | Tennessee 2007 $NO_X$ budget emissions (tons/season) |
|---|---|---|
| EGUs | 25,814 | 25,814 |
| Non-EGUs | 5,519 | 5,519 |
| Area Sources | 13,333 | 13,333 |
| Non-road Sources | 52,920 | 52,920 |
| Highway Sources | 66,342 | 66,342 |
| Total | 163,928 | 163,928 |

*C. What Is the Compliance Supplement Pool?*

To provide additional flexibility for complying with emission control requirements associated with the $NO_X$ SIP Call, the final $NO_X$ SIP Call rule provided each affected state with a ''compliance supplement pool.'' The compliance supplement pool is a quantity of $NO_X$ allowances that may be used to cover excess emissions from sources that are unable to meet control requirements during the 2004 and 2005 ozone seasons. Allowances from the compliance supplement pool will not be valid for compliance past the 2005 ozone season. The $NO_X$ SIP Call included these voluntary provisions in order to address commenters' concerns about the possible adverse effect that the control requirements might have on the reliability of the electricity supply or on other industries required to install controls as the result of a state's response to the $NO_X$ SIP Call.

A state may issue some or all of the compliance supplement pool via two mechanisms.

First, a state may issue some or all of the pool to sources with credits from implementing $NO_X$ reductions beyond all applicable requirements in the ozone season during 2000–2003 (i.e., early reductions). This allows sources that cannot install controls prior to May 31, 2004, to purchase other sources' early reduction credits in order to comply. Second, a state may issue some or all of the pool to sources that demonstrate a need for an extension of the May 31, 2004, compliance deadline due to undue risk to the electricity supply or other industrial sectors, and where early reductions are not available. See 40 CFR 51.121(e)(3). In Tennessee's rule, each $NO_X$ Budget unit for which the owner or operator requests any early reduction credits shall reduce its $NO_X$ emission rate, for each control period in 2001, 2002, and 2003 for which early reduction credits are requested, to less than both 0.25 lb/mmBtu and 80 percent of the unit's $NO_X$ emission rate in the 2000 control period for EGUs, and for non-EGUs, to less than 95 percent of the unit's $NO_X$ emission rate in the 2000 control period. In order to qualify for early reduction credits, a source will have had to been monitoring according to part 75, subpart H, in the 2000 ozone season to establish a baseline against which the subsequent reductions may be demonstrated. Further, all reductions must be above and beyond any requirement under the Clean Air Act.

*D. What Is the New Source Set-Aside?*

40 CFR Part 96 requires that new sources hold allowances to cover their emissions. EPA maintains that as much as possible within the context of the overall trading budget, allocations should be provided to new sources on the same basis as that used for existing units until the time when the new sources receive an allocation as part of an updating allocation system. In order to provide $NO_X$ allowances to new $NO_X$ Budget units, § 96.42(d) establishes an allocation set-aside account equaling 5 percent of the State trading program budget in 2004 and 2005, and 2 percent thereafter. (However, a state may have any size set-aside, may allocate the set-aside in whatever manner it chooses, and may carry over from one year to the next any amount of allowances.) Authorized account representatives from a new source may request $NO_X$ allowances from the State on a first-come, first-served basis, at an emission rate (0.15 lb/mmBtu for EGUs and 0.17 lb/mmBtu for non-EGUs) multiplied by a budget unit's maximum design heat input and by the hours in the control period starting with the first hour of operation. After the control period, EPA will deduct $NO_X$ allowance based on the unit's actual utilization during the control period. As a result of the deduction, the allocation for the new unit from the set-aside will effectively equal the product of the emission rate and the unit's actual heat input for the control period season. Allowances not issued to new sources in the applicable control period will be returned to the existing sources in the State on a pro-rata basis to guard against the possibility of a disproportionately large set-aside.

Tennessee's SIP provides for New Source Set-asides. For EGUs the allocation set-aside will be allocated $NO_X$ allowances equal to 4.3 percent of the tons of $NO_X$ emissions in the State trading program budget apportioned to EGUs under section 96.40, rounded to the nearest whole $NO_X$ allowance as appropriate. The allocation set-aside for new source growth will be the $NO_X$ allowances remaining in the state trading program budget for non-EGUs after allocations are set for all $NO_X$ budget units. This approach to allocations for new units is acceptable because it falls within the flexibility of the $NO_X$ SIP Call requirements for a state's allocation to new sources.

## III. Proposed Action

EPA is proposing to conditionally approve the Tennessee's SIP revision consisting of its draft $NO_X$ Budget Trading Program, which was submitted on November 7, 2000, with additional material submitted on January 11, 2001, and State-effective rules submitted on October 4, 2001. EPA finds that Tennessee's submittal is approvable with one exception because it meets the requirements of the Phase I $NO_X$ SIP Call.

The exception refers to Section 96.40 State trading program budget. Tennessee revised the model rule at 1200–3–27–.06(1)(f) to allow for the allocation of additional allowances to $NO_X$ budget units that have been generated through $NO_X$ emission reductions from industrial, mobile, and area source sectors. However, Tennessee's rule provides for approval of the allocation of additional allowances solely by the permitting authority, without approval by EPA. Therefore, EPA is proposing to approve Tennessee's $NO_X$ Reduction and Trading Program, including a rule for cement kilns, with the condition that Tennessee correct the deficiencies in Section 96.40 State trading program budget by removing or revising the unapprovable language.

## IV. Administrative Requirements

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this proposed action is not a ''significant regulatory action'' and therefore is not subject to review by the Office of Management and Budget. For this reason, this action is also not subject to Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001). This proposed action merely proposes to approve state law as meeting Federal requirements and imposes no additional requirements beyond those imposed by state law. Accordingly, the Administrator certifies that this proposed rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). Because this rule proposes to approve pre-existing requirements under state law and does not impose any additional enforceable duty beyond that required by state law, it does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Public Law 104–4).

This proposed rule also does not have tribal implications because it will 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, as specified by Executive Order 13175 (65 FR 67249, November 9, 2000). This action also does not have Federalism implications because it does not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). This action merely proposes to approve a state rule implementing a Federal standard, and does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act. This proposed rule also is not subject to Executive Order 13045 ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997), because it is not economically significant.

In reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. In this context, in the absence of a prior existing requirement

for the State to use voluntary consensus standards (VCS), EPA has no authority to disapprove a SIP submission for failure to use VCS. It would thus be inconsistent with applicable law for EPA, when it reviews a SIP submission, to use VCS in place of a SIP submission that otherwise satisfies the provisions of the Clean Air Act. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. This proposed rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

**List of Subjects in 40 CFR Part 52**

Environmental protection, Air pollution control, Carbon monoxide, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

**Authority:** 42 U.S.C. 7401 *et seq.*

Dated: July 30, 2002.

**A. Stanley Meiburg,**

*Acting Regional Administrator, Region 4.*

[FR Doc. 02–20580 Filed 8–13–02; 8:45 am]

**BILLING CODE 6560–50–P**

## ENVIRONMENTAL PROTECTION AGENCY

## 40 CFR Part 300

**[FRL–7257–4]**

## National Oil and Hazardous Substances Pollution Contingency Plan; National Priorities List

**AGENCY:** Environmental Protection Agency.

**ACTION:** Notice of intent to delete Standard Steel and Metals Salvage Yard Site from the National Priorities List.

**SUMMARY:** The Environmental Protection Agency (EPA), Region 10, announces its intent to delete the Standard Steel and Metals Salvage Yard Site (Site) from the National Priorities List (NPL) and requests public comment on this proposed action. The NPL constitutes appendix B of 40 CFR part 300 which is the National Oil and Hazardous Substances Pollution Contingency Plan (NCP), which EPA promulgated pursuant to section 105 of the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) of 1980, as amended. EPA and the State of Alaska Department of Environmental Conservation have determined that the remedial action for the site has been successfully executed by the responsible parties and no further response under CERCLA is needed.

**DATES:** Comments concerning the proposed deletion of this Site from the NPL may be submitted on or before September 14, 2002.

**ADDRESSES:** Comments may be mailed to: Beverly Gaines, EPA Point of Contact, U.S. Environmental Protection Agency, Region 10, 1200 Sixth Avenue, Mail Stop, ECL–110, Seattle, Washington 98101.

Comprehensive information on this Site is available through the Region 10 public docket which is available for reviewing at: U.S. Environmental Protection Agency, Region 10, Superfund Records Center, 1200 Sixth Avenue, Seattle, Washington 98101.

Information on the site and a copy of the deletion docket are available for viewing at the Information Repository which is located at: Alaska Resources Library & Information Services, 3150 C Street, Suite 100, Anchorage, Alaska 99513, (907) 272–7547.

**FOR FURTHER INFORMATION CONTACT:** Beverly Gaines, EPA Point of Contact, U.S. Environmental Protection Agency, Region 10, 1200 Sixth Avenue, Mail Stop, ECL–110, Seattle, Washington 98101, phone: (206) 553–1066, fax: (206) 553–0124, e-mail: gaines.beverly@epa.gov.

**SUPPLEMENTARY INFORMATION:**

**Table of Contents**



### I. Introduction

The U.S. Environmental Protection Agency (EPA) Region 10 announces its intent to delete the Standard Steel and Metals Salvage Yard Site, which is located in Anchorage, Alaska, from the National Priorities List (NPL) and requests public comment on this proposed action. The NPL constitutes appendix B of 40 CFR part 300 which is the National Oil and Hazardous Substances Pollution Contingency Plan (NCP), which EPA promulgated pursuant to section 105 of the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) of 1980, as amended. EPA identifies sites that appear to present a significant risk to public health, welfare, or the environment and maintains the NPL as the list of these sites. EPA and the State of Alaska Department of Environmental Conservation have determined that the remedial action for the site has been successfully executed by the responsible parties and no further response under CERCLA is needed.

EPA will accept comments on the proposal to delete this site for thirty (30) days after publication of this document in the **Federal Register**.

Section II of this document explains the criteria for deleting sites from the NPL. Section III discusses the procedures EPA is using for this action. Section IV discusses the Standard Steel & Salvage Yard Site and explains how the site meets the deletion criteria.

### II. NPL Deletion Criteria

Section 300.425(e) of the NCP provides that sites may be deleted from, or recategorized on the NPL, where no further response is appropriate. In making a determination to delete a site from the NPL, EPA shall consider, in consultation with the State, whether any of the following criteria have been met:

(i) Responsible parties or other parties have implemented all appropriate response actions required; or

(ii) All appropriate Fund-financed responses under CERCLA have been implemented, and no further action by responsible parties is appropriate, or

(iii) The Remedial Investigation has shown that the site poses no significant threat to public health or the environment and, therefore, remedial measures are not appropriate.

Even if a site is deleted from the NPL, where hazardous substances, pollutants or contaminants remain at the site above levels that allow for unlimited use and unrestricted exposure, a subsequent review of the site will be conducted at least every five years after the initiation of the remedial action at the site to ensure that the site remains protective of public health and the environment. If new information becomes available which indicates a need for further action, EPA may initiate additional remedial actions. Whenever there is a significant release from a deleted site from the NPL, the site may be restored to the NPL without application of the Hazard Ranking System.

In the case of this site, the selected remedy is protective of human health and the environment, however, because the remedy leaves waste on site above levels that allow for unlimited use and unrestricted exposure, a review of the selected remedy will be conducted at least every five years from initiation of the remedial action.

### III. Deletion Procedures

The following procedures were used for the intended deletion of this site: (1) Responsible parties have implemented all appropriate response actions

required; (2) the State of Alaska has concurred with the proposed deletion decision; (3) a notice has been published in the local newspapers and has been distributed to appropriate federal, state, and local officials and other interested parties announcing the commencement of a 30-day public comment period on EPA's Notice of Intent to Delete; and (4) all relevant documents have been compiled in the site deletion docket and made available in the local site information repositories.

Deletion of the site from the NPL does not in itself, create, alter or revoke any individual's rights or obligations. The NPL is designed primarily for informational purposes and to assist Agency management. As mentioned in section II of this document, § 300.425(e)(3) of the NCP states that the deletion of a site from the NPL does not preclude eligibility for future response actions.

For deletion of this site, EPA's Regional Office will accept and evaluate public comments on EPA's Notice of Intent to Delete before making a final decision to delete. If necessary, the Agency will prepare a Responsiveness Summary to address any significant public comments received.

A deletion occurs when the Regional Administrator places a final notice in the **Federal Register**. Generally, the NPL will reflect deletions in the final update following the notice. Public notices and copies of the Responsiveness Summary will be made available to local residents by the Regional Office.

**IV. Basis for Intended Site Deletion**

The following site summary provides the Agency's rationale for the proposal to delete this Site from the NPL.

*Site Background and History*

The Standard Steel and Metals Salvage Yard Site was a 6.2 acre metal salvage yard in Anchorage, Alaska. The site is located near the intersection of Railroad Avenue and Yakutat Street, adjacent to Ship Creek. The site is zoned I–2, denoting a heavy industrial district, by the Municipality of Anchorage. The property is in the possession and control of the Alaska Railroad Corporation. The site is located within the City of Anchorage, where the majority of the population of the State of Alaska live. A residential area is located a half mile southeast of the site on the other side of Ship Creek and Elmendorf Air Force Base is a third of a mile to the North.

The first documented use of the site occurred in October 1950, when it was leased by a construction company for maintenance and storage equipment. Beginning in 1955, various metal recycling and salvage business operated at the site. During recycling and salvage activities, electrical transformers and batteries were handled. Releases of hazardous substances occurred from these activities and inappropriate burial or burning of transformer oil.

From 1986 through 1988, EPA conducted a series of removal actions to address widespread contamination. EPA removed 1000 gallons of polychlorinated biphenyls (PCBs) contaminated oil, eighty-two 55 gallon drums of Resource Conservation and Recovery Act (RCRA) hazardous waste, 10,450 gallons of waste oil, 185 PCB-contaminated transformers, and 781,000 pounds of lead acid batteries. EPA proposed the site to the NPL on July 14, 1989. The site was finalized on the NPL on August 30, 1990.

An Remedial Investigation/Feasibility Study was completed in January 1996. The study identified polychlorinated biphenyls (PCBs), lead, and dioxin/furans as contaminants of concern at the site. The site posed potential threats to human health and the environment through ingestion, dermal contact, and inhalation of contaminated soils. Site groundwater was impacted by soil contamination. Off-site groundwater was not impacted. Dioxin/furans were determined to be a contaminant of concern; however, all detections of dioxin/furans were collocated with soils contaminated with 10 mg/kg or greater PCBs. Therefore, all actions taken to address PCBs would also address dioxin/furans.

*Selected Remedy*

On July 16, 1996, the Regional Administrator signed a Record of Decision (ROD) selecting the following remedy:

—Removal of regulated material currently stockpiled on-site and investigation derived wastes with subsequent disposal in a RCRA Subtitle C or D landfill, or recycling of the materials;
—Off-site disposal of remaining scrap debris by recycling or disposal in a RCRA Subtitle D landfill or, if the debris is a characteristic hazardous waste or contains greater than 50 mg/kg PCBs or 10ug/100cm$^2$ PCBs by standard wipe tests, treatment, and disposal in a RCRA Subtitle C or Toxic Substances Control Act (TSCA) landfill;
—Excavation and consolidation of all soils exceeding cleanup levels; the Settling Defendants chose to incorporate cleanup criteria stricter than the Record of Decision for soils within three feet of the surface, namely; 1mg/Kg for PCBs and 250mg/Kg for lead.
—Treatment of all soils at or greater than 1000 mg/kg lead or 50 mg/kg PCB by stabilization/solidification;
—On-site disposal of treated soils and excavated soils between 10 mg/kg and 50 mg/kg PCBs in a TSCA landfill. Certain TSCA landfill requirements were waived subsequent to the remedial action due to design changes. The waivers were consistent with TSCA and were not implemented through CERCLA waiver provisions;
—Excavation of soils impacted above 1.0 mg/kg PCBs and 500 mg/kg lead from the flood plain and consolidation of these soils elsewhere on the site;
—Maintenance and repair of the erosion control structure on the bank of Ship Creek;
—Maintenance of treated soils and the landfill;
—Institutional controls to limit land uses of the site and, if appropriate, access;
—Monitoring of groundwater at the site to ensure the effectiveness of the remedial action.

*Response Actions*

On January 26, 1996, a Consent Decree to conduct a Remedial Action (RA) design and RA construction was entered into by Chugach Electric Association, Inc., J.C. Penney Company, Inc., Bridgestone/Firestone, Inc., Sears Roebuck and Company, and Westinghouse Electric Corporation. The Alaska Railroad Corporation signed the Consent Decree exclusively for the purpose of agreeing to provide access and implement institutional controls. The Settling Defendants agreed to perform the remedial design/remedial action selected in the ROD. The remedial design was conducted in conformance with the approved ROD and Statement of Work for the consent decree. The remedial action was formally initiated in March 1998. The contractor conducted the remedial actions pursuant to the approved remedial design/remedial action work plans. The only significant new contaminant encountered was potential unexploded ordnance. However, the work plans anticipated this possibility and remedial actions proceeded with some changes. All suspected unexploded ordnance was removed and treated by a U.S. Military Explosive Ordnance Detachment from Fort Richardson, Alaska.

The TSCA disposal cell is located on 2.5 acres of the 6.2 acre site along the

northwest boundary of the site. It is approximately 320 feet by 340 feet and extends to a depth of approximately 15 feet below finished grade. The cell holds approximately 55,000 tons of contaminated material, 22,272 of which was stabilized. The contaminated soils are covered with a closed cell foam insulation, 40 mil geomembrane cover, geocomposite drainage layer, and three feet of clean soil. The cell is designed to be utilized for vehicle/equipment storage or future building area. The cell is surrounded on three sides by a 14,000 ton rip rap barrier wall designed to protect against a 500 year (minimum) flood event.

The selected remedy was enhanced by the following approved design changes, which were implemented in 1998 and 1999:

—Excavating all upland surface soils outside the limits of the TSCA landfill which exceed 1.0 mg/Kg PCBs or 250 mg/Kg lead to a depth of three feet; and disposal in the on-site TSCA landfill.
—Including a geomembrane cover system consisting of a four-inch foam insulation layer, 40 mil liner, geonet drainage layer, filter fabric and three feet of clean soil over the landfill;
—Creation of a flood protection barrier on three sides of the landfill;
—Replacement of the rip rap erosion control wall adjacent to Ship Creek with an Alaska Department of Fish and Game requested natural erosion protection system. This system incorporates native vegetation and artificial logs to secure the stream bank and provide habitat. Based on these changes, an Explanation of Significant Differences was signed on November 18, 1998 to waive 40 CFR 761.75(b)(9)(i), which requires a fence around a TSCA landfill. A Remedial Action Report was signed on August 1, 1999 and a Final Closeout Report was signed on June 26, 2002 which documents that all work at the site has been completed and all cleanup levels established in the ROD have been achieved.

*Operation and Maintenance*

Pursuant to the Consent Decree, Chugach Electric Association, Inc., Westinghouse Electric Corporation, Sears, Roebuck and Company, J. C. Penney Company, Inc., and Bridgestone/Firestone, Inc. are responsible for the operation and maintenance procedures. The remedy requires maintenance of the landfill to ensure that it retains its structural integrity and prevents the release of PCBs and lead through erosion, leaching, and excavation. The Operation and Maintenance requirements are presented in the Operations and Maintenance Plan (revised) July 2001 by Alta GeoSciences, Inc. Operation and maintenance has been happening properly, with the exception of damage to an up gradient well. EPA was notified of the damage and the well was restored.

*Institutional Controls*

The Site has institutional controls in place to restrict access, prevent use of groundwater, and land use on the property. The Alaska Railroad Corporation (ARRC) is the owner of an exclusive license to the property under the Alaska Railroad Transfer Act. ARRC executed and filed the Declaration of Restrictive Covenants per the Consent Decree requirements with the local land recording district office in Anchorage. ARRC's lease agreements for the property notify the lessee of the Institutional Controls which must be complied with. Additionally, notice of the remedy and the Declaration of Restrictive Covenants was provided to applicable state and local government agencies and all local utility companies.

The Institutional Controls contained in the RD/RA Consent Decree, Record of Decision and recorded through a Declaration of Restrictive Covenants are:

—Ensure that site use continues to be industrial or commercial and prevent use of the site for commercial developments that involve potential chronic exposures of children to soil (*e.g.*, use of the site for a day care center);
—Restrict activities at the site that could potentially impair the integrity of the TSCA landfill;
—Prevent movement of soil containing greater than 1,000 mg/kg lead or 10mg/kg PCBs to the surface or within the top foot of soil where chronic long-term worker exposure could occur;
—Groundwater use restriction recorded with local, regional, and State agencies, departments and utilities.

*Five-Year Review*

Hazardous substances will remain at the site above levels that allow unlimited use and unrestricted exposure after the completion of the remedial action. Pursuant to CERCLA section 121(c) and provided in the current guidance on Five-Year Reviews, EPA must conduct a statutory five-year review to ensure that the remedy continues to provide adequate protection of human health and the environment. The Five-Year Review Report will be completed prior to March 2003.

*Community Involvement*

EPA held four public meetings, issued five fact sheets and published three public comment periods in the **Federal Register**. The meetings and fact sheets focused on CERCLA-required comment periods, informational meetings, publications of previous cleanup actions, enforcement actions, alternative analysis or schedule announcements, and public involvement sessions. There was not much public involvement at this site.

*Applicable Deletion Criteria*

One of the three criteria for deletion specifies that EPA may delete a site from the NPL if ''responsible parties have implemented all appropriate response actions required.'' EPA, with the concurrence of the State of Alaska, believe that this criterion for deletion has been met. There is no significant threat to human health or the environment and; therefore, no further remedial action is necessary. Subsequently, EPA is proposing deletion of this site from the NPL. Documents supporting this action are available in the deletion docket at the information repositories.

*State Concurrence*

In a letter dated July 24, 2002, from the Alaska Department of Environmental Conservation (ADEC), ADEC concurs with the proposed deletion of the Standard Steel and Metals Salvage Yard Superfund Site from the NPL.

Dated: August 2, 2002.

**L. John Iani,**

*Regional Administrator, Region 10.*

[FR Doc. 02–20351 Filed 8–13–02; 8:45 am]

**BILLING CODE 6560–50–P**

## FEDERAL COMMUNICATIONS COMMISSION

### 47 CFR Part 73

**[DA 02–1913, MM Docket No. 01–44, RM–10022]**

### Digital Television Broadcast Service; Derby, KS

**AGENCY:** Federal Communications Commission.

**ACTION:** Proposed rule.

**SUMMARY:** The Commission requests comments on a petition filed by Pappas Telecasting of America proposing the allotment of DTV channel 46 to Derby, Kansas. DTV Channel 46 can be allotted to Derby, Kansas at reference coordinates 37–54–12 N. and 97–37–06

W. with a power of 1000, a height above average terrain HAAT of 246 meters.

**DATES:** Comments must be filed on or before September 30, 2002, and reply comments on or before October 15, 2002.

**ADDRESSES:** The Commission permits the electronic filing of all pleadings and comments in proceeding involving petitions for rule making (except in broadcast allotment proceedings). *See Electronic Filing of Documents in Rule Making Proceedings,* GC Docket No. 97–113 (rel. April 6, 1998). Filings by paper 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, Office of the Secretary, Federal Communications Commission, Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve the petitioner, or its counsel or consultant, as follows: Vincent J. Curtis, Jr. Fletcher, Heald & Hildreth, PLC, 1300 North 17th Street, Eleventh Floor, Arlington, Virginia 22209 (Counsel for Pappas Telecasting of America).

**FOR FURTHER INFORMATION CONTACT:** Pam Blumenthal, Media Bureau, (202) 418–1600.

**SUPPLEMENTARY INFORMATION:** This is a synopsis of the Commission's Further Notice of Proposed Rule Making, MM Docket No. 01–44, adopted August 2, 2002, and released August 9, 2002. The full text of this document is available for public inspection and copying during regular 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.*

Provisions of the Regulatory Flexibility Act of 1980 do not apply to this proceeding.

Members of the public should note that from the time a Notice of Proposed Rule Making is issued until the matter is no longer subject to Commission consideration or court review, all *ex parte* contacts are prohibited in Commission proceedings, such as this one, which involve channel allotments. See 47 CFR 1.1204(b) for rules governing permissible *ex parte* contacts.

For information regarding proper filing procedures for comments, see 47 CFR 1.415 and 1.420.

**List of Subjects in 47 CFR Part 73**

Digital television broadcasting, Television.

For the reasons discussed in the preamble, the Federal Communications Commission proposes to amend 47 CFR Part 73 as follows:

## PART 73—RADIO BROADCAST SERVICES

1. The authority citation for part 73 continues to read as follows:

**Authority:** 47 U.S.C. 154, 303, 334 and 336.

**§ 73.622 [Amended]**

2. Section 73.622(b), the Table of Digital Television Allotments under Kansas is amended by adding Georgetown, DTV channel 46.

Federal Communications Commission.

**Barbara A. Kreisman,**

*Chief, Video Division, Media Bureau.*

[FR Doc. 02–20592 Filed 8–13–02; 8:45 am]

BILLING CODE 6712–01–P

## FEDERAL COMMUNICATIONS COMMISSION

### 47 CFR Part 73

**[DA 02–1901, MB Docket No. 02–220, RM–10518]**

### Digital Television Broadcast Service; Christiansted, VI

**AGENCY:** Federal Communications Commission.

**ACTION:** Proposed rule.

**SUMMARY:** The Commission requests comments on a petition filed by Virgin Blue, Inc., licensee of station WCVI-TV, Christiansted, Virgin Islands, requesting the substitution of DTV channel 23 for DTV channel 5. DTV Channel 23 can be allotted to at reference coordinates 17–44–40 N. and 64–43–40 W. with a power of 0.85, a height above average terrain (HAAT) of 130 meters.

**DATES:** Comments must be filed on or before September 30, 2002, and reply comments on or before October 15, 2002.

**ADDRESSES:** The Commission permits the electronic filing of all pleadings and comments in proceeding involving petitions for rule making (*except in broadcast allotment proceedings*). *See Electronic Filing of Documents in Rule Making Proceedings,* GC Docket No. 97–113 (rel. April 6, 1998). Filings by paper 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 8:00 a.m. to 7:00 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, Office of the Secretary, Federal Communications Commission, Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve the petitioner, or its counsel or consultant, as follows: Victor A. Gold, President, WCVI-TV, P.O. Box 24027, Christiansted, Virgin Islands (Petitioner).

**FOR FURTHER INFORMATION CONTACT:** Pam Blumenthal, Media Bureau, (202) 418–1600.

**SUPPLEMENTARY INFORMATION:** This is a synopsis of the Commission's Notice of Proposed Rule Making, MB Docket No. 02–220, adopted August 2, 2002, and released August 9, 2002. The full text of this document is available for public inspection and copying during regular 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.*

Provisions of the Regulatory Flexibility Act of 1980 do not apply to this proceeding.

Members of the public should note that from the time a Notice of Proposed Rule Making is issued until the matter is no longer subject to Commission consideration or court review, all *ex parte* contacts are prohibited in Commission proceedings, such as this one, which involve channel allotments. See 47 CFR 1.1204(b) for rules governing permissible *ex parte* contacts.

For information regarding proper filing procedures for comments, see 47 CFR 1.415 and 1.420.

**List of Subjects in 47 CFR Part 73**

Digital television broadcasting, Television.

For the reasons discussed in the preamble, the Federal Communications Commission proposes to amend 47 CFR Part 73 as follows:

## PART 73—RADIO BROADCAST SERVICES

1. The authority citation for part 73 continues to read as follows:

**Authority:** 47 U.S.C. 154, 303, 334 and 336.

**§ 73.622 [Amended]**

2. Section 73.622(b), the Table of Digital Television Allotments under Virgin Islands is amended by removing DTV channel 5 and adding DTV channel 23 at Christiansted.

Federal Communications Commission.

**Barbara A. Kreisman,**

*Chief, Video Division, Media Bureau.*

[FR Doc. 02–20602 Filed 8–13–02; 8:45 am]

**BILLING CODE 6712–01–P**

## FEDERAL COMMUNICATIONS COMMISSION

### 47 CFR Part 73

**[DA 02–1900, MB Docket No. 02–221, RM–10519]**

### Digital Television Broadcast Service; Wailuku, HI

**AGENCY:** Federal Communications Commission.

**ACTION:** Proposed rule.

**SUMMARY:** The Commission requests comments on a petition filed by LeSea Broadcasting Corporation, licensee of station KWHM(TV), Wailuku, Hawaii, requesting the substitution of DTV channel 45 for station KWHM(TV)'s assigned DTV channel 20. DTV Channel 20 can be allotted to Wailuku at reference coordinates 20–40–58 N. and 156–19–07 W. with a power of 87, a height above average terrain HAAT of 1298 meters.

**DATES:** Comments must be filed on or before September 30, 2002, and reply comments on or before October 15, 2002.

**ADDRESSES:** The Commission permits the electronic filing of all pleadings and comments in proceeding involving petitions for rule making (except in broadcast allotment proceedings). *See Electronic Filing of Documents in Rule Making Proceedings*, GC Docket No. 97–113 (rel. April 6, 1998). Filings by paper 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, Office of the Secretary, Federal Communications Commission, Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve the petitioner, or its counsel or consultant, as follows: Joseph C. Chautin, III, Hardy, Carey & Chautin, LLP, 110 Veterans Boulevard, Suite 300, Metairie, Louisiana 70005, (Counsel for LeSea Broadcasting Corporation).

**FOR FURTHER INFORMATION CONTACT:** Pam Blumenthal, Media Bureau, (202) 418–1600.

**SUPPLEMENTARY INFORMATION:** This is a synopsis of the Commission's Notice of Proposed Rule Making, MB Docket No. 02–221, adopted August 2, 2002, and released August 9, 2002. The full text of this document is available for public inspection and copying during regular 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.*

Provisions of the Regulatory Flexibility Act of 1980 do not apply to this proceeding.

Members of the public should note that from the time a Notice of Proposed Rule Making is issued until the matter is no longer subject to Commission consideration or court review, all *ex parte* contacts are prohibited in Commission proceedings, such as this one, which involve channel allotments. *See* 47 CFR 1.1204(b) for rules governing permissible *ex parte* contacts.

For information regarding proper filing procedures for comments, *see* 47 CFR 1.415 and 1.420.

**List of Subjects in 47 CFR Part 73**

Digital television broadcasting, Television.

For the reasons discussed in the preamble, the Federal Communications Commission proposes to amend 47 CFR part 73 as follows:

## PART 73—RADIO BROADCAST SERVICES

1. The authority citation for part 73 continues to read as follows:

**Authority:** 47 U.S.C. 154, 303, 334 and 336.

**§ 73.622 [Amended]**

2. Section 73.622(b), the Table of Digital Television Allotments under Hawaii is amended by removing DTV channel 20 and adding DTV channel 45 at Wailuku.

Federal Communications Commission

**Barbara A. Kreisman,**

*Chief, Video Division, Media Bureau.*

[FR Doc. 02–20603 Filed 8–13–02; 8:45 am]

**BILLING CODE 6712–01–P**

## FEDERAL COMMUNICATIONS COMMISSION

### 47 CFR Part 73

**[DA 02–1897, MB Docket No. 02–219, RM–10506]**

### Digital Television Broadcast Service; Lawton, OK

**AGENCY:** Federal Communications Commission.

**ACTION:** Proposed rule.

**SUMMARY:** The Commission requests comments on a petition filed by KSWO Television Company, Inc., licensee of station KSWO–TV, Lawton, Oklahoma, requesting the substitution of DTV channel 11 for station KSWO–TV's assigned DTV channel 23. DTV Channel 11 can be allotted to Lawton at reference coordinates 34–12–55 N. and 98–43–13 W. with a power of 138, a height above average terrain (HAAT) of 327 meters.

**DATES:** Comments must be filed on or before September 30, 2002, and reply comments on or before October 15, 2002.

**ADDRESSES:** The Commission permits the electronic filing of all pleadings and comments in proceeding involving petitions for rule making (*except in broadcast allotment proceedings*). *See Electronic Filing of Documents in Rule Making Proceedings*, GC Docket No. 97–113 (rel. April 6, 1998). Filings by paper 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, Office of the Secretary, Federal Communications Commission, Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve the petitioner, or its counsel or consultant, as follows: David D. Oxenford, Shaw Pittman LLP, 2300 N Street, NW., Washington, DC 20037–1128 (Counsel for KSWO Television Company, Inc.).

**FOR FURTHER INFORMATION CONTACT:** Pam Blumenthal, Media Bureau, (202) 418–1600.

**SUPPLEMENTARY INFORMATION:** This is a synopsis of the Commission's Notice of Proposed Rule Making, MB Docket No. 02–219, adopted August 2, 2002, and released August 9, 2002. The full text of this document is available for public inspection and copying during regular 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*.

Provisions of the Regulatory Flexibility Act of 1980 do not apply to this proceeding.

Members of the public should note that from the time a Notice of Proposed Rule Making is issued until the matter is no longer subject to Commission consideration or court review, all *ex parte* contacts are prohibited in Commission proceedings, such as this one, which involve channel allotments. See 47 CFR 1.1204(b) for rules governing permissible *ex parte* contacts.

For information regarding proper filing procedures for comments, see 47 CFR 1.415 and 1.420.

**List of Subjects in 47 CFR Part 73**

Digital television broadcasting, Television.

For the reasons discussed in the preamble, the Federal Communications Commission proposes to amend 47 CFR Part 73 as follows:

## PART 73—RADIO BROADCAST SERVICES

1. The authority citation for part 73 continues to read as follows:

**Authority:** 47 U.S.C. 154, 303, 334 and 336.

**§ 73.622 [Amended]**

2. Section 73.622(b), the Table of Digital Television Allotments under Oklahoma is amended by removing DTV channel 23 and adding DTV channel 11 at Lawton.

Federal Communications Commission.

**Barbara A. Kreisman,**

*Chief, Video Division, Media Bureau.*

[FR Doc. 02–20604 Filed 8–13–02; 8:45 am]

BILLING CODE 6712–01–U

## FEDERAL COMMUNICATIONS COMMISSION

### 47 CFR Part 73

**[DA 02–1912, MB Docket No. 02–222, RM–10491]**

### Digital Television Broadcast Service; Spokane, WA

**AGENCY:** Federal Communications Commission.

**ACTION:** Proposed rule.

**SUMMARY:** The Commission requests comments on a petition filed by KSKN Television, Inc., licensee of station KSKN–TV, NTSC channel 22, Spokane, Washington, proposing the substitution of DTV channel 48 for station KSKN–TV's assigned DTV channel 36. DTV Channel 48 can be allotted to at reference coordinates 47–35–41 N. and 117–17–53 W. With a power of 1000, a height above average terrain HAAT of 596 meters. Since the community of Spokane is located within 400 kilometers of the U.S.-Canadian border, concurrence from the Canadian must be obtained for this allotment.

**DATES:** Comments must be filed on or before September 30, 2002, and reply comments on or before October 15, 2002.

**ADDRESSES:** The Commission permits the electronic filing of all pleadings and comments in proceeding involving petitions for rule making (*except in broadcast allotment proceedings*). *See Electronic Filing of Documents in Rule Making Proceedings*, GC Docket No. 97–113 (rel. April 6, 1998). Filings by paper 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, Office of the Secretary, Federal Communications Commission, Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve the petitioner, or its counsel or consultant, as follows: James R. Bayes, Wiley, Rein & Fielding LLP, 1776 K Street, NW, Washington, DC 20006 (Counsel for KSKN Television, Inc.).

**FOR FURTHER INFORMATION CONTACT:** Pam Blumenthal, Media Bureau, (202) 418–1600.

**SUPPLEMENTARY INFORMATION:** This is a synopsis of the Commission's Notice of Proposed Rule Making, MB Docket No. 02–222, adopted August 2, 2002, and released August 9, 2002. The full text of this document is available for public inspection and copying during regular 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*.

Provisions of the Regulatory Flexibility Act of 1980 do not apply to this proceeding.

Members of the public should note that from the time a Notice of Proposed Rule Making is issued until the matter is no longer subject to Commission consideration or court review, all *ex parte* contacts are prohibited in Commission proceedings, such as this one, which involve channel allotments. See 47 CFR 1.1204(b) for rules governing permissible *ex parte* contacts.

For information regarding proper filing procedures for comments, see 47 CFR 1.415 and 1.420.

**List of Subjects in 47 CFR Part 73**

Digital television broadcasting, Television.

For the reasons discussed in the preamble, the Federal Communications Commission proposes to amend 47 CFR part 73 as follows:

## PART 73—RADIO BROADCAST SERVICES

1. The authority citation for part 73 continues to read as follows:

**Authority:** 47 U.S.C. 154, 303, 334 and 336.

**§ 73.622 [Amended]**

2. Section 73.622(b), the Table of Digital Television Allotments under Washington is amended by removing DTV channel 36 and adding DTV channel 48 at Spokane.

Federal Communications Commission

**Barbara A. Kreisman,**

*Chief, Video Division, Media Bureau.*

[FR Doc. 02–20605 Filed 8–13–02; 8:45 am]

**BILLING CODE 6712–01–U**

## FEDERAL COMMUNICATIONS COMMISSION

### 47 CFR Part 73

**[DA 02–1874; MB Docket No. 02–209, RM–10512; MB Docket No. 02–210, RM–10510; MB Docket No. 02–211, RM–10511]**

### Radio Broadcasting Services; Greenwood, MS; Hyannis, NE; and Wall, SD

**AGENCY:** Federal Communications Commission.

**ACTION:** Proposed rule.

**SUMMARY:** This document proposes three new allotments in Greenwood, Mississippi, Hyannis Nebraska, and Wall, South Dakota. The Audio Division requests comment on a petition filed by David P. Garland proposing the allotment of Channel 277A at Greenwood, Mississippi, as the community's fourth local aural transmission service. Channel 277A can be allotted to Greenwood in compliance with the Commission's minimum distance separation requirements with a site restriction of 10.1 kilometers (6.3 miles) east to avoid a short-spacing to an application site of Station KZYQ, Channel 278C2, Lake Village, Arkansas. The coordinates for Channel 277A at Greenwood are 33–32–19 North Latitude and 90–04–27 West Longitude. *See* Supplementary Information, *infra.*

**DATES:** Comments must be filed on or before September 23, 2002, and reply comments on or before October 8, 2002.

**ADDRESSES:** Federal Communications Commission, 445 Twelfth Street, SW., Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve the petitioner, his counsel, or consultant, as follows: David P. Garland, 1110 Hackney Street, Houston, Texas, 77023 (petitioner); John M. Pelkey, Garvey, Schubert & Barer, 5th Floor, 1000 Potomac Street, NW., Washington, DC 20007 (Counsel for Grant County Broadcasters and Wall Radio Broadcasters).

**FOR FURTHER INFORMATION CONTACT:** Rolanda F. Smith, Media Bureau, (202) 418–2180.

**SUPPLEMENTARY INFORMATION:** This is a synopsis of the Commission's Notice of Proposed Rule Making, MB Docket Nos. 02–209, 02–210, and 02–211, adopted July 24, 2002, and released August 2, 2002. The full text of this Commission decision is available for inspection and copying during regular business hours at the FCC's Reference Information Center, Portals II, 445 Twelfth Street, SW., Room CY–A257, Washington, DC 20554. The complete text of this decision 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.*

The Audio Division requests comments on a petition filed by Grant County Broadcasters proposing the allotment of Channel 250C1 at Hyannis, Nebraska, as the community's first local aural transmission service. Channel 250C1 can be allotted to Hyannis in compliance with the Commission's minimum distance separation requirements at city reference coordinates. The coordinates for Channel 250C1 at Hyannis are 42–00–02 North Latitude and 101–45–41 West Longitude.

The Audio Division requests comments on a petition filed by Wall Radio Broadcasters proposing the allotment of Channel 288C at Wall, South Dakota, as the community's first local aural transmission service. Channel 288C can be allotted to Wall in compliance with the Commission's minimum distance separation requirements at city reference coordinates.

The coordinates for Channel 288C at Wall are 43–59–47 North Latitude and 102–13–07 West Longitude.

Provisions of the Regulatory Flexibility Act of l980 do not apply to this proceeding.

Members of the public should note that from the time a Notice of Proposed Rule Making is issued until the matter is no longer subject to Commission consideration or court review, all *ex parte* contacts are prohibited in Commission proceedings, such as this one, which involve channel allotments. See 47 CFR 1.1204(b) for rules governing permissible *ex parte* contact.

For information regarding proper filing procedures for comments, see 47 CFR 1.415 and 1.420.

**List of Subjects in 47 CFR Part 73**

Radio, Radio broadcasting.

For the reasons discussed in the preamble, the Federal Communications Commission proposes to amend 47 CFR Part 73 as follows:

## PART 73—RADIO BROADCAST SERVICES

1. The authority citation for part 73 continues to read as follows:

**Authority:** 47 U.S.C. 154, 303, 334 and 336.

**§ 73.202 [Amended]**

2. Section 73.202(b), the Table of FM Allotments under Mississippi, is amended by adding Channel 277A at Greenwood.

3. Section 73.202(b), the Table of FM Allotments under Nebraska, is amended by adding Hyannis, Channel 250C1.

4. Section 73.202(b), the Table of FM Allotments under South Dakota, is amended by adding Wall, Channel 288C.

Federal Communications Commission.

**John A. Karousos,**

*Assistant Chief, Audio Division, Media Bureau.*

[FR Doc. 02–20594 Filed 8–13–02; 8:45 am]

**BILLING CODE 6712–01–P**

## FEDERAL COMMUNICATIONS COMMISSION

### 47 CFR Part 73

**[DA 02–1805; MB Docket No. 02–197; RM–10509]**

### Radio Broadcasting Services; Bishopville and Lamar, SC

**AGENCY:** Federal Communications Commission.

**ACTION:** Proposed rule.

**SUMMARY:** This document requests comments on a petition for rule making filed on behalf of Miller Communications, Inc., licensee of Station WKHT(FM), Channel 229A, Bishopville, South Carolina, requesting the reallotment of Channel 229A from Bishopville to Lamar, South Carolina, and modification of its authorization accordingly, pursuant to the provisions of section 1.420(i) of the Commission's Rules. The coordinates for requested Channel 229A at Lamar, South Carolina, are 34–07–10 NL and 80–08–49 WL.

Petitioner's reallotment proposal complies with the provisions of section 1.420(i) of the Commission's Rules, and therefore, the Commission will not accept competing expressions of interest in the use of Channel 229A at Lamar, South Carolina, or require the petitioner to demonstrate the availability of an additional equivalent class channel.

**DATES:** Comments must be filed on or before September 23, 2002, and reply comments on or before October 8, 2002.

**ADDRESSES:** Secretary, Federal Communications Commission, 445 12th Street, SW., Room TW–A325, Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve the petitioner's counsel, as follows: Gary S. Smithwick, Esq., Smithwick & Belendiuk, P.C.; 5028 Wisconsin Avenue, NW., Suite 301; Washington, DC 20016.

**FOR FURTHER INFORMATION CONTACT:** R. Barthen Gorman, Media Bureau, (202) 418–2180.

**SUPPLEMENTARY INFORMATION:** This is a synopsis of the Commission's Notice of Proposed Rule Making, MB Docket No. 02–197, adopted July 17, 2002, and released August 2, 2002. The full text of this Commission decision is available for inspection and copying during regular business hours in the FCC's Reference Information Center at Portals II, 445 12th Street, SW., CY–A257, Washington, DC, 20554. This document may also be purchased from the Commission's duplicating contractors, 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.*

The provisions of the Regulatory Flexibility Act of 1980 do not apply to this proceeding.

Members of the public should note that from the time a Notice of Proposed Rule Making is issued until the matter is no longer subject to Commission consideration or court review, all *ex parte* contacts are prohibited in Commission proceedings, such as this one, which involve channel allotments. *See* 47 CFR 1.1204(b) for rules governing permissible *ex parte* contacts.

For information regarding proper filing procedures for comments, *See* 47 CFR 1.415 and 1.420.

**List of Subjects in 47 CFR Part 73**

Radio, Radio broadcasting.

For the reasons discussed in the preamble, the Federal Communications Commission proposes to amend 47 CFR Part 73 as follows:

## PART 73—RADIO BROADCAST SERVICES

1. The authority citation for Part 73 continues to read as follows:

**Authority:** 47 U.S.C. 154, 303, 334 and 336.

**§ 73.202 [Amended]**

2. Section 73.202(b), the Table of FM Allotments under South Carolina, is amended by adding Lamar, Channel 229A, and removing Bishopville, Channel 229A.

Federal Communications Commission.

**John A. Karousos,**

*Assistant Chief, Audio Division, Media Bureau.*

[FR Doc. 02–20595 Filed 8–13–02; 8:45 am]

**BILLING CODE 6712–01–P**

## FEDERAL COMMUNICATIONS COMMISSION

### 47 CFR Part 73

**[DA 02–1873; MB Docket No. 02–208; RM–10515]**

### Radio Broadcasting Services; Buttonwillow, CA

**AGENCY:** Federal Communications Commission.

**ACTION:** Proposed rule.

**SUMMARY:** This document requests comments on a petition filed by Dangerous Broadcasting, L.P., II proposing the allotment of Channel 265A at Buttonwillow, California, as that community's first local FM service. The coordinates for Channel 265A at Buttonwillow are 35–23–56 and 119–29–52. There is a site restriction 2.5 kilometers (1.6 miles) west of the community to avoid a short-spacing to a license site of Station KGFM, Channel 268B, Bakersfield, CA.

**DATES:** Comments must be filed on or before September 23, 2002, and reply comments on or before October 8, 2002.

**ADDRESSES:** Federal Communications Commission, 445 Twelfth Street, SW., Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve the petitioner, as follows: Dangerous Broadcasting, L.P., II, c/o John J. McVeigh, Attorney at Law, 12101 Blue Paper Trail, Columbia, Maryland, 21044–2787.

**FOR FURTHER INFORMATION CONTACT:** Rolanda F. Smith, Media Bureau, (202) 418–2180.

**SUPPLEMENTARY INFORMATION:** This is a summary of the Commission's Notice of Proposed Rule Making, MB Docket No. 02–208, adopted July 24 , 2002, and released August 2, 2002. The full text of this Commission decision is available for inspection and copying during normal business hours in the Commission's Reference Center, 445 Twelfth Street, SW., Washington, DC 20554 (CY–A257). The complete text of this decision 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.*

Provisions of the Regulatory Flexibility Act of l980 do not apply to this proceeding.

Members of the public should note that from the time a Notice of Proposed Rule Making is issued until the matter is no longer subject to Commission consideration or court review, all *ex parte* contacts are prohibited in Commission proceedings, such as this one, which involve channel allotments. See 47 CFR 1.1204(b) for rules governing permissible *ex parte* contact.

For information regarding proper filing procedures for comments, see 47 CFR 1.415 and 1.420.

**List of Subjects in 47 CFR Part 73**

Radio, Radio broadcasting.

For the reasons discussed in the preamble, the Federal Communications Commission proposes to amend 47 CFR part 73 as follows:

## PART 73—RADIO BROADCAST SERVICES

1.The authority citation for part 73 continues to read as follows:

**Authority:** 47 U.S.C. 154, 303, 334 and 336.

**§ 73.202 [Amended]**

2. Section 73.202(b), the Table of FM Allotments under California, is amended by adding Buttonwillow, Channel 265A.

Federal Communications Commission.

**John A. Karousos,**

*Assistant Chief, Audio Division, Media Bureau.*

[FR Doc. 02–20598 Filed 8–13–02; 8:45 am]

**BILLING CODE 6712–01–P**

## DEPARTMENT OF COMMERCE

## National Oceanic and Atmospheric Administration

## 50 CFR Part 600

**[I.D. 073002C]**

## Magnuson-Stevens Act Provisions; General Provisions for Domestic Fisheries; Application for Exempted Fishing Permits (EFPs)

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

**ACTION:** Notification of a proposal for EFPs to conduct experimental fishing; request for comments.

**SUMMARY:** The Administrator, Northeast Region, NMFS (Regional Administrator) has made a preliminary determination that the subject exempted fishing permit (EFP) application contains all the required information and warrants further consideration. The Regional Administrator has also made a preliminary determination that the activities authorized under the EFP would be consistent with the goals and objectives of the Northeast Multispecies Fishery Management Plan (FMP). However, further review and consultation may be necessary before a final determination is made to issue the EFP. Therefore, NMFS announces that the Regional Administrator proposes to issue an EFP that would allow one vessel to conduct fishing operations that are otherwise restricted by the regulations governing the fisheries of the Northeastern United States. The EFP would allow for exemptions from the Gulf of Maine (GOM) cod landing exemption certificate requirement for vessels fishing in the Georges Bank Regulated Mesh Area (GB RMA); the landing and possession limit restriction for GB cod; the requirement to possess on board an exemption certificate to fish for, possess, or land yellowtail flounder, minimum mesh size requirements for the GB RMA and minimum fish size requirements specified for the temporary retention of undersized fish for data collection purposes.

Regulations under the Magnuson-Stevens Fishery Conservation and Management Act require publication of this notification to provide interested parties the opportunity to comment on applications for proposed EFPs.

**DATES:** Comments on this document must be received on or before August 29, 2002.

**ADDRESSES:** Written comments should be sent to Patricia A. Kurkul, Regional Administrator, National Marine Fisheries Service, Northeast Regional Office, 1 Blackburn Drive, Gloucester, MA 01930. Mark the outside of the envelope ''Comments on URI Large Codend Mesh Size Selectivity EFP Proposal.'' Comments may also be sent via facsimile (fax) to (978) 281–9135.

**FOR FURTHER INFORMATION CONTACT:** Bonnie L. Van Pelt, Fishery Policy Analyst, 978–281–9244.

**SUPPLEMENTARY INFORMATION:** An application for an EFP was submitted by URI on June 18, 2002, with a final submission on June 24, 2002. The EFP would facilitate the collection of data on mesh sizes and shapes that are the same or larger than those currently required by regulation to provide mesh size selectivity curves for commercially important groundfish species. These data would be used to conduct YPR and SSBPR analyses to determine optimal yields (overall and per recruit) for each species targeted by the larger mesh sizes, including 6.5-, 7.0-, and 8.0–inch square and diamond shaped (16.5, 17.8, and 20.3 cm, respectively) mesh codends. The results of the study would be presented to resource managers (New England Fisheries Management Council, NMFS, state agencies, and others) and fishers in various fora, as requested, and allow these groups to evaluate the potential conservation equivalencies resulting from increases in codend mesh size.

The EFP would cover the period September 1, 2002, through December 31, 2002; however, the field sampling portion of the mesh selectivity study would require 15 days at sea on board one commercial fishing vessel. The experiment proposes to conduct mesh selectivity studies with current minimum mesh sizes/shapes, as well as larger mesh size codends to develop selectivity curves for four species of regulated groundfish, including Atlantic cod, haddock, winter flounder, and yellowtail flounder on GB. This information would be integrated into yield per recruit (YPR) and spawning stock biomass per recruit (SSBPR) analyses to determine whether incremental increases in mesh size could reduce growth overfishing and improve percent spawning stock biomass. That is, the study would attempt to determine if increasing mesh size would decrease fishing mortality on younger-aged fish in the stock and increase the number of age classes in the stock for greater overall yields of commercially important Northeast (NE) multispecies. While these yields may not be realized immediately, the experiment proposes to conduct an outreach program to educate fisheries managers and fishers on the benefits and costs associated with increasing mesh size based on the results of industry-cooperative mesh selectivity studies in the region. The EFP would allow these exemptions for one commercial vessel, for not more than 15 days of sea trials. All experimental work would be monitored by University of Rhode Island (URI) scientists/observers.

The experimental tows would be conducted by alternating ''experimental'' mesh sizes (i.e., mesh size larger than that currently regulated under the FMP and mesh sizes that are currently in use), with small mesh control codends (3–inch (7.62 cm)) within the GB RMA. The experimental protocol would require 9 tows of 2 hour duration per day, thus including the 6 experimental codends and 3 control codends in a randomly selected sequence for 15 days of sea trials (roughly 60 experimental tows

required). The anticipated bycatch of regulated species incidental to the catch of target species retained by all experimental codends (6 tows per day) is expected to be minimal. For those control tows using small mesh (3 per tows day) the proposal estimated a 50% discard rate of sub-legal size fish. Total catch rates were estimated at 10,000 lb (4,536 kg) per day, of which 2,000–4,000 lb (907–1814 kg) would be discarded and 6,000–8,000 lb (2722–3629 kg) would be retained. The percent composition of species in the total catch, including discards is 30% Atlantic cod (3,000 lb (1361 kg) per day total catch), 30% winter flounder (3,000 lb (1361 kg) per day total catch), 20% yellowtail flounder (2,000 lb (907 kg) per day total catch), and 20% haddock (2,000 lb (907 kg) per day total catch).

The participating vessel would be required to report all regulated species catch retained for commercial sale in its Vessel Trip Report. During the sea trial phase each data collection trip would have a URI sea sampler/scientist on board and the catch would be measured according to NMFS sea sampling methodology and recorded on NMFS logbooks. Any sub-legal sized fish would be processed by the sea samplers (e.g., measured and recorded) and returned immediately to the water. The results of the analysis phase would be summarized in a report that presents selectivity curves for each species according to mesh size and shape, and the results of the YPR and SSBPR analyses including isopleth diagrams. The collection of mesh size selectivity data for mesh sizes at or above the current minimum is expected to increase our understanding of factors that may effect sustainable stock production due to growth overfishing and the potential to increase spawning stock biomass.

An exemption from the requirement to carry an exemption certificate to fish for, possess, and land NE multispecies that are harvested from the GB RMA (i.e., Atlantic cod and yellowtail flounder) is necessary because the work may involve exceeding the applicable landing and/or possession limit restrictions for these species. The applicant has justified the number of trips (i.e., the level of catch) in terms of a target sample size that if not reached may not yield meaningful results. The Regional Administrator is seeking comments on this aspect of the request.

The EFP would exempt one federally permitted commercial fishing vessel from certain requirements of the NE Multispecies FMP. Specifically, the vessel would be exempt from the requirement to carry a GOM cod exemption certificate to fish for, possess, and land cod in excess of the GOM cod landing limits while fishing in the GB RMA, the GB cod landing and possession limit restrictions (50 CFR 648.86(b)(2)), the requirement to possess on board an exemption certificate to fish for, possess, or land yellowtail flounder in the GB RMA (50 CFR 648.86(h)(1)(i)), to temporarily possess regulated species less than the minimum fish size, and to fish with mesh less than the minimum mesh size specified at 50 CFR part 648, subpart F.

Based on the results of this EFP, this action may lead to future rulemaking.

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

Dated: August 8, 2002.

**Virginia M. Fay,**

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

[FR Doc. 02–20652 Filed 8–13–02; 8:45 am]

**BILLING CODE 3510–22–S**

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

### 50 CFR Part 600

**[I.D. 080502B]**

### Magnuson-Stevens Act Provisions; General Provisions for Domestic Fisheries; Application for Exempted Fishing Permits (EFPs)

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

**ACTION:** Notification of a proposal for EFPs to conduct experimental fishing; request for comments.

**SUMMARY:** The Administrator, Northeast Region, NOAA Fisheries (Regional Administrator) has made a preliminary determination that the subject EFP application contains all the required information and warrants further consideration. The Regional Administrator has also made a preliminary determination that the activities authorized under the EFP would be consistent with the goals and objectives of the Northeast Multispecies Fishery Management Plan (FMP). However, further review and consultation may be necessary before a final determination is made to issue the EFP. Therefore, NOAA Fisheries announces that the Regional Administrator proposes to issue an EFP that would allow one vessel to conduct fishing operations that are otherwise restricted by the regulations governing the fisheries of the Northeastern United States. The EFP would allow for a 20–day exemption from the Gulf of Maine (GOM) Rolling Closures specified at 50 CFR 648.81 and for a 20–day exemption from the northeast (NE) multispecies days-at-sea (DAS) notification requirements at 50 CFR 648.10(c) and 648.82(a). The exempted fishing activity would support research to design, develop and test a soft species separation system for commercial flatfish trawls in the GOM. The system is intended to separate roundfish (particularly cod) from flatfish in trawl nets by exploiting behavioral differences between the species.

Regulations under the Magnuson-Stevens Fishery Conservation and Management Act require publication of this notification to provide interested parties the opportunity to comment on applications for proposed EFPs.

**DATES:** Comments on this document must be received on or before August 29, 2002.

**ADDRESSES:** Written comments should be sent to Patricia A. Kurkul, Regional Administrator, NMFS, Northeast Regional Office, 1 Blackburn Drive, Gloucester, MA 01930. Mark the outside of the envelope ''Comments on UNH Species Separation System EFP Proposal.'' Comments may also be sent via facsimile (fax) to (978) 281–9135.

**FOR FURTHER INFORMATION CONTACT:** Richard A. Pearson, Fishery Policy Analyst, 978–281–9279.

**SUPPLEMENTARY INFORMATION:** The application for an EFP was submitted by the University of New Hampshire (UNH) Cooperative Extension for research being funded through NOAA Fisheries' Cooperative Research Partners Program. The applicant is requesting an exemption for one commercial vessel from the NE multispecies DAS notification requirements at 50 CFR 648.10(c) and 648.82(a) for 20 days of at-sea gear testing and from the GOM Rolling Closures specified at 50 CFR 648.81 for the same duration. This experiment proposes to design, develop and test a soft species separation system for commercial flatfish trawls in the GOM. The objective of the research is to separate flatfish from roundfish in trawl nets and to reduce the inadvertent bycatch of roundfish (particularly cod) when fishing for flatfish. The separation device is designed to separate roundfish from flatfish by exploiting behavioral differences that exist between the species. The experimental design consists of a soft species separation panel, or ramp, that would be positioned in front of a double codend in a trawl net. It would take advantage

of the tendency of flatfish to swim towards the ocean bottom after encountering the separation panel and thereby into the lower codend portion of the net. Roundfish, which are not expected to swim towards the seafloor after encountering the panel, would swim into the upper codend portion of the net, which could be left open if roundfish were not being retained.

Underwater video equipment would be employed to observe fish behavior and functioning of the experimental selectivity device. Catch and bycatch are proposed to be sampled from each tow. If available, 100 each of cod, haddock, yellowtail flounder, whiting (silver hake), American plaice and witch flounder (including both legal and sub-legal sizes) would be measured from the catch in both the control net (commercial trawl net) and from the experimental trawl net, using alternating tows. The total weight of roundfish and flatfish would be determined from the upper and lower codends of the experimental trawl net and from the control net. Finally, the catch of each species in the upper and lower codend of the experimental net would be analyzed using statistical methods to calculate a separation index to determine whether the experimental system is effective at separating the species.

To avoid the Cape Cod yellowtail flounder stock area, the vessel would be required to conduct experimental fishing activity north of 42°50' N. lat. (the northern boundary of the Cape Cod yellowtail flounder stock area), due to the significant reduction in fishing mortality that is currently required for that stock to eliminate overfishing. The sea trials would be conducted in shallow water (30 to 50 fathoms (54.9 - 91.4 meters)) off the coasts of New Hampshire, southern Maine, and a small portion of northern Massachusetts. UNH researchers would be aboard the vessel during all experimental work. All undersized fish, and/or protected species, would be returned to the sea as quickly as possible after measurement. However, legal-sized fish that would otherwise have to be discarded would be allowed to be retained and sold. The overall catch levels are not expected to have a detrimental impact on the NE multispecies resource. Estimated total landings for the 20 days are: Cod - 6,000 lb (2721.5 kg); flatfish (witch flounder, American plaice, winter flounder, yellowtail flounder) - 6,000 lb (2721.5 kg); other groundfish (haddock, cusk, white hake, silver hake, red hake, ocean pout, wolffish, etc.) - 4,000 lb (1814.4 kg). This is approximately one-half the level of landings that would be expected for 20 days of normal commercial fishing for this vessel. The participating vessel would be required to report all of its landings in its Vessel Trip Reports.

This experimental work is important because it could lead to the development of gear that could reduce bycatch of species that are subject to restrictive trip limits, such as cod, when fishing for species that are not subject to restrictive trip limits. The successful development of a soft species separation device, which could easily be installed in commercial trawl nets, could provide the fishing industry with more flexibility in conducting fishing activities, while simultaneously providing additional conservation for overfished species.

Based on the results of this EFP, this action may lead to future rulemaking.

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

Dated: August 9, 2002.

**Virginia M. Fay,**

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

[FR Doc. 02–20657 Filed 8–13–02; 8:45 am]

**BILLING CODE 3510–22–S**

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

### 50 CFR Part 660

**[I.D. 080602E]**

### Fisheries off the West Coast States and in the Western Pacific; Pacific Coast Groundfish Fishery; Intent to Prepare an Environmental Impact Statement (EIS) for Fishing Conducted Under the Pacific Coast Groundfish Fishery Management Plan (FMP)

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

**ACTION:** Notice of intent to prepare an EIS; request for written comments.

**SUMMARY:** The Pacific Fishery Management Council (Council) announces its intention to prepare an EIS in accordance with the National Environmental Policy Act (NEPA) to assess the impacts of the 2003 Pacific Coast groundfish fishery specifications and management measures on the human environment.

**DATES:** Written comments must be received no later than 5 p.m, local time (l.t.), on September 13, 2002. A public scoping meeting is scheduled as part of the Council's August 28–29, 2002, Allocation Committee meeting in Portland, OR (see **SUPPLEMENTARY INFORMATION**).

**ADDRESSES:** Written comments on suggested alternatives and potential impacts should be sent to Donald McIsaac, Executive Director, Pacific Fishery Management Council (Council), 7700 NE Ambassador Place, Suite 200, Portland, OR 97220–1384. Comments may also be sent via facsimile (fax) to 503–820–2299. Comments will not be accepted if submitted via e-mail or Internet. See **SUPPLEMENTARY INFORMATION** for specific dates and times.

**FOR FURTHER INFORMATION CONTACT:** John DeVore, Groundfish Fishery Management Coordinator; phone: 503–820–2280 and e-mail: john.devore@noaa.gov.

**SUPPLEMENTARY INFORMATION:**

#### Background

There are more than 80 species managed under the Pacific Coast Groundfish FMP, nine of which have been declared overfished. The groundfish stocks support an array of commercial, recreational, and Indian tribal fishing interests in state and Federal waters off the coasts of Washington, Oregon, and California. In addition, groundfish are also harvested incidentally in nongroundfish fisheries, most notably the trawl fisheries for pink shrimp, spot/ridgeback prawns, California halibut, and sea cucumber. Restrictive management measures intended to rebuild overfished species have been adopted and implemented over the past several years for most commercial and recreational fishing sectors.

The proposed action is the identification and evaluation of 2003 groundfish harvest level specifications and fishery management measures intended to meet but not exceed those specifications. These specifications include acceptable biological catches and optimum yields (OYs) for groundfish species or species groups in need of particular protection; OYs may be represented by harvest guidelines or quotas for species that need individual management. The allocation of commercial OYs between the open access and limited entry segments of the fishery is also part of the proposed action. The FMP requires that these specifications for groundfish be annually evaluated and revised as necessary, and that management measures designed to achieve the OYs be published in the **Federal Register** and made effective by January 1, the beginning of the fishing year. The Magnuson-Stevens Fishery

Conservation and Management Act and the FMP also require that NMFS implement actions to prevent overfishing and to rebuild overfished stocks. These specifications include fish caught in state ocean waters (0–3 nautical miles (nm) offshore) as well as fish caught in the U.S. exclusive economic zone (3–200 nm offshore). Management measures intended to control the rate at which different groundfish species or species groups are taken in the fisheries include trip limits, bag limits, size limits, time/area closures, and gear restrictions.

For 2003, the Council is considering management measures that could include time/area closures of large portions of the continental shelf off the U.S. West Coast. These measures would be necessary to prevent fishing vessels from directly targeting or incidentally catching the overfished species that are primarily found on the continental shelf. In particular, large time/area closures would focus on protecting bocaccio, canary rockfish, darkblotched rockfish, and yelloweye rockfish. While other overfished species could also be expected to benefit from these closures, the rebuilding needs of these particular overfished species would likely shape the design of the closed areas. A more detailed description of the management alternatives that will be considered by the Council at its September 9–13, 2002, meeting in Portland, OR is available on the Council's web site at *http://www.pcouncil.org.*

A principal objective of the scoping and public input process is to identify significant issues that will be analyzed in depth in the EIS. The EIS will address these significant issues through a range of reasonable management alternatives and an analysis of their impacts on the human environment. Alternatives will be analyzed for impacts on essential fish habitat, target and non-target species of fish, discarded fish, marine mammals, and other protected species present in the Pacific Coast ecosystem. In addition, the environmental consequences section of the EIS will contain an analysis of impacts from fishery management measures on the following groups of individuals: (1) Those who participate in harvesting the fishery resources and other living marine resources; (2) those who process and market the fish and fish products; (3) those who are involved in allied support industries; (4) those who consume fish products; (5) those who rely on living marine resources in the management area, either for subsistence needs or for recreational benefits; (6) those who benefit from non-consumptive uses of living marine resources; (7) those involved in managing and monitoring fisheries; and (8) fishing communities.

Scoping documents that identify the management issues, initial alternatives, and an outline of the proposed analysis will be made available at the August 28–29, 2002, meeting.

### Dates and Times of the Scoping Meeting and Associated Informational Meetings

A scoping meeting for this EIS will be held in concurrence with a meeting of the Council's Allocation Committee on August 28–29, 2002, at the Shilo Inn, 11707 NE Airport Way, Portland, OR 97220. The Council will be particularly seeking comments on the EIS at 4 p.m., l.t., on August 28, 2002. The purpose of the Allocation Committee's meeting is to discuss the Council's proposed 2003 groundfish specifications and management measures prior to and in preparation for the Council's September 9–13, 2002 meeting in Portland, OR. Issues to be analyzed in this EIS were also discussed at the Council's June 18–21, 2002 meeting in Foster City, CA, at the meetings of the Allocation Committee and the Groundfish Management Team (GMT) that preceded that June Council meeting, and a July 29 through August 2, 2002, meeting of the Council's GMT. The scoping hearing held as part of the Council's August 28–29, 2002, Allocation Committee meeting, and the earlier meetings listed above are intended to meet NEPA scoping guidelines at 40 CFR 1501.7(b).

### Special Accommodations

These meetings are accessible to people with physical disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Carolyn Porter 503–820–2280 (voice) or 503–820–2299 (fax), at least 5 days prior to the scheduled meeting date.

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

Dated: August 9, 2002.

**Virginia M. Fay,**

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

[FR Doc. 02–20663 Filed 8–13–02; 8:45 am]

BILLING CODE 3510–22–S

## DEPARTMENT OF COMMERCE

## National Oceanic and Atmospheric Administration

## 50 CFR Part 660

**[I.D.080902A]**

## Western Pacific Fishery Management Council; Public Meetings

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

**ACTION:** Notice of public meetings/public hearings.

**SUMMARY:** The Western Pacific Fishery Management Council (Council) will meet on August 29, 2002, at 2 p.m.

**ADDRESSES:** The Council meeting will be held via telephone conference call at the Council offices, 1164 Bishop Street, Suite 1400, Honolulu Hawaii 96813; telephone: 808–522–8220; FAX: (808)522–8226.

**FOR FURTHER INFORMATION CONTACT:** Kitty M. Simonds, Executive Director; telephone: 808–522–8220.

**SUPPLEMENTARY INFORMATION:**

### Public Hearing

A public hearing will be conducted for final action on American Samoa longline fishery limited entry program, on Wednesday, August 29, 2002, at 3 p.m.

Public comment periods will be provided throughout the agenda. The order in which agenda items are addressed may change. The Council will meet as late as necessary to complete scheduled business. The agenda during the Council meeting will include the items listed below:

1.Pelagic Fisheries

(i) American Samoa longline limited entry program

(ii) public hearing

The Council will hold a public hearing on the preferred alternative for the American Samoa longline fishery limited entry program, and may take final action on these management measures. At its 113th meeting, the Council adopted a limited entry program for the American Samoa longline fishery. This action was prompted by the doubling of the number of fishing vessels participating in the American Samoa longline fishery during 2001, and a fourfold rise in the level of fishing effort in terms of hooks set. Unlike Hawaii, American Samoa is surrounded by the exclusive economic zones (EEZs) of other nations and options for fishing elsewhere are

limited. Consequently, gear conflict and competition for resources are likely to increase as the level of fishing within the American Samoa EEZ increases. At the 113th Council meeting, the Council reviewed the options for a limited entry program and developed and adopted a preferred alternative that would limit entry into the American Samoa EEZ longline fishery. The proposed program would create four vessel size classes and limit initial entry to historical participants in the longline fishery. Permits would be transferable subject to certain criteria. Provisions would be made to allow participants to upgrade from small to larger longline vessels. The Council also discussed measures to require observers and vessel monitoring systems on some vessels. However, the Council recognized that the final format of the limited entry program required additional revisions to the draft Pelagic Fisheries Management Plan (PFMP) amendment and the draft regulations therein and put these on the agenda for the 114th Council meeting. The Council will review the revised PFMP amendment and regulations, consider final management measures, and vote on whether to send the amendment document to NMFS for review and approval.

2. Fishery rights of indigenous peoples: Community demonstration projects program

A. selection of projects for funding

B. solicitation of new project proposalsFollowing the reauthorization of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) in 1996, The Secretary of Commerce and the Secretary of the Interior were authorized to make direct grants to eligible western Pacific communities, as recommended by the Council, for the purpose of establishing fishery demonstration projects to foster and promote traditional indigenous fishing practices. Criteria for fishery demonstration projects were published in April 2002, and proposals for fishery demonstration projects were subsequently solicited. The Native and Indigenous Advisory Panel will review these proposals in the week preceding the Council meeting and recommend to the Council which projects should be funded. The Council may concur with these recommendations or prefer to make recommendations of its own on those projects for funding. The Council may also decide to initiate another request for project proposals.

*Other Business*

Although non-emergency issues not contained in this agenda may come before the Council for discussion, those issues may not be the subject of formal Council action during this meeting. Council action will be restricted to those issues specifically listed in this document and to any issue arising after publication of this document that requires emergency action under section 305(c) of the Magnuson-Stevens Act, provided that the public has been notified of the Council's intent to take final action to address the emergency.

**Special Accommodations**

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Kitty M. Simonds, 808–522–8220 (voice) or 808–522–8226 (fax), at least 5 days prior to the meeting date.

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

Dated: August 9, 2002.

**Richard W. Surdi,**

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

[FR Doc. 02–20662 Filed 8–13–02; 8:45 am]

**BILLING CODE 3510–22–S**

# Notices

**Federal Register**

Vol. 67, No. 157

Wednesday, August 14, 2002

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

## DEPARTMENT OF AGRICULTURE

### Federal Crop Insurance Corporation

### Notice of Request for Extension of a Currently Approved Information Collection

**AGENCY:** Federal Crop Insurance Corporation, USDA.

**ACTION:** Extension of approval of an information collection; comment request.

**SUMMARY:** This notice announces a public comment period on the information collection requests (ICRs) associated with the interpretation of statutory and regulatory provisions administered by Federal Crop Insurance Corporation (FCIC).

**DATES:** Written comments on this notice will be accepted until close of business October 15, 2002.

**ADDRESSES:** Interested persons are invited to submit written comments to Craig Witt, Acting Deputy Administrator Insurance Services Division, Federal Crop Insurance Corporation, United States Department of Agriculture, 1400 Independence Ave. SW., Stop 0805, Washington, DC 20250–0805. Comments titled ''Information Collection OMB 0563–0055'' may be sent via the Internet to: *Craig_Witt@usda.gov.*

**FOR FURTHER INFORMATION CONTACT:** Anne Jenkins, Insurance Management Specialist, Federal Crop Insurance Corporation, at the above address, telephone (814) 624–0737.

**SUPPLEMENTARY INFORMATION:**

*Title:* General Administrative Regulations; Interpretations of Statutory and Regulatory Provisions.

*OMB Number:* 0563–0055.

*Expiration Date of Approval:* August 31, 2002.

*Type of Request:* Extension of a currently approved information collection.

*Abstract:* FCIC is proposing to renew the currently approved information collection, OMB Number 0563–0055. It is currently up for renewal and extension for three years. FCIC is conducting a thorough review of information collections associated with providing an interpretation of statutory and regulatory provisions under this collection. The information collection requirements for this renewal package are necessary for FCIC to provide an interpretation of statutory and regulatory provisions upon request. This data is used to administer the provisions of 7 CFR part 400, subpart X in accordance with the Federal Crop Insurance Act, as amended.

We are asking the Office of Management and Budget (OMB) to extend its approval of our use of this information collection activity for an additional 3 years.

The purpose of this notice is to solicit comments from the public concerning this information collection activity. These comments will help us:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information has practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, through use, as appropriate, of automated, electronic, mechanical, and other collection technologies, e.g., permitting electronic submission of responses.

*Estimate of burden:* The public reporting burden for this collection of information is estimated to average 0.5 hours per response.

*Respondents/Affected Entities:* Parties affected by the information collection requirements included in this Notice are any applicant for crop insurance, a producer with a valid crop insurance policy, or a private insurance company with a reinsurance agreement with FCIC or their agents, loss adjusters, employees or contractors.

*Estimated annual number of respondents:* 45.

*Estimated annual number of responses per respondent:* 3.5.

*Estimated annual number of responses:* 156.

*Estimated total annual burden hours on respondents:* 78.

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.

Signed in Washington DC, on August 7, 2002.

**Ross J. Davidson, Jr.,**

*Manager, Federal Crop Insurance Corporation.*

[FR Doc. 02–20444 Filed 8–13–02; 8:45 am]

**BILLING CODE 3410–08–M**

## DEPARTMENT OF AGRICULTURE

### Forest Service

### Forest Counties Payments Committee Meeting; Cancellation

**AGENCY:** Forest Service, USDA.

**ACTION:** Notice.

**SUMMARY:** Due to the conflicting schedules of committee members, the Forest Counties Payments Committee meeting that was scheduled for August 23, 2002, in Rhinelander, WI, is cancelled. The meeting will be rescheduled for sometime in September. Date and location for the September meeting will be published in the **Federal Register** within the next two weeks.

**FOR FURTHER INFORMATION CONTACT:** Randle G. Phillips, Executive Director, Forest Counties Payments Committee, (202) 208–6574 or via e-mail at *rphillips01@fs.fed.us.*

**SUPPLEMENTARY INFORMATION:** The Forest Counties Payments Committee was created by the 2001 Interior and Related Agencies Appropriations Act (Pub. L. 106–291). The committee meets periodically in different locations to discuss and make recommendations to Congress on a long term solution for making Federal payments to eligible States and counties in which Federal lands are situated.

Notice of the now-cancelled Rhinelander, WI, meeting was published in the **Federal Register** on August 1, 2002 (67FR49903).

Dated: August 8, 2002.

**Mary H. Davis,**

*Acting Deputy Chief, Programs and Legislation.*

[FR Doc. 02–20557 Filed 8–13–02; 8:45 am]

**BILLING CODE 3410–11–P**

## DEPARTMENT OF AGRICULTURE

### Forest Service

### Notice of Resource Advisory Committee Meeting

**AGENCY:** Crook County Resource Advisory Committee, Sundance, Wyoming, USDA, Forest Service.

**ACTION:** Notice of meeting.

**SUMMARY:** Pursuant to the authorities in the Federal Advisory Committee Act (Pub. L. 92–463) and under the Secure Rural Schools and Community Self-Determination Act of 2000 (Pub. L. 106–393) the Black Hills National Forests' Crook County Resource Advisory Committee will meet Monday, September 16, 2002, in Sundance, Wyoming for a business meeting. The meeting is open to the public.

**SUPPLEMENTARY INFORMATION:** The business meeting on September 16, begins at 6:30 PM, at Crook County Courthouse Community Room, 309 Cleveland St, Sundance, Wyoming. Agenda topics will include an overview of the committee's enabling legislation, the committee charter, development of operating guidelines, election of chairperson, and scheduling of future meetings. A public forum will begin at 8:30 PM (MT).

**FOR FURTHER INFORMATION CONTACT:** Steve Kozel, Bearlodge District Ranger and Designated Federal Officer, at (307) 283–1361.

Dated: August 8, 2002.

**John Twiss,**

*Forest Supervisor.*

[FR Doc. 02–20558 Filed 8–13–02; 8:45 am]

**BILLING CODE 3410–11–M**

## 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:* 2003 National Census Test.

*Form Number(s):* DA–11A Questionnaires: DA–1B, DA–1C, DA–1D, DA–1DD, DA–1(RH–1), DA–1(RH–2), DA–1(RH–3), DA–1(RH–4), DA–1(RH–5), DA–1(RH–6), DA–1(RH–7) Guides: DA–3IVR, DA 3I/IVR.

*Agency Approval Number:* None.

*Type of Request:* New collection.

*Burden:* 40,000 hours.

*Number of Respondents:* 240,000.

*Avg Hours Per Response:* 10 minutes.

*Needs and Uses:* The U.S. Census Bureau requests authorization from the Office of Management and Budget (OMB) to conduct the two-part 2003 National Census Test. The first part, which tests self-response options, is planned to take advantage of evolving technology. The Census Bureau needs to research various self-response options in order to develop a strategy that encourages the public to respond to the census using either paper or electronic means before Nonresponse Followup (NRFU) occurs. This part will examine the impact of offering various options on overall response rates and data quality. These options include mail, Internet, Telephone Interactive Voice Response (IVR), and a combination of Internet and IVR. Also, part of this test is designed to address questions about the effectiveness of various types of contacts with respondents.

*In part one of this test, we hope to answer the following questions:*

1. What is the effect of offering alternative data collection modes on response (*e.g.*, increase, decrease, shift)?

2. What is the effect of new or additional contact strategies on overall response?

3. Do any of the alternative panels offer a gain over the Census 2000 approach?

The goal of the self-response options part of the test is to identify for further testing, in 2004, the best strategy for increasing self-enumerated response to the census, thus reducing the NRFU workload. Successful accomplishment of this goal will greatly reduce the cost of data collection while improving the data quality of Census 2010.

The second part of the test will examine revisions to the question on Hispanic origin and race. The goal of this portion of the test is to develop question wording and content that will lead to improved self-reporting of both race and Hispanic origin in the census and surveys. In order to obtain more complete reporting of these detailed groups, the revisions will include additional examples of ''Other Hispanic, ''Other Asian'', and ''Other Pacific Islander'' groups for these response categories. Adding examples of these groups may improve comparability between the decennial census and survey data.

In addition, we will examine the effect of dropping the ''Some other race'' (SOR) response option to the question on race. Although the Census Bureau received an exception from the OMB which allowed it to include a SOR category in past decennial censuses, this category is a source of non-comparability between the decennial census and survey data produced by other agencies.

*Affected Public:* Individuals or households.

*Frequency:* One time.

*Respondent's Obligation:* Mandatory.

*Legal Authority:* Title 13 U.S.C., Sections 141 and 193.

*OMB Desk Officer:* Susan Schechter, (202) 395–5103.

Copies of the above information collection proposal can be obtained by calling or writing Madeleine Clayton, Departmental Paperwork Clearance Officer, (202) 482–3129, Department of Commerce, room 6608, 14th and Constitution Avenue, NW., Washington, DC 20230 (or via the Internet at *mclayton@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, room 10201, New Executive Office Building, Washington, DC 20503.

Dated: August 8, 2002.

**Madeleine Clayton,**

*Departmental Paperwork Clearance Officer, Office of the Chief Information Officer.*

[FR Doc. 02–20502 Filed 8–13–02; 8:45 am]

**BILLING CODE 3510–07–P**

## DEPARTMENT OF COMMERCE

### Economic Development Administration

### Revolving Loan Fund Reporting Requirements—Request for Comments; Submission for OMB Review; Comment Request

The Department of Commerce (DoC) has submitted to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 5).

*Agency:* Economic Development Administration (EDA).

*Title:* Revolving Loan Fund (RLF) Reporting Requirements (includes RLF Standards Terms and Conditions, RLF Plan, RLF Annual Report, RLF Semiannual Report, RLF Income and Expense Statement and RLF Audit Requirements).

*Agency Form Number:* ED–209A, ED–209S and ED–209I.

*OMB Approval Number:* 0610–0095.

*Type of Request:* Extension of a currently approved collection.

*Burden:* 15,448 hours.

*Average Hours Per Response:* 12 burden hours for post-approval monitoring; and 40 hours for the Revolving Loan Fund Plan.

*Number of Respondents:* Approximately 627 respondents (1,254 responses annually for post-approval monitoring) and 10 respondents annually for the RLF Plan.

*Needs and Uses:* The Economic Development Administration (EDA) provides investments that will help our partners across the nation (states, regions and communities) create wealth and minimize poverty by promoting a favorable business environment to attract private capital investment and high skill, high wage jobs through world-class capacity building, infrastructure, business assistance, research grants and strategic initiatives. EDA's Revolving Loan Fund (RLF) Reporting Requirements are needed to ensure proper monitoring and compliance with program and administrative requirements as set forth in EDA's authorizing legislation (Pub. L. 105–393) and EDA's implementing regulations at 13 CFR Chapter III.

The RLF Reporting Requirements are used by EDA to monitor grantee progress in establishing the loan funds, making initial loans, collecting and relending the proceeds from loans, and compliance with time schedules and federal requirements for administering grants, civil rights, environmental and other requirements prior to grant disbursement. The RLF Reporting Requirements are based on OMB administrative requirements for Federal grants as implemented by DOC rules at 15 CFR Parts 14, 24, 29, and CFR 13 CFR Part III and are intended to supplement and explain such requirements and are not intended to replace or negate such requirements.

*Affected Public:* State, local or Tribal Government and not-for-profit organizations.

*Frequency:* On occasion for post-approval monitoring, and related reports.

*Respondent's Obligation:* Required to obtain or retain benefits.

*OMB Desk Officer:* David Rostker, (202) 395–7340.

Copies of the above information collection proposal can be obtained by calling or writing Madeleine G. Clayton, Departmental Paperwork Clearance Officer, (202) 482–3129, U.S. Department of Commerce, Room 6608, 14th and Constitution Avenue, NW., Washington, DC 20230, (or via Internet at *Mclayton@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: August 8, 2002.

**Madeleine G. Clayton,**

*Departmental Paperwork Clearance Officer, Office of the Chief Information Officer.*

[FR Doc. 02–20501 Filed 8–13–02; 8:45 am]

**BILLING CODE 3510–34–P**

## DEPARTMENT OF COMMERCE

### International Trade Administration

**[A–427–801, A–428–801, A–475–801, A–588–804, A–412–801]**

### Ball Bearings and Parts Thereof from France, Germany, Italy, Japan, and the United Kingdom; Notice of Extension of Time Limit for Final Results of Antidumping Duty Administrative Reviews

**AGENCY:** Import Administration, International Trade Administration, Department of Commerce.

**ACTION:** Notice of Extension of Time Limit for Final Results of Antidumping Duty Administrative Reviews.

**EFFECTIVE DATE:** August 14, 2002.

**SUMMARY:** The Department of Commerce is extending the time limit for the final results of the administrative reviews of the antidumping duty orders on ball bearings and parts thereof from France, Germany, Italy, Japan, and the United Kingdom. The reviews covers 40 manufacturers/exporters. The period of review is May 1, 2000, through April 30, 2001.

**FOR FURTHER INFORMATION CONTACT:** Kristin Case or Mark Ross, AD/CVD Enforcement 3, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, N.W., Washington, D.C. 20230; telephone: (202) 482–3174 or (202) 482–4794, respectively.

**SUPPLEMENTARY INFORMATION:**

#### The Applicable Statute

Unless otherwise indicated, all citations to the Tariff Act of 1930, as amended (the Act), are references to the provisions effective January 1, 1995, the effective date of the amendments made to Act by the Uruguay Round Agreements Act.

#### Extension of Time Limit for Final Results

The Department of Commerce (the Department) published the preliminary results of these administrative reviews on April 10, 2002 (67 FR 17361). The deadline for completing the final results of these reviews is August 8, 2002. Under section 751(a)(3)(A) of the Act, the Department may extend the deadline for completion of an administrative review if it determines that it is not practicable to complete the review within the statutory time limit. Due to the complexity of the issues and the large number of companies involved in these reviews, the Department determines that it is not practicable to complete the final results of these administrative reviews within the statutory time limit. Therefore, the Department is extending the time limit for the final results of these administrative reviews by 15 days to August 23, 2002.

Dated: August 7, 2002.

**Richard W. Moreland,**

*Deputy Assistant Secretary for Import Administration.*

[FR Doc. 02–20562 Filed 8–13–02; 8:45 am]

**BILLING CODE 3510–DS–S**

## DEPARTMENT OF COMMERCE

### International Trade Administration

**[A–570–846]**

### Continuation of Antidumping Duty Order: Brake Rotors from the People's Republic of China

**AGENCY:** Import Administration, International Trade Administration, Department of Commerce.

**ACTION:** Notice of Continuation of Antidumping Duty Order: Brake Rotors from the People's Republic of China.

**SUMMARY:** On July 9, 2002, the Department of Commerce (''the Department''), pursuant to sections 751(c) and 752 of the Tariff Act of 1930, as amended (''the Act''), determined that revocation of the antidumping duty order on brake rotors from the People's Republic of China (''PRC'') would be likely to lead to continuation or recurrence of dumping.[1] On August 2, 2002, the International Trade Commission (''the Commission''), pursuant to section 751(c) of the Act, determined that revocation of the antidumping duty order on brake rotors from the PRC would be likely to lead to

[1] *Final Results of Expedited Sunset Review: Brake Rotors from the People's Republic of China*, 67 FR 45458 (July 9, 2002).

continuation or recurrence of material injury to an industry in the United States within a reasonably foreseeable time.[2] Therefore, pursuant to 19 CFR 351.218(f)(4), the Department is publishing notice of the continuation of the antidumping duty order on brake rotors from the PRC.

**EFFECTIVE DATE:** August 14, 2002.

**FOR FURTHER INFORMATION CONTACT:** Martha V. Douthit or James Maeder, Office of Policy for Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Ave., NW, Washington, D.C. 20230; telephone: (202) 482–5050 or (202) 482–3330, respectively.

**SUPPLEMENTARY INFORMATION:**

**Background:**

On March 1, 2002, the Department initiated, and the Commission instituted, a sunset review of the antidumping duty order on brake rotors from PRC, pursuant to section 751(c) of the Act.[3] As a result of its review, the Department found that revocation of the antidumping duty order would be likely lead to continuation or recurrence of dumping and notified the Commission of the magnitude of the margins likely to prevail were the order to be revoked.[4]

On August 2, 2002, the Commission determined, pursuant to section 751(c) of the Act, that revocation of the antidumping duty order on brake rotors from the PRC would be likely to lead to continuation or recurrence of material injury to an industry in the United States within a reasonably foreseeable time.[5]

**Scope:**

The products covered by this antidumping duty order are brake rotors made of gray cast iron, whether finished, semifinished, or unfinished, ranging in diameter from 8 to 16 inches (20.32 to 40.64 centimeters) and in weight from 8 to 45 pounds (3.63 to 20.41 kilograms). The size parameters (weight and dimension) of the brake rotors limit their use to the following types of motor vehicles: automobiles, all-terrain vehicles, vans and recreational vehicles under ''one ton and a half,'' and light trucks designated as ''one ton and a half.'' Finished brake rotors are those that are ready for sale and installation without any further operations. Semi-finished rotors are those on which the surface is not entirely smooth, and have undergone some drilling. Unfinished rotors are those which have undergone some grinding or turning. These brake rotors are for motor vehicles, and do not contain in the casting a logo of an original equipment manufacturer (''OEM'') which produces vehicles sold in the United States (e.g., General Motors, Ford, Chrysler, Honda, Toyota, Volvo). Brake rotors covered in the order are not certified by OEM producers of vehicles sold in the United States. The scope also includes composite brake rotors that are made of gray cast iron, which contain a steel plate, but otherwise meet the above criteria. Excluded from the scope of the order are brake rotors made of gray cast iron, whether finished, semifinished, or unfinished, with a diameter less than 8 inches or greater than 16 inches (less than 20.32 centimeters or greater than 40.64 centimeters) and a weight less than 8 pounds or greater than 45 pounds (less than 3.63 kilograms or greater than 20.41 kilograms).

Brake rotors are currently classifiable under subheading 8708.39.50.10 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 merchandise subject to the order is dispositive.

**Determination:**

As a result of the determinations by the Department and the Commission that revocation of this antidumping duty order would be likely to lead to continuation or recurrence of dumping and material injury to an industry in the United States, pursuant to section 751(d)(2) of the Act, the Department hereby orders the continuation of the antidumping duty order on brake rotors from the PRC. The Department will instruct Customs to continue to collect antidumping at the rates in effect at the time of entry for all imports of subject merchandise. The effective date of continuation of this order will be the date of publication in the **Federal Register** of this Notice of Continuation. Pursuant to section 751(c)(2) and 751(c)(6) of the Act, the Department intends to initiate the next five-year review of this order not later than July 2007.

Dated: August 8, 2002.

**Faryar Shirzad,**

*Assistant Secretary for Import Administration.*

[FR Doc. 02–20643 Filed 8–13–02; 8:45 am]

**BILLING CODE 3510–DS–S**

[2] *Brake Rotors from China*, 67 FR 50459 (August 2, 2002).

[3] *Antidumping and Countervailing Duties: Five Year Reviews*, 67 FR 9439 (March 1, 2002), and *Brake Rotors From China*, 67 FR 9462 (March 1, 2002).

[4] *Final Results of Expedited Sunset Review: Brake Rotors from the People's Republic of China*, 67 FR 45458 (July 9, 2002).

[5] *See Brake Rotors from China*, 67 FR 50459 (August 2, 2002), and USITC Publication 3528 (July 2002), Brake Rotors From China: Investigation No. 731-TA-744 (Review).

## DEPARTMENT OF COMMERCE

### International Trade Administration

**[A–602–804]**

### Notice of Correction to Final Determination of Sales at Less Than Fair Value: Certain Cold-Rolled Carbon Steel Flat Products From Australia

**AGENCY:** Import Administration, International Trade Administration, Department of Commerce.

**EFFECTIVE DATE:** August 14, 2002.

**FOR FURTHER INFORMATION CONTACT:** Sam Zengotitabengoa at (202) 482–4195, Office of AD/CVD Enforcement IV, Group II, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW, Washington, DC 20230.

**SUPPLEMENTARY INFORMATION:**

**The Applicable Statute and Regulations**

Unless otherwise indicated, all citations to the statute are references to the provisions effective January 1, 1995, the effective date of the amendments made to the Tariff Act of 1930 (the Act) by the Uruguay Round Agreements Act (URAA). In addition, unless otherwise indicated, all citations to the Department of Commerce (Department) regulations are to the regulations at 19 CFR part 351 (April 2001).

**Correction to Scope of Investigations**

On July 19, 2002, the Department issued the Notice of Final Determination of Sales at Less Than Fair Value for Certain Cold-Rolled Carbon Steel Flat Products From Australia (*Australia Cold-Rolled Final*), one of the concurrent investigations on cold-rolled steel products, 67 FR 47509 (July 19, 2002). A description of the scope of these investigations was contained in the ''Scope Appendix'' attached to the *Australia Cold-Rolled Final.* However, one of the exclusions of porcelain enameling sheet was not fully described in that appendix and the exclusion of texture-rolled steel strip (SORBITEX) did not contain the proper width measurement in that appendix. The corrected scope is appended to this notice. For a full discussion of the comments received on the preliminary scope rulings see the ''Issues and

Decision Memorandum for the Final Scope Rulings in the Antidumping Duty Investigations on Certain Cold-Rolled Carbon Steel Flat Products from Argentina, Australia, Belgium, Brazil, France, Germany, India, Japan, Korea, the Netherlands, New Zealand, the People's Republic of China, the Russian Federation, South Africa, Spain, Sweden, Taiwan, Thailand, Turkey, and Venezuela, and in the Countervailing Duty Investigations of Certain Cold-Rolled Carbon Steel Flat Products from Argentina, Brazil, France, and Korea,'' dated July 10, 2002, which is on file in the Department of Commerce's Central Records Unit, room B099.

**Notification**

The Department will notify the U.S. Customs Service and the International Trade Commission of these corrections to the scope.

This determination is issued and published in accordance with sections 735(d) and 777(i)(1) of the Act.

Dated: July 30, 2002.

**Faryar Shirzad,**

*Assistant Secretary for Import Administration.*

**Appendix I: Final Scope Rulings; Scope of the AD/CVD Investigations on Certain Cold-Rolled Steel Products**

*Scope of Investigation*

For purposes of this investigation, the products covered are certain cold-rolled (cold-reduced) flat-rolled carbon-quality steel products, neither clad, plated, nor coated with metal, but whether or not annealed, painted, varnished, or coated with plastics or other non-metallic substances, both in coils, 0.5 inch wide or wider, (whether or not in successively superimposed layers and/or otherwise coiled, such as spirally oscillated coils), and also in straight lengths, which, if less than 4.75 mm in thickness having a width that is 0.5 inch or greater and that measures at least 10 times the thickness; or, if of a thickness of 4.75 mm or more, having a width exceeding 150 mm and measuring at least twice the thickness. The products described above may be rectangular, square, circular or other shape and include products of either rectangular or non-rectangular cross-section.

Specifically included in this scope are vacuum degassed, fully stabilized (commonly referred to as interstitial-free (IF)) steels, high strength low alloy (HSLA) steels, and motor lamination steels. IF steels are recognized as low carbon steels with micro-alloying levels of elements such as titanium and/or niobium added to stabilize carbon and nitrogen elements. HSLA steels are recognized as steels with micro-alloying levels of elements such as chromium, copper, niobium, titanium, vanadium, and molybdenum. Motor lamination steels contain micro-alloying levels of elements such as silicon and aluminum.

Steel products included in the scope of this investigation, regardless of definitions in the HTSUS, are products in which: (1) Iron predominates, by weight, over each of the other contained elements; (2) the carbon content is 2% or less, by weight, and; (3) none of the elements listed below exceeds the quantity, by weight, respectively indicated: 1.80% of manganese, or 2.25% of silicon, or 1.00% of copper, or 0.50% of aluminum, or 1.25% of chromium, or 0.30% of cobalt, or 0.40% of lead, or 1.25% of nickel, or 0.30% of tungsten, or 0.10% of molybdenum, or 0.10% of niobium (also called columbium), or 0.15% of vanadium, or 0.15% of zirconium.

All products that meet the written physical description, and in which the chemistry quantities do not exceed any one of the noted element levels listed above, are within the scope of this investigation unless specifically excluded.

The following products, by way of example, are outside and/or specifically excluded from the scope of this investigation:

- SAE grades (formerly also called AISI grades) above 2300;
- Ball bearing steels, as defined in the HTSUS;
- Tool steels, as defined in the HTSUS;
- Silico-manganese steel, as defined in the HTSUS;
- Silicon-electrical steels, as defined in the HTSUS, that are grain-oriented;
- Silicon-electrical steels, as defined in the HTSUS, that are not grain-oriented and that have a silicon level exceeding 2.25%;
- All products (proprietary or otherwise) based on an alloy ASTM specification (sample specifications: ASTM A506, A507);
- Non-rectangular shapes, not in coils, which are the result of having been processed by cutting or stamping and which have assumed the character of articles or products classified outside chapter 72 of the HTSUS;
- Silicon-electrical steels, as defined in the HTSUS, that are not grain-oriented and that have a silicon level less than 2.25%, and (a) fully-processed, with a core loss of less than 0.14 watts/pound per mil (0.001 inch), or (b) semi-processed, with core loss of less than 0.085 watts/pound per mil (0.001 inch);
- Certain shadow mask steel, which is aluminum killed cold-rolled steel coil that is open coil annealed, has an ultra-flat, isotropic surface, and which meets the following characteristics:

  Thickness: 0.001 to 0.010 inch
  Width: 15 to 32 inches

CHEMICAL COMPOSITION

| Element | C |
|---|---|
| Weight | <0.002% |

- Certain flapper valve steel, which is hardened and tempered, surface polished, and which meets the following characteristics:

  Thickness: ≤1.0 mm
  Width: ≤152.4 mm

CHEMICAL COMPOSITION

| Element | C | Si | Mn | P | S |
|---|---|---|---|---|---|
| Weight % | 0.90–1.05 | 0.15–0.35 | 0.30–0.50 | ≤0.03 | ≤0.006 |

MECHANICAL PROPERTIES

| | |
|---|---|
| Tensile Strength | ≥ 162 Kgf/mm$^2$. |
| Hardness | ≥ 475 Vickers hardness number. |

PHYSICAL PROPERTIES

| | |
|---|---|
| Flatness | < 0.2% of nominal strip width. |

Microstructure: Completely free from decarburization. Carbides are spheroidal and fine within 1% to 4% (area percentage) and are undissolved in the uniform tempered martensite.

NON-METALLIC INCLUSION

| | Area percentage |
|---|---|
| Sulfide Inclusion | ≤ 0.04 |

NON-METALLIC INCLUSION—Continued

| | Area percentage |
|---|---|
| Oxide Inclusion | ≤ 0.05 |

Compressive Stress: 10 to 40 Kgf/mm$^2$

SURFACE ROUGHNESS

| Thickness (mm) | Roughness (μm) |
|---|---|
| t ≤ 0.209 | Rz ≤ 0.5 |
| 0.209 < t ≤ 0.310 | Rz ≤ 0.6 |
| 0.310 < t ≤ 0.440 | Rz ≤ 0.7 |
| 0.440 < t ≤ 0.560 | Rz ≤ 0.8 |
| 0.560 < t | Rz ≤ 1.0 |

• Certain ultra thin gauge steel strip, which meets the following characteristics:
Thickness: ≤0.100 mm ± 7%
Width: 100 to 600 mm

CHEMICAL COMPOSITION

| Element | C | Mn | P | S | Al | Fe |
|---|---|---|---|---|---|---|
| Weight % | ≤0.07 | 0.2–0.5 | ≤0.05 | ≤0.05 | ≤0.07 | Balance |

MECHANICAL PROPERTIES

| | |
|---|---|
| Hardness | Full Hard (Hv 180 minimum) |
| Total Elongation | < 3% |
| Tensile Strength | 600 to 850 N/mm |

PHYSICAL PROPERTIES

| | |
|---|---|
| Surface Finish | ≤0.3 micron. |
| Camber (in 2.0 m) | <3.0 mm. |
| Flatness (in 2.0 m) | ≤0.5 mm. |
| Edge Burr | <0.01 mm greater than thickness. |
| Coil Set (in 1.0 m) | <75.0 mm. |

• Certain silicon steel, which meets the following characteristics:
Thickness: 0.024 inch ± 0.0015 inch
Width: 33 to 45.5 inches

CHEMICAL COMPOSITION

| Element | C | Mn | P | S | Si | Al |
|---|---|---|---|---|---|---|
| Min. Weight % | | | | | 0.65 | |
| Max. Weight % | 0.004 | 0.4 | 0.09 | 0.009 | | 0.4 |

MECHANICAL PROPERTIES

| | |
|---|---|
| Hardness | B60–75 (AIM 65) |

PHYSICAL PROPERTIES

| | |
|---|---|
| Finish | Smooth (30–60 microinches). |
| Gamma Crown (in 5 inches) | 0.0005 inch, start measuring one-quarter inch from slit edge. |
| Flatness | 20 I–UNIT max. |
| Coating | C3A–.08A max. (A2 coating acceptable). |
| Camber (in any 10 feet) | 1/16 inch. |
| Coil Size I.D. | 20 inches. |

MAGNETIC PROPERTIES

| | |
|---|---|
| Core Loss (1.5T/60 Hz) NAAS | 3.8 Watts/Pound max. |
| Permeability (1.5T/60 Hz) NAAS | 1700 gauss/oersted typical.<br>1500 minimum. |

• Certain aperture mask steel, which has an ultra-flat surface flatness and which meets the following characteristics:
Thickness: 0.025 to 0.245 mm
Width: 381–1000 mm

CHEMICAL COMPOSITION

| Element | C | N | Al |
|---|---|---|---|
| Weight % | < 0.01 | 0.004 to 0.007 | < 0.007 |

• Certain annealed and temper-rolled cold-rolled continuously cast steel, which meets the following characteristics:

CHEMICAL COMPOSITION

| Element | C | Mn | P | S | Si | Al | As | Cu | B | N |
|---|---|---|---|---|---|---|---|---|---|---|
| Min. Weight % | 0.02 | 0.20 | | | | 0.03 | | | | 0.003 |
| Max. Weight % | 0.06 | 0.40 | 0.02 | 0.023 (Aiming 0.018 Max.) | 0.03 | 0.08 (Aiming 0.05) | 0.02 | 0.08 | | 0.008 (Aiming 0.005) |

Non-metallic Inclusions: Examination with the S.E.M. shall not reveal individual oxides >1 micron (0.000039 inch) and inclusion groups or clusters shall not exceed 5 microns (0.000197 inch) in length.
Surface Treatment as follows: The surface finish shall be free of defects (digs, scratches, pits, gouges, slivers, etc.) and suitable for nickel plating.

SURFACE FINISH

| | Roughness, RA microinches (micrometers) | | |
|---|---|---|---|
| | Aim | Min. | Max. |
| Extra Bright | 5(0.1) | 0(0) | 7(0.2) |

• Certain annealed and temper-rolled cold-rolled continuously cast steel, in coils, with a certificate of analysis per Cable System International (''CSI'') Specification 96012, with the following characteristics:

CHEMICAL COMPOSITION

| Element | C | Mn | P | S |
|---|---|---|---|---|
| Max. Weight % | 0.13 | 0.60 | 0.02 | 0.05 |

PHYSICAL AND MECHANICAL PROPERTIES

| | |
|---|---|
| Base Weight | 55 pounds. |
| Theoretical Thickness | 0.0061 inch (±10% of theoretical thickness). |
| Width | 787 mm to 813 mm. |
| Tensile Strength | 45,000–55,000 psi. |
| Elongation | minimum of 15% in 2 inches. |

• Concast cold-rolled drawing quality sheet steel, ASTM A–620–97, Type B, or single reduced black plate, ASTM A–625–92, Type D, T–1, ASTM A–625–76 and ASTM A–366–96, T1–T2–T3 Commercial bright/luster 7a both sides, RMS 12 max. Thickness range of 0.0088 to 0.038 inches, width of 23.0 inches to 36.875 inches.
• Certain single reduced black plate, meeting ASTM A–625–98 specifications, 53 pound base weight (0.0058 inch thick) with a Temper classification of T–2 (49–57 hardness using the Rockwell 30 T scale).
• Certain single reduced black plate, meeting ASTM A–625–76 specifications, 55 pound base weight, MR type matte finish, TH basic tolerance as per A263 trimmed.
• Certain single reduced black plate, meeting ASTM A–625–98 specifications, 65 pound base weight (0.0072 inch thick) with a Temper classification of T–3 (53–61 hardness using the Rockwell 30 T scale).
• Certain cold-rolled black plate bare steel strip, meeting ASTM A–625 specifications, which meet the following characteristics:

CHEMICAL COMPOSITION

| Element | C | Mn | P | S |
|---|---|---|---|---|
| Max. Weight % | 0.13 | 0.60 | 0.02 | 0.05 |

PHYSICAL AND MECHANICAL PROPERTIES

| | |
|---|---|
| Thickness | 0.0058 inch ±0.0003 inch. |
| Hardness | T2/HR 30T 50—60 aiming. |
| Elongation | ≥15%. |
| Tensile Strength | 51,000.0 psi ±4.0. |

• Certain cold-rolled black plate bare steel strip, in coils, meeting ASTM A–623, Table II, Type MR specifications, which meet the following characteristics:

CHEMICAL COMPOSITION

| Element | C | Mn | P | S |
|---|---|---|---|---|
| Max. Weight % | 0.13 | 0.60 | 0.04 | 0.05 |

PHYSICAL AND MECHANICAL PROPERTIES

| | |
|---|---|
| Thickness | 0.0060 inch (±0.0005 inch). |
| Width | 10 inches (+¼ to ⅜ inch ±0). |
| Tensile Strength | 55,000 psi max. |
| Elongation | Minimum of 15% in 2 inches. |

- Certain ''blued steel'' coil (also known as ''steamed blue steel'' or ''blue oxide''), with a thickness of 0.30 mm to 0.42 mm and width of 609 mm to 1219 mm, in coil form;
- Certain cold-rolled steel sheet, coated with porcelain enameling prior to importation, which meets the following characteristics:

Thickness (nominal): ≤0.019 inch
Width: 35 to 60 inches

CHEMICAL COMPOSITION

| Element | C | O | B |
|---|---|---|---|
| Max. Weight % | 0.004 | | |
| Min. Weight % | | 0.010 | 0.012 |

- Certain cold-rolled steel, which meets the following characteristics:

Width: > 66 inches

CHEMICAL COMPOSITION

| Element | C | Mn | P | Si |
|---|---|---|---|---|
| Max. Weight % | 0.07 | 0.67 | 0.14 | 0.03 |

PHYSICAL AND MECHANICAL PROPERTIES

| | |
|---|---|
| Thickness Range (mm) | 0.800–2.000 |
| Min. Yield Point (MPa) | 265 |
| Max. Yield Point (MPa) | 365 |
| Min. Tensile Strength (MPa). | 440 |
| Min. Elongation % | 26 |

- Certain band saw steel, which meets the following characteristics:

Thickness: ≤1.31 mm
Width: ≤80 mm

CHEMICAL COMPOSITION

| Element | C | Si | Mn | P | S | Cr | Ni |
|---|---|---|---|---|---|---|---|
| Weight % | 1.2 to 1.3 | 0.15 to 0.35 | 0.20 to 0.35 | ≤0.03 | ≤0.007 | 0.3 to 0.5 | ≤0.25 |

Other properties:
Carbide: Fully spheroidized having > 80% of carbides, which are ≤ 0.003 mm and uniformly dispersed
Surface finish: Bright finish free from pits, scratches, rust, cracks, or seams, smooth edges.
Edge camber (in each 300 mm of length): ≤ 7 mm arc height
Cross bow (per inch of width): 0.015 mm max.

- Certain transformation-induced plasticity (TRIP) steel, which meets the following characteristics:

*Variety 1*

CHEMICAL COMPOSITION

| Element | C | Si | Mn |
|---|---|---|---|
| Min. Weight % | 0.09 | 1.0 | 0.90 |
| Max. Weight % | 0.13 | 2.1 | 1.7 |

PHYSICAL AND MECHANICAL PROPERTIES

| | |
|---|---|
| Thickness Range (mm) | 1.000–2.300 (inclusive). |
| Min. Yield Point (MPa) | 320. |
| Max. Yield Point (MPa) | 480. |
| Min. Tensile Strength (MPa) | 590. |
| Min. Elongation % | 24 (if 1.000–1.199 thickness range).<br>25 (if 1.200–1.599 thickness range). |

PHYSICAL AND MECHANICAL PROPERTIES—Continued

| | |
|---|---|
| | 26 (if 1.600–1.999 thickness range).<br>27 (if 2.000–2.300 thickness range). |

*Variety 2*

CHEMICAL COMPOSITION

| Element | C | Si | Mn |
|---|---|---|---|
| Min. Weight % | 0.12 | 1.5 | 1.1 |
| Max. Weight % | 0.16 | 2.1 | 1.9 |

PHYSICAL AND MECHANICAL PROPERTIES

| | |
|---|---|
| Thickness Range (mm) | 1.000–2.300 (inclusive). |
| Min. Yield Point (MPa) | 340. |
| Max. Yield Point (MPa) | 520. |
| Min. Tensile Strength (MPa) | 690. |
| Min. Elongation % | 21 (if 1.000–1.199 thickness range).<br>22 (if 1.200–1.599 thickness range).<br>23 (if 1.600–1.999 thickness range).<br>24 (if 2.000–2.300 thickness range). |

*Variety 3*

CHEMICAL COMPOSITION

| Element | C | Si | Mn |
|---|---|---|---|
| Min. Weight % | 0.13 | 1.3 | 1.5 |
| Max. Weight % | 0.21 | 2.0 | 2.0 |

PHYSICAL AND MECHANICAL PROPERTIES

| | |
|---|---|
| Thickness Range (mm) | 1.200–2.300 (inclusive). |
| Min. Yield Point (MPa) | 370. |
| Max. Yield Point (MPa) | 570. |
| Min. Tensile Strength (MPa) | 780. |
| Min. Elongation % | 18 (if 1.200–1.599 thickness range).<br>19 (if 1.600–1.999 thickness range).<br>20 (if 2.000–2.300 thickness range). |

• Certain cold-rolled steel, which meets the following characteristics:

*Variety 1*

CHEMICAL COMPOSITION

| Element | C | Mn | P | Cu |
|---|---|---|---|---|
| Min. Weight % | | | | 0.15 |
| Max. Weight % | 0.10 | 0.40 | 0.10 | 0.35 |

PHYSICAL AND MECHANICAL PROPERTIES

| | |
|---|---|
| Thickness Range (mm) | 0.600–0.800. |
| Min. Yield Point (MPa) | 185. |
| Max. Yield Point (MPa) | 285. |
| Min. Tensile Strength (MPa) | 340. |
| Min. Elongation | 31 (ASTM standard 31% = JIS standard 35. |

*Variety 2*

CHEMICAL COMPOSITION

| Element | C | Mn | P | Cu |
|---|---|---|---|---|
| Min. Weight % | | | | 0.15 |
| Max. Weight % | 0.05 | 0.40 | 0.08 | 0.35 |

PHYSICAL AND MECHANICAL PROPERTIES

| | |
|---|---|
| Thickness Range (mm) | 0.800–1.000. |
| Min. Yield Point (MPa) | 145. |
| Max. Yield Point (MPa) | 245. |
| Min. Tensile Strength (MPa) | 295. |
| Min. Elongation % | 31 (ASTM standard 31% = JIS standard 35% ). |

*Variety 3*

CHEMICAL COMPOSITION

| Element | C | Si | Mn | P | S | Cu | Ni | Al | Nb, V, Ti, B | Mo |
|---|---|---|---|---|---|---|---|---|---|---|
| Max.Weight % | 0.01 | 0.05 | 0.40 | 0.10 | 0.023 | 0.15–.35 | 0.35 | 0.10 | 0.10 | 0.30 |

PHYSICAL AND MECHANICAL PROPERTIES

| | |
|---|---|
| Thickness (mm) | 0.7 |
| Elongation % | ≥ 35 |

- Porcelain enameling sheet, drawing quality, in coils, 0.014 inch in thickness, +0.002, −0.000, meeting ASTM A–424–96 Type 1 specifications, and suitable for two coats.
- Porcelain-enameling sheet whether or not coated prior to importation with the following additional characteristics:
  Cold-rolled steel for porcelain enameling, the foregoing being continuous annealed cold-reduced steel with a nominal thickness of not more than 0.48 mm and widths from 762 mm to 1,524 mm, having a chemical composition, by weight, of not more than 0.004 percent carbon, nor more than 0.010 percent aluminum, 0.006 percent or more of nitrogen, 0.012 percent or more of boron, and more than 0.005 percent silicon, and 0.010 percent or more of oxygen; having no intentional addition of and less than 0.002 percent by weight of titanium, no intentional addition of and less than 0.002 percent by weight of vanadium, no intentional addition of and less than 0.002 percent by weight of niobium, and no intentional addition of and less than 0.002 percent of antimony; having a yield strength of from 179.3 MPa to 344.7 MPa, a tensile strength of from 303.7 MPa to 413.7 MPa, a percent of elongation of from 28 percent to 46 percent on a standard ASTM sample with a 5.08 mm gauge length; for Fishscale resistance; hydrogen traps provided; with a product shape of flat after annealing, with flat defined as less than or equal to 1 I unit with no coil set.
- Cold-rolled steel strip to specification SAE 4130, with the following characteristics:
  HTSUS item number 7226.92.80.50
  Width up to 24 inches
  Gauge of ''0.0500.014 inches,'' and gauge tolerance of ±0.0018 inches
- Texture-rolled steel strip (SORBITEX), with the following characteristics:
  Thickness: 0.0039 to 0.0600 inches
  Width: 0.118 to <0.5 inches (3 to <12.7 mm)

CHEMICAL COMPOSITION

| C | Si | Mn | P | S | Al | Cr | Ni | Cu |
|---|---|---|---|---|---|---|---|---|
| 0.76–0.96% | 0.10–.035% | 0.30–0.60% | <.025% | <.020% | <.060% | <.30% | <.20% | <.20% |

  Tensile strength ranges: 245,000 to 365,000 psi.
  HTSUS 7211.29.20.30 and HTSUS 7211.29.45.00
- Reed steel, with the following characteristics:
  Grades Eberle 18, 18C (SAE 1095 modified alloyed steel) HTSUS 7211.90.00

PHYSICAL CHARACTERISTICS

| | |
|---|---|
| Thickness | 0.0008 to 0.04 inches (0.0203 to 1.015 mm). |
| Width | 0.276 to 0.472 inches (7 mm to 12.0 mm), with width tolerances of ±0.04 to 0.06 mm. |
| Tensile strength | 1599 Mpa to 2199 Mpa. |

CHEMICAL COMPOSITION

| C | Si | Mn | P | S | Cr |
|---|---|---|---|---|---|
| 0.95–1.05% | 0.15–0.30% | 0.25–0.50% | less than 0.015% | less than 0.012% | less than 0.040% |

  Surface: Rmax 1.5 to 3.0 micrometers
  Straightness: Max. deviation of 0.56mm/m
  Flatness: Deviation of 0.1 to 0.3% of the width
- Feeler gauge steel, with the following characteristics:
  Polished surface and deburred or rounded edges Grades Eberle 18, 18C (SAE 1095 modified alloyed steel) HTSUS 7211.90.00

PHYSICAL AND MECHANICAL PROPERTIES

| | |
|---|---|
| Max. width | 0.4975 inches width. |

PHYSICAL AND MECHANICAL PROPERTIES—Continued

| | |
|---|---|
| Thickness Range | 0.001–0.045 inches. |
| Thickness tolerances | T2–T4 international standard. |
| Tensile strength UTS | 246–304 ksi. |

• Wood Band Saw Steel with Nickel Content Exceeding 1.25% by Weight, with the following characteristics:
Both variety 1 and variety 2 are classified under HTSUS item number 7226.99.00.00

*Variety # 1*

Nickel-alloyed Band Saw Steel, which meets the following characteristics:
Thickness: >1.1 mm, ≤3.00 mm
Width: <400 mm

CHEMICAL COMPOSITION

| Element | C | Si | Mn | P | S | Cr | Ni | Cu | Al |
|---|---|---|---|---|---|---|---|---|---|
| Weight % | 0.70–0.80 | 0.20–0.35 | 0.30–0.45 | max. 0.020 | max. 0.006 | 0.05–0.20 | 1.90–2.10 | max. 0.15 | 0.02–0.04 |

Microstructure: Tempered Martensite with Bainite, no surface decarburization
Mechanical Properties: Hardness: 446 +12/−23 HV respectively 45 +1/−2 HRC
Surface Finish: bright, polished
Edges: treated edges
Cross Bow: max. 0.1 mm per mm width

*Variety #2*

UHB15N20 band saw steel according to the alloy composition:

CHEMICAL COMPOSITION

| Element | C | Si | Mn | P | S | Cr | Ni |
|---|---|---|---|---|---|---|---|
| Weight % | 0.70–0.80 | 0.20–0.35 | 0.30–0.45 | Pmax. 0.020 | S max. 0.016 | — | 1.90–2.10 |

Typical material properties: Hardened and tempered
Tensile Strength: 1450 N/mm² for thickness < 2 mm and 1370 N/mm² for thickness > 2mm
Width tolerance: B1 = ±0.35 mm
Thickness tolerance: T1 (±0.039 mm)
Flatness: P4 (max. deviation 0.1 % of width of strip)
Straightness: (±0.25 mm/1000 mm)
Dimensions:
Widths: 6.3–412.8 mm
Thickness: 0.40 to 3.05 mm
• 2% nickel T5 tolerances and ra less than 8 my, with the following characteristics:
Thickness: 0.5–3.5 mm
Width: 50–650 mm

CHEMICAL COMPOSITION

| Element | C | Si | Mn | P | S | Al | Cr | Ni |
|---|---|---|---|---|---|---|---|---|
| Weight % | 0.70–0.80 | 0.15–0.35 | 0.30–0.50 | max. 0.020 | max. 0.010 | max. 0.020 | 0.05–0.30 | 1.90–2.20 |

High precision T5 tolerance
Roughness: Ra (RMS) max. 8 inches
The product is classified under HTSUS item number 7226.92.50.00
• Ski-edge profile steel, with the following characteristics:
For both Grade SAE 1070 and German Grade SAE X35CrMo17:
HTSUS item numbers 7228.60.80 and 7216.69.00
Hardened and tempered, HRC 44–52
Surface: bright finished, sandblasted or primer coated stamped condition

DIMENSIONS

| | Width mm | Width mm | Thick-ness mm | Thick-ness mm |
|---|---|---|---|---|
| Ski 39 | 6 | 1.90 | 2 | 0.50 |
| Ski 40 | 6 | 1.70 | 2 | 0.50 |
| Ski 129 | 7.70 | 2.00 | 2.20 | 0.60 |

CHEMICAL COMPOSITION FOR GRADE SAE 1070:

| Element | C | Si | Mn | P | S |
|---|---|---|---|---|---|
| Weight % | 0.65–0.75 | max. 0.40 | max. 0.60–0.90 | max. 0.04 | max. 0.05 |

CHEMICAL COMPOSITION FOR GERMAN GRADE SAE X35CRMO17

| Element | C | Si | Mn | P | S | CR | Mo | Ni |
|---|---|---|---|---|---|---|---|---|
| Weight % | 0.33–0.45 | max. 1.0 | max 1.50 | max 0.04 | max 0.025 | 15.5–17.5 | 0.8–1.3 | max. 1.0 |

Note that this is an angle shape or section steel that is not covered by this scope.

- Flat wire, with the following characteristics:
  SAE 1074 alloyed, annealed, skin passed
  Hardened and tempered
  Formed edges
  Widths of less than 12.7 mm
  Thickness from 0.50–2.40 mm
- Shadow/aperture mask steel, which is Aluminum killed cold-rolled steel coil that is open coil annealed, has an ultra-flat, isotropic surface, and meets the following characteristics:
  Thickness: 0.001 to 0.010 inch
  Width: 15 to 35 inches
  Increased tensile strength of 800 to 1,200 N/mm$^2$

CHEMICAL COMPOSITION

| Element | C | N | Mn |
|---|---|---|---|
| Weight % | < 0.01 % | 0.01–0.017% | 0.06–0.85 % |

HTSUS item numbers 7209.18.25.10 or 7211.23.60.75, depending on the width of the material.

- Grade 13C cement kiln steel, with the following specifications:

CHEMICAL COMPOSITION

| Element | C | Si | Mn | P | S |
|---|---|---|---|---|---|
| Weight % | 0.65 | 0.25 | 0.65 | max. 0.020 | max. 0.010 |

Microstructure: Fine grained and homogenous. Matrix of tempered martensite with a small amount of undissolved carbides
Decarburization: No free ferrit is allowed. Total decarburization should not exceed 4% per plane
Mechanical Properties: Tensile strength: 1200–1700 N/mm2, (Standard 1280 ±80 N/mm2)
Surface Finish: Gray hardened condition. Ra/CLA—max. 0.25 m. Cut off 0.25 mm Rmax—max. 2.5 m
Edge Condition: Slit edges free from cracks and damages
Dimensions:
Thickness: 0.4–1.40 mm, Tolerance: T1
Width: 250–1200 mm, Tolerance: B1
Flatness: Unflatness Across Strip: max. 0.4% of the nominal strip width
Coil Size: Inside Diameter: 600 mm
Coil Weight: max. 6.5 kg/mm strip width

- Certain valve steel (type 2), with the following specifications: Hardened tempered high-carbon strip, characterized by high fatigues strength and wear resistance, hardness combined with ductility, surface and end-finishes, and good blanking and forming properties.
  HTSUS item number: 7211.90.00.00
  Typical size ranges:
  Thickness: 0.15–1.0 mm
  Width: 10.0–140 mm

CHEMICAL COMPOSITION

| Element | C | Si | Mn | P | S | Ni | Cr |
|---|---|---|---|---|---|---|---|
| Weight % | 0.7–0.8 | 0.2–0.35 | 0.3–0.45 | Max. 0.020 | Max. 0.016 | 1.9–2.1 | — |

The merchandise subject to this investigation is typically classified in the HTSUS at item numbers: 7209.15.0000, 7209.16.0030, 7209.16.0060, 7209.16.0090, 7209.17.0030, 7209.17.0060, 7209.17.0090, 7209.18.1530, 7209.18.1560, 7209.18.2550, 7209.18.6000. 7209.25.0000, 7209.26.0000, 7209.27.0000, 7209.28.0000, 7209.90.0000, 7210.70.3000, 7210.90.9000, 7211.23.1500, 7211.23.2000, 7211.23.3000, 7211.23.4500, 7211.23.6030, 7211.23.6060, 7211.23.6085, 7211.29.2030, 7211.29.2090, 7211.29.4500, 7211.29.6030, 7211.29.6080, 7211.90.0000, 7212.40.1000, 7212.40.5000, 7212.50.0000, 7225.19.0000, 7225.50.6000, 7225.50.7000, 7225.50.8010, 7225.50.8085, 7225.99.0090, 7226.19.1000, 7226.19.9000, 7226.92.5000, 7226.92.7050, 7226.92.8050, and 7226.99.0000.

Although the HTSUS item numbers are provided for convenience and Customs purposes, the written description of the merchandise under investigation is dispositive.

[FR Doc. 02–20561 Filed 8–13–02; 8:45 am]

**BILLING CODE 3510–DS–P**

## DEPARTMENT OF COMMERCE

### International Trade Administration

**[A–552–801]**

## Investigation of Certain Frozen Fish Fillets From the Socialist Republic of Vietnam: Opportunity To Comment on Petitioner's Allegation That Vietnam Has a Non-Market Economy

**AGENCY:** Import Administration, International Trade Administration, Department of Commerce.

**ACTION:** Request for comments.

**SUMMARY:** The Department of Commerce is requesting comment on Petitioner's

allegation that Vietnam has a non-market economy.

**DATES:** August 14, 2002.

**FOR FURTHER INFORMATION CONTACT:** Shauna Lee-Alaia or George Smolik, Office of Policy, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone: (202) 482–2097, (202) 482–1843, respectively.

**SUPPLEMENTARY INFORMATION:**

**The Applicable Statute**

Unless otherwise indicated, all citations to the Tariff Act of 1930, as amended (the Act) are references to the provisions effective January 1, 1995, the effective date of the amendments made to the Act by the Uruguay Round Agreements Act (URAA). In addition, unless otherwise indicated, all citations to the Department of Commerce's (''Department's'') regulations are to 19 CFR part 351 et al. (2001).

**Background**

On June 28, 2002, the Department of Commerce (''Department'') received a petition on imports of certain frozen fish fillets from the Socialist Republic of Vietnam (''Vietnam'') filed in proper form by Catfish Farmers of America (''CFA'') and the individual U.S. catfish processors America's Catch Inc.; Consolidated Catfish Co., L.L.C.; Delta Pride Catfish, Inc.; Harvest Select Catfish, Inc.; Heartland Catfish Company; Pride of the Pond; Simmons Farm Raised Catfish, Inc.; and Southern Pride Catfish Co., Inc., hereinafter referred to collectively as ''the petitioners.'' In accordance with section 732(b) of the Act, the petitioners alleged that imports of certain frozen fish fillets from Vietnam are being, 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 such imports are materially injuring and threaten to injure an industry in the United States. Based upon our examination of the petition on frozen fish fillets from Vietnam, we found that the petition met the requirements of section 732 of the Act and subsequently initiated an antidumping duty investigation on July 18, 2002.

Petitioners have also alleged that Vietnam has a non-market economy. We are therefore undertaking an analysis of Vietnam's economy in the context of the investigation referred to herein. In order to provide greater certainty to all parties as this investigation proceeds, we intend to carry out this analysis on an expedited basis and anticipate that a determination on the market/non-market economy status of Vietnam will be issued prior to or concurrent with the issuance of the preliminary determination.

**Opportunity for Public Comment**

The Department invites public comment on Vietnam's economy in regards to the factors listed in section 771(18)(B) of the Act, which the Department must take into account when making a non-market economy status determination:

(i) The extent to which the currency of the foreign country is convertible into the currency of other countries;

(ii) The extent to which wage rates in the foreign country are determined by free bargaining between labor and management;

(iii) The extent to which joint ventures or other investments by firms of other foreign countries are permitted in the foreign country;

(iv) The extent of government ownership or control of the means of production;

(v) The extent of government control over allocation of resources and over price and output decisions of enterprises; and

(vi) Such other factors as the administering authority considers appropriate.

**Comments—Deadline, Format, and Number of Copies**

The deadline for submission of comments will be 21 calender days after the date of publication of this notice in the **Federal Register**. All comments should be filed at the Department of Commerce Central Records Unit located at the address listed below. Rebuttal comments may be submitted up to10 calender days after the date initial comments are due.

Each party submitting comments should include his or her name and address, and fully document or support all assertions and claims, using the following format: (1) Begin each comment on a separate page; (2) concisely state the issue identified and discussed in the comment and include any supporting documentation in exhibits or appendices; (3) provide a brief summary of the comment (a maximum of 3 sentences) and label this section ''summary of comment''; (4) provide an index or table of contents; and (5) include the case number A–552–801 in the top right hand corner of the submission.

To simplify the processing and distribution of comments, the Department requests that submission of documents in electronic form be accompanied by an original and 6 copies in paper form. We require that documents filed in electronic form be on DOS formatted 3.5'' diskettes and prepared in either WordPerfect 9 format or a format that the Word Perfect program can convert and import into WordPerfect 9. Please submit comments in separate files on the diskette. Comments received on diskette will be made available to the public on the Internet at Import Administration's Web site, *http://ia.ita.doc.gov*. Paper copies will be available for reading and photocopying in the Central Records Unit, Room B–099, U.S. Department of Commerce, Pennsylvania Avenue and 14th Street, NW., Washington, DC 20230. Any questions concerning file formatting, document conversion, access on the Internet, or other file requirements should be addressed to Andrew Lee Beller, Import Administration Webmaster, (202) 482–0866.

**Public Hearing**

After reviewing all comments and rebuttal comments, the Department will determine if a public hearing on the non-market economy issue is warranted, if one is requested in the initial comments on this issue, and, if so, will announce a place and time for that hearing, which will be held no later than 30 days after the final rebuttal comments are due.

This determination is issued and published in accordance with section 771(18)(c)(ii).

Dated: August 9, 2002.

**Bernard T. Carreau,**

*Acting Assistant Secretary for Import Administration.*

[FR Doc. 02–20674 Filed 8–13–02; 8:45 am]

**BILLING CODE 3510–DS–P**

## DEPARTMENT OF COMMERCE

### International Trade Administration

**[A–821–802]**

### Uranium from the Russian Federation: Rescission of Administrative Review of the Agreement Suspending the Antidumping Duty Investigation

**AGENCY:** Import Administration, International Trade Administration, Department of Commerce.

**ACTION:** Notice of rescission of administrative review.

**SUMMARY:** In response to a request from the Ministry of the Russian Federation for Atomic Energy (''MINATOM''), the Department of Commerce (''the Department'') initiated an administrative review of the suspension

agreement on uranium from the Russian Federation on November 21, 2001 (66 FR 58433). On July 17, 2002, the Department received a letter from MINATOM withdrawing its request for the administrative review. This review has now been rescinded as a result of the withdrawal of the request for review by MINATOM, the only party which requested the review.

**EFFECTIVE DATE:** August 14, 2002.

**FOR FURTHER INFORMATION CONTACT:** James Doyle or Catherine Bertrand, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington DC 20230; telephone: (202) 482–0159 or (202) 482–3207, respectively.

**SUPPLEMENTARY INFORMATION:**

### The Applicable Statute

Unless otherwise indicated, all citations to the Tariff Act of 1930, as amended (''the Act''), are to the provisions effective January 1, 1995, the effective date of the amendments made to the Act by the Uruguay Round Agreements Act (''URAA''). In addition, unless otherwise indicated, all citations to the Department's regulations are to 19 CFR part 351 (2001).

### Background

On October 31, 2001, the Department received a timely request from MINATOM to conduct an administrative review of the Suspension Agreement (''Agreement'') on uranium from the Russian Federation. On November 21, 2001, the Department initiated a review of the Agreement. See Notice of Initiation of Antidumping and Countervailing Duty Administrative Reviews, 66 FR 58433 (November 21, 2001).

On April 22, 2002, the Department extended the time limits for the preliminary results of review by 120 days. See Notice of Extension of Time Limits of the Preliminary Results of Administrative Review of Agreement Suspending the Antidumping Investigation of Uranium from the Russian Federation, as Amended, 67 FR 19554 (April 22, 2002). On July 17, 2002, MINATOM withdrew its request for the review.

### Rescission of Review

Pursuant to 19 CFR 351.213(d)(1) of the Department's regulations, the Department will allow a party that requests an administrative review to withdraw such request within 90 days of the date of publication of the notice of initiation of the administrative review. Furthermore, the Department may extend this time limit if the Secretary decides it is reasonable to do so, pursuant to 19 CFR 351.213(d)(1). Given that we have received no submissions opposing MINATOM's request for withdrawal of the administrative review and the fact that MINATOM was the only party to request a review, we find it reasonable to extend the 90 days time period for filing a withdrawal request. Therefore, we are rescinding this review of the agreement suspending the antidumping duty investigation on uranium from the Russian Federation.

This notice is issued and published in accordance with section 351.213(d)(4) of the Department's regulations.

Dated: August 7, 2002.

**Faryar Shirzad,**

*Assistant Secretary for Import Administration.*

[FR Doc. 02–20646 Filed 8–13–02; 8:45 am]

**BILLING CODE 3510–DS–P**

## DEPARTMENT OF COMMERCE

### International Trade Administration

### Applications for Duty-Free Entry of Scientific Instruments

Pursuant to section 6(c) of the Educational, Scientific and Cultural Materials Importation Act of 1966 (Pub. L. 89–651; 80 Stat. 897; 15 CFR part 301), we invite comments on the question of whether instruments of equivalent scientific value, for the purposes for which the instruments shown below are intended to be used, are being manufactured in the United States.

Comments must comply with 15 CFR 301.5(a)(3) and (4) of the regulations and be filed within 20 days with the Statutory Import Programs Staff, U.S. Department of Commerce, Washington, DC 20230. Applications may be examined between 8:30 a.m. and 5 p.m. in Suite 4100W, U.S. Department of Commerce, Franklin Court Building, 1099 14th Street, NW., Washington, DC.

*Docket Number:* 02–032. *Applicant:* Thomas Jefferson University, 1020 Walnut Street, Philadelphia, PA 19107–5587. *Instrument:* Electron Microscope, Model Morgagni 268 Film version. *Manufacturer:* FEI Company, The Netherlands. *Intended Use:* The instrument is intended to be used in research on fixed rat brain tissue to identify interactions between endogenous opioids and corticotropin-releasing factor (CFR) that impact on a biogenic amine system which is involved in both stress and opioid actions, the locus coeruleus (LC)-norepinephrine (NE) system. *Application accepted by Commissioner of Customs:* July 16, 2002.

*Docket Number:* 02–033. *Applicant:* University of Vermont, Burlington, VT 05405. *Instrument:* High Speed CCD Camera, Model CPL MS1000. *Manufacturer:* Canadian Photonic Labs, Canada. Intended Use: The instrument is intended to be used to visualize high speed fluid flow in a variety of applications including: (1) Detachment of mechanisms of compound droplets from submerged needles and (2) visualize particulate flows in microchannels under videomicroscopy. The experimental objectives are to aid in the understanding of fundamental fluid mechanical mechanisms which cannot be observed with the human eye or normal video. The camera may be used for educational purposes in the following courses: (1) ME143 (Intro to Fluid Mechanics), (2) ME243 (Inviscid Flow), (3) ME249 (Computational Fluids Engineering) and (4) ME343 (Advanced Fluid Dynamics). *Application accepted by Commissioner of Customs:* July 30, 2002.

*Docket Number:* 02–034. *Applicant:* Alaska Department of Fish & Game, Division of Commercial Fisheries, 333 Raspberry Road, Anchorage, AK 99518. *Instrument:* (Two) Digital Fish Measuring Boards. Model FMB IV/64/10. *Manufacturer:* Limnoterra Ltd., Canada. *Intended Use:* The instrument is intended to be used to monitor salmon and herring populations including measuring fish weight and lengths. Growth data will be collected from discreet herring and salmon runs when they enter their spawning grounds to understand the relationships between natural cycling, environmental pressures, and fish stock overall health more completely. *Application accepted by Commissioner of Customs:* July 30, 2002.

*Docket Number:* 02–035. *Applicant:* West Chester University of Pennsylvania, Purchasing Office, 201 Carter Drive, Suite 200, West Chester, PA 19383. *Instrument:* Electron Microscope, Model Tecnai 12 TWIN. *Manufacturer:* FEI Company, The Netherlands. Intended Use: The instrument is intended to be used in research programs including: (1) A taxonomic investigation of bryophytes, (2) the nuclear localization of the retinol metabolizing enzyme 9-cis retinol dehydrogenase within cancerous and normal mammary tissue and (3) the visualization of the early events that occur at the gap junctions of insect ovarian follicle cells. The instrument will also be used in the following

courses: (1) Research Techniques I (Comparative Microscopy, Internship, and Independent Study and (2) Field Techniques, Techniques in Mineralogy and Internship. *Application accepted by Commissioner of Customs:* August 1, 2002.

**Gerald A. Zerdy,**

*Program Manager, Statutory Import Programs Staff.*

[FR Doc. 02–20644 Filed 8–13–02; 8:45 am]

**BILLING CODE 3510–DS–P**

## DEPARTMENT OF COMMERCE

## International Trade Administration

**[C–122–839]**

## Preliminary Results of Countervailing Duty Expedited Reviews: Certain Softwood Lumber Products from Canada

**AGENCY:** Import Administration, International Trade Administration, Department of Commerce.

**ACTION:** Notice of preliminary results of countervailing duty expedited reviews.

**SUMMARY:** The Department of Commerce (the Department) is conducting expedited reviews of the countervailing duty order on certain softwood lumber products from Canada for the period April 1, 2000 through March 31, 2001. This notice includes the preliminary results for 18 of the companies that are being reviewed under the expedited methodology. *See* ''Notice of Initiation of Expedited Reviews'' (67 FR 46955, July 17, 2002) (Notice of Initiation). For information on estimated net subsidies, please see the ''Preliminary Results of Reviews'' section of this notice. If the final results remain the same as these preliminary results of reviews, we will instruct the U.S. Customs Service (Customs) to amend the cash deposit for each reviewed company as detailed in the ''Preliminary Results of Reviews'' section of this notice. Interested parties are invited to comment on these preliminary results.

**EFFECTIVE DATE:** August 14, 2002.

**FOR FURTHER INFORMATION CONTACT:** Maria MacKay or Gayle Longest, Office of AD/CVD Enforcement VI, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone: (202) 482–1775 or (202) 482–3338.

**SUPPLEMENTARY INFORMATION:**

### Applicable Statute

Unless otherwise indicated, all citations to the statute are references to the provisions effective January 1, 1995, the effective date of the amendments made to the Tariff Act of 1930, (the Act) by the Uruguay Round Agreements Act (URAA). In addition, unless otherwise indicated, all citations to the Department's regulations are to the regulations codified at 19 CFR part 351 (2002).

### Background

On May 22, 2002, the Department published in the **Federal Register** its amended final affirmative countervailing duty determination and countervailing duty order on certain softwood lumber products (subject merchandise) from Canada (67 FR 36068), as corrected (67 FR 37775, May 30, 2002). On July 17, 2002, the Department published the Notice of Initiation of Expedited Reviews. As indicated in that notice, the Department had received 100 timely requests for expedited review. Since the publication of that notice, we have accepted as timely nine other applications for expedited review (*see, Memorandum to the File* from Gayle Longest, Case Analyst, through Melissa Skinner, Director, Office VI, dated August 2, 2002, concerning Reconsideration of Timeliness of Certain Applications—Expedited Reviews of the Countervailing Duty Order on Softwood Lumber from Canada, filed in the Central Record Unit, Room B–099, Main Commerce Building (CRU)).

In the Notice of Initiation, we initiated expedited reviews on the 73 companies that we found to have filed complete and timely applications. We have provided the remaining 36 companies, which we found to have filed incomplete applications, the opportunity to perfect their filings.

As explained in the Notice of Initiation, we reached the conclusion that the most efficient way to conduct such a large number of reviews in an expedited manner, and at the same time respond to the concerns expressed by the interested parties, is to adopt a bifurcated and streamlined methodology. The comments we received support this view. Our methodology involves segregating the applicants into two groups. Group 1 consists of companies that obtain the majority of their wood (over 50 percent of their inputs) from the United States, the Maritime Provinces, Canadian private lands, and Canadian companies excluded from the order; as well as companies that source less than a majority of their wood from these sources and do not have tenure. Group 2 includes companies that source less than a majority of their wood from these sources and have acquired Crown timber through their own tenure contracts. We reviewed the applications we received and assigned each of the 73 companies to one of the two groups. We found that 45 companies satisfied the requirements of Group 1 and 28 companies satisfied the requirements of Group 2. Within Group 1, 17 companies primarily used inputs from the United States, Canadian private forests, or the Maritime Provinces, and 25 primarily used Crown inputs but did not have tenure (for three companies, we need additional information to determine whether they will be in Group 1(a) or (b)).

In our review of the applications in Group 1, we noted that, in order to conduct our analysis, we required only minimal supplemental data for 24 of the 45 companies. The other Group 1 companies require additional information and more extensive analysis. Rather than delaying the process to provide all Group 1 companies the opportunity to submit the necessary information, we issued a short questionnaire to the 24 companies requiring only minimal information and set a short deadline for the response. Of the 24 companies, 18 were able to supply the information by the deadline. We have therefore been able to complete our preliminary analysis of those 18 companies, using the Group 1 methodology (see ''Methodology'' section below). We are continuing to process the other applications in Groups 1 and 2, and will be issuing additional questionnaires shortly.

Four of the companies to whom we sent questionnaires asked for extensions of time to submit their responses; we granted the extensions. In addition, two companies, Olav Haavalsrud Timber Company Limited and Western Commercial Millwork withdrew their requests for review. This notice includes the preliminary results of review for the following 18 companies:

Bois Daaquam Inc.
Bois Omega Ltée
City Lumber Sales & Services Limited
Herridge Sawmills Ltd.
Interbois, Inc.
J. A. Fontaine et fils Inc.
Jointfor (3207021 Canada Inc.)
Les Bois d'Oeuvre Beaudoin & Gauthier Inc.
Les Moulures Jacomau 2000, Inc.
Les Produits Forestiers Dube Inc
Lonestar Lumber Inc.
Maibec Industries, Inc.

Materiaux Blanchet Inc.
Meunier Lumber Company Ltd.
MF Bernard Inc.
Richard Lutes Cedar, Inc.
Scierie Nord-Sud Inc.
Scierie West-Brome Inc.

**Scope of the Reviews**

The products covered by this order are softwood lumber, flooring and siding (softwood lumber products). Softwood lumber products include all products classified under headings 4407.1000, 4409.1010, 4409.1090, and 4409.1020, respectively, of the Harmonized Tariff Schedule of the United States (HTSUS), and any softwood lumber, flooring and siding described below. These softwood lumber products include:

(1) Coniferous wood, sawn or chipped lengthwise, sliced or peeled, whether or not planed, sanded or finger-jointed, of a thickness exceeding six millimeters;

(2) Coniferous wood siding (including strips and friezes for parquet flooring, not assembled) continuously shaped (tongued, grooved, rabbeted, chamfered, v-jointed, beaded, molded, rounded or the like) along any of its edges or faces, whether or not planed, sanded or finger-jointed;

(3) Other coniferous wood (including strips and friezes for parquet flooring, not assembled) continuously shaped (tongued, grooved, rabbeted, chamfered, v-jointed, beaded, molded, rounded or the like) along any of its edges or faces (other than wood moldings and wood dowel rods) whether or not planed, sanded or finger-jointed; and

(4) Coniferous wood flooring (including strips and friezes for parquet flooring, not assembled) continuously shaped (tongued, grooved, rabbeted, chamfered, v-jointed, beaded, molded, rounded or the like) along any of its edges or faces, whether or not planed, sanded or finger-jointed.

Although the HTSUS subheadings are provided for convenience and Customs purposes, the written description of the merchandise subject to this order is dispositive.

As specifically stated in the Issues and Decision Memorandum accompanying the *Notice of Final Determination of Sales at Less Than Fair Value: Certain Softwood Lumber Products from Canada,* 67 FR 15539 (April 2, 2002) (*see* comment 53, item D, page 116, and comment 57, item B–7, page 126), available at *www.ia.ita.doc.gov,* drilled and notched lumber and angle cut lumber are covered by the scope of this order.

The following softwood lumber products are excluded from the scope of this order provided they meet the specified requirements detailed below:

(1) *Stringers* (pallet components used for runners): if they have at least two notches on the side, positioned at equal distance from the center, to properly accommodate forklift blades, properly classified under HTSUS 4421.90.98.40.

(2) *Box-spring frame kits:* if they contain the following wooden pieces—two side rails, two end (or top) rails and varying numbers of slats. The side rails and the end rails should be radius-cut at both ends. The kits should be individually packaged, they should contain the exact number of wooden components needed to make a particular box spring frame, with no further processing required. None of the components exceeds 1″ in actual thickness or 83″ in length.

(3) *Radius-cut box-spring-frame components,* not exceeding 1″ in actual thickness or 83″ in length, ready for assembly without further processing. The radius cuts must be present on both ends of the boards and must be substantial cuts so as to completely round one corner.

(4) *Fence pickets* requiring no further processing and properly classified under HTSUS heading 4421.90.70, 1″ or less in actual thickness, up to 8″ wide, 6′ or less in length, and have finials or decorative cuttings that clearly identify them as fence pickets. In the case of dog-eared fence pickets, the corners of the boards should be cut off so as to remove pieces of wood in the shape of isosceles right angle triangles with sides measuring ¾ inch or more.

(5) *U.S. origin lumber* shipped to Canada for minor processing and imported into the United States, is excluded from the scope of this order if the following conditions are met: (1) The processing occurring in Canada is limited to kiln-drying, planing to create smooth-to-size board, and sanding, and (2) if the importer establishes to Customs' satisfaction that the lumber is of U.S. origin.

(6) *Softwood lumber products contained in single family home packages or kits,*[1] regardless of tariff classification, are excluded from the scope of this order if the importer certifies to items 6 A, B, C, D, and requirement 6 E is met:

A. The imported home package or kit constitutes a full package of the number of wooden pieces specified in the plan, design or blueprint necessary to produce a home of at least 700 square feet produced to a specified plan, design or blueprint;

B. The package or kit must contain all necessary internal and external doors and windows, nails, screws, glue, sub floor, sheathing, beams, posts, connectors, and if included in the purchase contract, decking, trim, drywall and roof shingles specified in the plan, design or blueprint.

C. Prior to importation, the package or kit must be sold to a retailer of complete home packages or kits pursuant to a valid purchase contract referencing the particular home design plan or blueprint, and signed by a customer not affiliated with the importer;

D. Softwood lumber products entered as part of a single family home package or kit, whether in a single entry or multiple entries on multiple days, will be used solely for the construction of the single family home specified by the home design matching the entry.

E. For each entry, the following documentation must be retained by the importer and made available to the U.S. Customs Service upon request:

i. A copy of the appropriate home design, plan, or blueprint matching the entry;

ii. A purchase contract from a retailer of home kits or packages signed by a customer not affiliated with the importer;

iii. A listing of inventory of all parts of the package or kit being entered that conforms to the home design package being entered;

iv. In the case of multiple shipments on the same contract, all items listed in E(iii) which are included in the present shipment shall be identified as well.

Lumber products that the Customs Service may classify as stringers, radius cut box-spring-frame components, and fence pickets, not conforming to the above requirements, as well as truss components, pallet components, and door and window frame parts, are covered under the scope of this order and may be classified under HTSUS subheadings 4418.90.45.90 , 4421.90.70.40, and 4421.90.97.40.

Finally, as clarified throughout the course of the investigation, the following products, previously identified as Group A, remain outside the scope of this order. They are:

1. Trusses and truss kits, properly classified under HTSUS 4418.90;

2. I-joist beams;

3. Assembled box spring frames;

4. Pallets and pallet kits, properly classified under HTSUS 4415.20;

5. Garage doors;

[1] To ensure administrability, we clarified the language of exclusion number 6 to require an importer certification and to permit single or multiple entries on multiple days as well as instructing importers to retain and make available for inspection specific documentation in support of each entry.

6. Edge-glued wood, properly classified under HTSUS item 4421.90.98.40;

7. Properly classified complete door frames;

8. Properly classified complete window frames;

9. Properly classified furniture.

**Methodology**

In the Notice of Initiation we invited comments on our approach and indicated that we would consider alternative methodologies. We received comments from petitioners, Fred Tebb and Sons (Fred Tebb) (a U.S. remanufacturer), and from 27 respondents. We also received rebuttal comments from six respondents. We are addressing in this notice those comments that are pertinent to (1) our methodology in general and (2) company-specific issues for the 18 companies covered by this notice.

*Comment 1:* Petitioners state that, even if the Department had authority to undertake expedited reviews in this case, it would have to observe limitations that apply to analogous situations. Specifically, the Department would have to follow the timeline applicable to the most expedited type of review addressed in section 751(a) of the Act, the new shipper review. Under those procedures, expedited reviews could not be initiated before November 2002, a preliminary determination would have to be issued 180 days later, and a final determination would be issued 90 days after the preliminary determination.

*Department's position:* Although the Department has the statutory authority to conduct expedited reviews of countervailing duty orders issued as a result of an investigation based on aggregate data, there is no statutory or regulatory guidance on the procedures for conducting such reviews. Nevertheless, as the Department explained in the Notice of Initiation, in establishing the approach to the conduct of this segment of the proceeding, we took into account, although we are not bound by, existing regulations for similar types of reviews. Unfortunately, none of our existing regulations was intended to provide workable timelines for expedited reviews of more than 100 companies. We concluded that, in order to reach our goal of completing these reviews in an expedited manner, it was incumbent upon the Department to divide the companies into two groups and to adopt a special bifurcated time schedule. This approach allows us to process the largest number of companies in the shortest period of time.

*Comment 2:* Petitioners claim that the methodology proposed by the Department sacrifices accuracy for the sake of expediency. Specifically, petitioners state that using the Province-wide average benefit for everyone underestimates the amount of the benefits for entities that are highly subsidized. Furthermore, petitioners object to the Department's treatment of private land timber as unsubsidized, since the Department did not investigate whether export restraints on Canadian logs give rise to subsidies, as alleged by the Coalition. In petitioners' view, the Department cannot now base decisions to grant expedited reviews on the claim that private logs are never subsidized.

*Department's position:* Petitioners expressed similar views during the investigation, in their comments on the methodology adopted by the Department in the exclusion process (*see* ''Company Exclusions'' section of the *Issues and Decision Memorandum* to Faryar Shirzad, Assistant Secretary for Import Administration from Bernard Carreau, Deputy Assistant Secretary for AD/CVD Enforcement II, concerning Final Results of the Countervailing Duty Investigation of Certain Softwood Lumber Products from Canada, dated March 21, 2002, on file in the CRU (Issues Memorandum)). At that time, we responded that the use of the Province-wide average benefit to measure whether a requestor received a *de minimis* benefit is appropriate and consistent with past practice.

Consideration of more in-depth methodologies, such as those presumably envisioned by petitioners, would require extensive information collection and analysis, and we are simply unable to do this consistent with our dual goals of providing company-specific analyses and conducting these reviews in an expeditious manner. Furthermore, we note that petitioners have not proposed an alternative methodology that addresses these dual goals, as we requested in the Notice of Initiation. As we stated during the investigation, we believe that the methodology we have adopted is appropriate in this case and in accordance with past practice. Furthermore, in seeking to strike a balance between accuracy and expeditiousness, we took into account the fact that these reviews are intended to provide an estimated cash deposit rate, rather than an assessment rate. Assessment rates will be determined in a full administrative review (if one is requested), in which the Department will have an opportunity to revisit methodological issues.

With regard to the issue of whether private land timber can be considered unsubsidized, this issue was also raised by petitioners during the investigation. In the investigation, we stated that we did not address the allegation that the log export ban provides a subsidy to softwood lumber producers ''because any conceivable benefit provided through a log ban would already be included in the calculation of the stumpage benefit based upon our selected market-based benchmark prices for stumpage.'' *See Notice of Preliminary Affirmative Countervailing Duty Determination, Preliminary Affirmative Critical Circumstances Determination, and Alignment of Final Countervailing Duty Determination With Final Antidumping Duty Determination: Certain Softwood Lumber Products from Canada,* 66 FR 43191, August 17, 2001. In the memorandum detailing the methodology that the Department adopted in the exclusion process, we stated that ''[c]ompanies that produce lumber from logs harvested in the Maritime Provinces, the United States, or on private lands in Canada, are unlikely to benefit to any significant extent from federal or provincial stumpage programs* * *'' *See Memorandum* to Faryar Shirzad, Assistant Secretary for Import Administration from Bernard T. Carreau, Deputy Assistant Secretary, Group II regarding Countervailing Duty (CVD) Investigation on Softwood Products from Canada, dated February 20, 2002, on file in the CRU (Exclusion Memorandum). Consequently, private land timber was treated as unsubsidized in the exclusion process. In the Notice of Initiation, we indicated that we would not revisit issues addressed in the investigation. Therefore, for purposes of these expedited reviews, we continue to treat private land timber as unsubsidized.

*Comment 3:* Petitioners note that the methodology described by the Department does not address verification and enforcement. In petitioners' view, all producers should have to certify the accuracy of their claims, specifically authorize on-going verification by the United States, commit to periodic reports, and specifically concede that if the basis of their claim should prove inaccurate or should change materially, their request can be denied.

Fred Tebb also expresses reservations concerning the accuracy of the information requested and obtained by the Department. Fred Tebb claims that, if a review is conducted, it should be conducted in an organized and verifiable fashion that results in

accurate findings. If, due to its limited resources, the Department must rely upon the applicants to provide accurate information, Tebb recommends that the Department require that the applications and any supplemental information be audited by independent U.S. auditors at applicant's expense.

*Department's position:* Concerning verification, we intend to verify all the companies that receive a zero or *de minimis* rate in the preliminary results. The decision of whether or not to verify other companies will be made on a case-by-case basis.

Concerning enforcement, companies covered by these reviews are subject to the legal requirements intended to address enforcement, such as certification and verification, as are companies in any other proceeding. With regard to those companies that may be excluded as a result of this process and therefore would not be subject to administrative reviews, they are receiving the same treatment as all companies that are excluded during an antidumping or countervailing duty investigation.

Concerning the accuracy of the information provided to the Department, we would point out that our regulations require all submissions to be accompanied by a statement by an official of the company attesting to the accuracy of the information provided to the Department. On this basis, it is the Department's standard practice to rely on questionnaire responses and, whenever we deem it necessary or are legally required to do so, to conduct verifications to ensure accuracy and completeness. Because of the highly technical and specialized nature of the analysis, review by an independent auditor is both unwarranted and unnecessary.

*Comment 4:* The Maine Forest Council expresses support for the request by Maibec and Materiaux Blanchet that the Department calculate mill-specific, not company-specific, rates. The Maine Forest Council claims that Maibec's and Materiaux Blanchet's mills are in the unique situation of sourcing a majority of their logs from the United States, as the Department verified during the investigation. Materiaux Blanchet also claims that the Department already conducted a mill-specific analysis of its St. Pamphile mill in the underlying investigation, calculated a mill-specific rate for that mill, and indeed relied on that rate in determining that the rate was just over the threshold for exclusion from the countervailing duty order. Thus, no change in methodology would be required in this review. Materiaux Blanchet further claims that the Department excluded a number of individual mills in Quebec that were affiliated with Maritime producers. A mill exclusion would also be consistent with 19 CFR section 351.214(k), which allows expedited reviews for non-investigated exporters. Furthermore, providing mill-specific rates is well within the Department's broad discretion in administering the countervailing duty law, as the Department acknowledged in the underlying investigation when it excluded the Maritime provinces completely. Maibec produces subject merchandise only at one of its mills. Since softwood stumpage for subject merchandise is used by that mill, and only that mill, which produces subject merchandise, an expedited review rate based only on Maibec's St. Pamphile mill alone is both feasible and not subject to potential circumvention.

*Department's position:* We disagree with respondents' contention that the Department should calculate subsidy rates for individual mills, rather than for the company as a whole. The Department's practice and regulations with respect to the calculation of *ad valorem* subsidy rates and attribution of domestic subsidies are clear. Under these rules, in the case of a domestic subsidy that is not tied to a specific product, the subsidy is attributed to all of the firm's sales. *See* section 351.525 of *Countervailing Duties; Final Rule*, 63 FR 65416, November 25, 1998 (*CVD Regulations*). Neither the statute nor the regulations provide for the attribution of a domestic subsidy to a specific entity within a firm. Rather, the attribution regulations distinguish among *products or markets*, not production facilities.

While these parties are correct that the Department indicated in the final determination that it calculated rates on a company- or mill-specific basis, no company or mill was excluded from the order on the basis of a mill-specific rate. The purpose of the exclusion process during the underlying investigation was to determine whether, based on the existence of a *de minimis* subsidy rate, a company should be excluded from the order. With respect to the mill related to a Maritime province company, we note that had the production of the remainder of the company, production that could not have benefitted from the subsidies under investigation, been included in our calculations, the calculated subsidy rate would only have decreased. Further, with respect to Materiaux Blanchet's mill-specific request, we note that the information we verified during the investigation, related to both of its mills, indicates that the subsidy rate would not have been *de minimis* regardless of whether the calculation was conducted on a mill- or company-specific basis.

*Comment 5:* Several respondents raise the issue of whether an arm's-length sale of logs or lumber allows for a pass-through of the stumpage benefit on timber and suggest alternative methodologies to measure whether or not the subsidy passes through. Dunkley Lumber suggests that the Department take into account the purchase price of the logs and compare it to one of the market benchmarks provided on the record. If the price is at or above the benchmark, the company is receiving no benefits from those logs.

Treeline Wood Products Ltd. contends that remanufacturers purchasing lumber on the open market are not receiving subsidies. Treeline claims to be an arm's length purchaser. Therefore, its lumber should be treated as non-subsidized. Alternatively, the Department should determine whether the subsidy passes through by establishing a benchmark on the basis of the manufacturing costs of comparable U.S. companies. The Department would determine the raw material inventory costs of comparable U.S. companies and determine the percentage of total sales that these costs represent (this could be derived from trade publications). If Treeline's ratio of material costs to sales is within the range established for these U.S. companies (approximately 50 percent), the Department should conclude that there are no subsidies.

Goodfellow Inc. (Goodfellow) recommends that the Department resolve early on in these reviews the threshold question of pass-through: whether any portion of the alleged subsidies should be attributed to a remanufacturer who purchases sawn lumber at arm's length from an unaffiliated primary mill. In Goodfellow's view, if the Department's position is that subsidies do not pass through, as allegedly stated in *Final Affirmative Countervailing Duty Determination: Certain Softwood Lumber Products from Canada*, 57 FR 22,574 (May 28, 1992) (Lumber III), at least 27 of the 73 companies (one third of the total) would be found not to be subsidized and this would save time and effort both for the companies and for the Department. If, instead, the Department has changed its position since Lumber III and determines that subsidies pass through, then Goodfellow and other remanufacturers may decide that further participation in this proceeding is not economically viable, because their records do not normally indicate the timber origin for each

lumber purchase and the search for such information would be expensive and not practicable.

Furthermore, Goodfellow contends that, if the Department does not resolve the pass-through issue early in these reviews, all respondents who intend to rely on the Department's alleged decision in Lumber III will continue to participate fully in the hope that the issue will be decided favorably. If the Department does not take a position or decides to abandon its prior position taken in Lumber III, as interpreted by Goodfellow, such efforts will have served no useful purpose. Even if the Department decides the issue favorably at the end of the review, respondents' and the Department's resources will have been wasted on an analysis that relies on elements such as the geographical source of the lumber, which has become a superfluous detail. Under any scenario, wasted effort is a natural result if the Department fails to make an early decision on the pass-through issue.

*Department's position:* Under the Department's proposed methodology, all Crown inputs into subject merchandise (logs and lumber) are included in the subsidy calculations. Because of the expedited nature of these reviews, we proposed not considering whether subsidies pass through in the context of alleged arm's-length transactions. As articulated in the Exclusion Memorandum from the investigation, such an analysis would require additional time to collect and examine information on the purchaser, the suppliers (whether or not they are affiliated), and the nature of the transaction itself. The determination of affiliation, for example, is an extremely complicated matter, as indicated by (1) the statutory definition contained in section 771(33) of the Act, (2) the discussion in the Statement of Administrative Action accompanying the URAA (H. R. Doc. 103–316 at 838 (1994)), and (3) section 351.102 of the regulations. Affiliation covers not just control through stock ownership, but also operational control, and the statute directs the Department to examine such factors as corporate or family groupings, franchises or joint venture agreements, debt financing, and close supplier relationships. *See Ferro Union, Inc. et al.* v. *United States*, 74 F.Supp.2d 1289 (Ct. Int'l Trade 1999); *Mitsubishi Heavy Industries, Ltd.,* v. *United States*, 54 F.Supp.2d 1183 (Ct. Int'l Trade 1999), aff'd, 275 F.3d 1056 (Fed. Cir. 2001).

Contrary to Goodfellow's contention, the Department did not in Lumber III reach any conclusions with respect to the pass-through of subsidies resulting from an arm's-length transaction. No remanufacturers were excluded on that basis in Lumber III. Furthermore, the question of whether, or to what extent, the stumpage benefit passes through in an arm's-length transaction was not directly addressed in the underlying investigation because we conducted the case on an aggregate basis. As such, the investigation provides no methodology, no benchmarks applicable to the log market, and no readily available information sources with which to approach this issue.

The methodologies proposed in the comments do not lend themselves to a rational and expedient analysis of this issue. Specifically, Dunkley Lumber proposes a methodology that relies on the comparison of log prices to a benchmark already on the record. However, in the underlying investigation, we compared stumpage costs, not log prices; the benchmarks already on the record would therefore not be helpful. The other proposal, by Treeline Wood Products, is also not relevant to this issue, because it is based on a comparative analysis of manufacturing costs between Canadian and U.S. companies. Such a comparison is irrelevant under the countervailing duty law. The third comment, by Goodfellow, does not put forward a new methodology but relies on Goodfellow's own interpretation of the Department's position in Lumber III. In that investigation, however, as pointed out above, the Department did not specifically address how to conduct a pass-through analysis of this type of transaction and took no position on the effect of an arm's-length transaction. In short, none of the comments offers the Department an approach that would enhance our ability to perform these complex reviews accurately and expeditiously.

After consideration of the above comments, we determined that the most expeditious approach would be to proceed with the issuance of the preliminary results for the first 18 companies of Group 1. None of those companies raised the issue of an arm's-length analysis. The Department is prepared, however, to conduct such analyses for companies that request them, to the extent practicable. Because of the complexity of the fact patterns and the extensive analysis involved, we will need to extend the time period to complete the reviews for companies that request an arm's-length analysis beyond the time frame we announced for Group 2 in the Notice of Initiation. Furthermore, given the time frame of these expedited reviews, and the number of companies involved, it is unlikely that we could conduct such analyses for more than a limited number of companies. Therefore, we invite those companies that wish the Department to conduct a pass-through analysis to advise the Department in writing. Such requests must be received by the Department within 14 days from the date of publication of this notice. We will determine, based on the number of the requests received, how many companies it is practicable to consider for such an analysis, as well as the amount of time that will be necessary for this aspect of the reviews.

We note that certain respondents (Bois Daquaam Inc., Bois Omega, Limitee, J.A. Fontaine et fils Inc., Maibec Industries Inc., Materiaux Blanchet Inc., and Scierie West Brome Inc.) have acquiesced to the Department's application of the exclusion methodology, but have reserved the right to raise methodological issues in the course of a regular administrative review. We would note that the Department's application of streamlined methodologies in these expedited reviews does not preclude *any* respondent from raising methodological issues in the context of full administrative reviews.

*Comment 6:* Woodtone Industries (Woodtone) recommends that the conversion factor from MFB (thousand board feet) to cubic meters for lumber inputs be standardized. Woodtone also expresses the view that benefits from other programs should not be included in the company-specific calculations on a pro-rata, averaging, or company-specific basis unless producers in fact benefitted from the programs.

*Department's position:* We examined extensively in the investigation the conversion factor from MFB to cubic meters for *logs.* Woodtone, however, raises the issue with regard to *lumber.* As explained below, for the subsidy calculations in these reviews, the Department does not need to adopt a standardized conversion factor for lumber inputs.

In Canada, lumber and logs are uniformly measured in cubic meters. The only instance in which we might need to convert MBF to cubic meters for lumber inputs would be in the case of lumber purchased from the United States. We are not, however, including the quantity of U.S. lumber in our calculations, because we are not attributing a subsidy to U.S. origin lumber.

With regard to the measurement of benefits other than stumpage, as we did in the exclusion process in the investigation, we intend to measure

those subsidies in these reviews on a company-by-company basis, in accordance with all relevant regulatory and statutory procedures.

**Preliminary Results of Reviews**

After consideration of all the above comments, we have applied the following methodology. We calculated company-specific rates based on the exclusion methodology used in the investigation. To obtain the company-specific stumpage benefit, we multiplied the quantity of Crown logs and the quantity of lumber inputs (except for those specified below) by the province-specific stumpage benefit calculated in the underlying investigation, i.e., the average per-unit differential between the calculated adjusted stumpage fee for the relevant province and the appropriate benchmark for that province. For those provinces, such as British Columbia and Ontario, for which we calculated more than one per-unit benefit in the investigation, we calculated one province-wide per-unit benefit in these reviews by weight-averaging the previously calculated values by the corresponding volumes of harvested softwood. As indicated in the Notice of Initiation, we have not attributed a benefit to (1) logs or lumber acquired from the Maritime Provinces, if accompanied by the appropriate certification, (2) logs or lumber of U.S. origin, (3) lumber produced by mills excluded in the investigation, or (4) logs from Canadian private land. We divided the stumpage benefit by the appropriate value of the company's sales to determine the company's estimated subsidy rate from stumpage and then added any benefit from other programs to obtain the cash deposit rate for the company.

In accordance with 19 CFR § 351.221(b)(4)(i), we calculated an individual subsidy rate for each producer/exporter subject to these expedited reviews. For the period April 1, 2002 to March 31, 2001, we preliminarily determine the net subsidy to be as follows:

| Net subsidies—producer/exporter | Net subsidy rate % |
|---|---|
| Bois Daaquam Inc. | 2.99 |
| Bois Omega Ltée | 3.10 |
| City Lumber Sales & Services Limited | 6.60 |
| Herridge Sawmills Ltd. | 4.91 |
| Interbois, Inc. | 0.88 |
| J. A. Fontaine et fils Inc. | 3.28 |
| Jointfor (3207021 Canada Inc. | 1.96 |
| Les Bois d'Oeuvre Beaudoin & Gauthier Inc. | 9.98 |
| Les Moulures Jacomau 2000, Inc. | 0.58 |
| Les Produits Forestiers Dube Inc | 1.39 |
| Lonestar Lumber Inc. | 13.42 |
| Maibec Industries, Inc. | 1.98 |
| Materiaux Blanchet Inc. | 10.32 |
| Meunier Lumber Company Ltd. | 35.35 |
| MF Bernard Inc. | 4.96 |
| Richard Lutes Cedar, Inc. | 0.25 |
| Scierie Nord-Sud Inc. | 2.22 |
| Scierie West-Brome Inc. | 1.16 |

If the final results of these reviews remain the same as these preliminary results, the Department intends to instruct Customs to collect cash deposits of estimated countervailing duties in the amounts indicated above of the f.o.b. invoice price on all shipments of the subject merchandise produced by the reviewed companies, entered, or withdrawn from warehouse, for consumption on or after the date of publication of the final results of these reviews.

Those exporters whose final estimated net subsidy rate, based on verified information, is zero or *de minimis* will be excluded from the order. Because, in the Department's view, there is no relevant difference for purposes of the *de minimis* rule between expedited reviews of orders resulting from investigations conducted on an aggregate basis and expedited reviews of orders resulting from investigations conducted on a company-specific basis, we believe it is appropriate in these reviews to treat *de minimis* rates in accordance with section 19 CFR section 351.214(k)(3)(iv). Therefore, after the issuance of its final results, the Department intends to instruct Customs to liquidate, without regard to countervailing duties, all outstanding shipments of the subject merchandise produced by those exporters, for whom the Department has calculated an estimated cash deposit rate of zero or *de minimis, i.e.* less than one percent *ad valorem*.

These expedited reviews cover only those companies that we have specifically identified as qualifying for expedited reviews. The cash deposit rate for all other companies will be adjusted in the final results of these reviews to account for the benefit and the sales values of the companies that have received company-specific rates. We will instruct Customs to collect cash deposits for all non-reviewed companies at the new cash deposit rates established in the final results of these reviews.

**Public Comment**

Pursuant to 19 CFR section 351.224(b), the Department will disclose to parties to the proceeding any calculations performed in connection with these preliminary results within five days after the date of publication of this notice. Pursuant to 19 CFR section 351.309, interested parties may submit written comments in response to these preliminary results. Case briefs must be received by the Department within 21 days after the date of publication of this notice, and rebuttal briefs, limited to arguments raised in case briefs, must be received no later than five days after the time limit for filing case briefs. Parties who submit argument in this proceeding are requested to submit with the argument: (1) A statement of the issue, and (2) a brief summary of the argument. Case and rebuttal briefs must be served on interested parties in accordance with 19 CFR section 351.303(f).

Representatives of parties to the proceeding may request disclosure of proprietary information under administrative protective order no later than 10 days after the representative's client or employer becomes a party to the proceeding, but in no event later than the date the case briefs, under 19 CFR section 351.309(c)(ii), are due. The Department will include the results of its analysis of issues raised in any case or rebuttal briefs in the final results of these expedited reviews. The Department will continue to issue preliminary results in the most expeditious manner practicable, and will follow the same approach in issuing final results of review.

In the interests of giving each respondent an informed opportunity to request rescission of their expedited review, we are amending the timeline announced in the application form. Requests for rescission must be received by the Department no later than 30 days after the date of publication of the preliminary results of the relevant expedited review.

These expedited reviews and notice are issued and published in accordance with section 751(a)(1) and 777(i)(1) of the Act (19 U.S.C. 1675(a)(1) and 19 U.S.C. 1677(f)(i)).

Dated: August 8, 2002.

**Faryar Shirzad,**

*Assistant Secretary for Import Administration.*

[FR Doc. 02–20645 Filed 8–13–02; 8:45 am]

BILLING CODE 3510–DS–P

## DEPARTMENT OF COMMERCE

### International Trade Administration

### North American Free-Trade Agreement, Article 1904 NAFTA Panel Reviews; Request for Panel Review

**AGENCY:** NAFTA Secretariat, United States Section, International Trade Administration, Department of Commerce.

**ACTION:** Notice of first request for panel review.

**SUMMARY:** On July 2, 2002, Sun Land Beef Company filed a First Request for Panel Review with the Mexican Section of the NAFTA Secretariat pursuant to Article 1904 of the North American Free Trade Agreement. Panel review was requested of the final antidumping duty determination made by the Secretaria de Economia, Unidad de Practicas Comerciales Internacionales, Direccion, General Adjunta Tecnica Juridica, Direccion de Procedimientos y Consultas, respecting Bovine Carcasses and Half Carcasses, Fresh or Chilled, Originating in the United States of America. This determination was published in the *Diario Oficial de la Federacion del,* on June 4, 2002. The NAFTA Secretariat has assigned Case Number MEX–USA–2002–1904–01 to this request.

**FOR FURTHER INFORMATION CONTACT:** Caratina L. Alston, United States Secretary, NAFTA Secretariat, Suite 2061, 14th and Constitution Avenue, Washington, DC 20230, (202) 482–5438.

**SUPPLEMENTARY INFORMATION:** Chapter 19 of the North American Free-Trade Agreement (''Agreement'') establishes a mechanism to replace domestic judicial review of final determinations in antidumping and countervailing duty cases involving imports from a NAFTA country with review by independent binational panels. When a Request for Panel Review is filed, a panel is established to act in place of national courts to review expeditiously the final determination to determine whether it conforms with the antidumping or countervailing duty law of the country that made the determination.

Under Article 1904 of the Agreement, which came into force on January 1, 1994, the Government of the United States, the Government of Canada and the Government of Mexico established *Rules of Procedure for Article 1904 Binational Panel Reviews* (''Rules''). These Rules were published in the **Federal Register** on February 23, 1994 (59 FR 8686).

A first Request for Panel Review was filed with the Mexican Section of the NAFTA Secretariat, pursuant to Article 1904 of the Agreement, on July 2, 2002, requesting panel review of the final determination described above.

The Rules provide that:

(a) A Party or interested person may challenge the final determination in whole or in part by filing a Complaint in accordance with Rule 39 within 30 days after the filing of the first Request for Panel Review (the deadline for filing a Complaint is August 1, 2002);

(b) A Party, investigating authority or interested person that does not file a Complaint but that intends to appear in support of any reviewable portion of the final determination may participate in the panel review by filing a Notice of Appearance in accordance with Rule 40 within 45 days after the filing of the first Request for Panel Review (the deadline for filing a Notice of Appearance is August 16, 2002); and

(c) The panel review shall be limited to the allegations of error of fact or law, including the jurisdiction of the investigating authority, that are set out in the Complaints filed in the panel review and the procedural and substantive defenses raised in the panel review.

Dated: July 29, 2002.

**Caratina L. Alston,**

*United States Secretary, NAFTA Secretariat.*

[FR Doc. 02–20436 Filed 8–13–02; 8:45 am]

**BILLING CODE 3510–GT–M**

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

**[I.D. 080102C]**

### Advisory Committee and Species Working Group Technical Advisor Appointments

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

**ACTION:** Nominations.

**SUMMARY:** NMFS is soliciting nominations to the Advisory Committee to the U.S. Section to the International Commission for the Conservation of Atlantic Tunas (ICCAT) as established by the Atlantic Tunas Convention Act (ATCA). NMFS is also soliciting nominations for technical advisors to the Advisory Committee's species working groups.

**DATES:** Nominations are due by September 16, 2002.

**ADDRESSES:** Nominations to the Advisory Committee or as technical advisor to a species working group should be sent to Dr. William T. Hogarth, Assistant Administrator, National Marine Fisheries Service, NOAA, 1315 East-West Highway, Silver Spring, MD 20912. A copy should also be sent to Erika Carlsen, International Fisheries Division, Office of Sustainable Fisheries, NMFS, Room 13137, 1315 East West Highway, Silver Spring, MD 20910.

**FOR FURTHER INFORMATION CONTACT:** Erika Carlsen, 301–713–2276.

**SUPPLEMENTARY INFORMATION:** Section 971b of the ATCA (16 U.S.C. 971 *et seq.*) requires that an advisory committee be established that shall be composed of (1) not less than 5 nor more than 20 individuals appointed by the U.S. Commissioners to ICCAT who shall select such individuals from the various groups concerned with the fisheries covered by the ICCAT Convention; and (2) the chairs (or their designees) of the New England, Mid-Atlantic, South Atlantic, Caribbean, and Gulf Fishery Management Councils. Each member of the Advisory Committee appointed under item (1) shall serve for a term of 2 years and shall be eligible for reappointment. Members of the Advisory Committee may attend all public meetings of the ICCAT Commission, Council, or any Panel and any other meetings to which they are invited by the ICCAT Commission, Council, or any Panel. The Advisory Committee shall be invited to attend all nonexecutive meetings of the U.S. Commissioners to ICCAT and, at such meetings, shall be given the opportunity to examine and be heard on all proposed programs of investigation, reports, recommendations, and regulations of the ICCAT Commission. Members of the Advisory Committee shall receive no compensation for such services. The Secretary of Commerce and the Secretary of State may pay the necessary travel expenses of members of the Advisory Committee.

There are currently 20 appointed Advisory Committee members. The terms of these members expire on December 31, 2002. New appointments will be made as soon as possible, but will not take effect until January 1, 2003.

Section 971b–1 of the ACTA specifies that the U.S. Commissioners may establish species working groups for the purpose of providing advice and recommendations to the U.S. Commissioners and to the Advisory Committee on matters relating to the conservation and management of any highly migratory species covered by the ICCAT Convention. Any species

working group shall consist of no more than seven members of the Advisory Committee and no more than four scientific or technical personnel, as considered necessary by the Commissioners. Currently, there are four species working groups advising the Committee and the U.S. Commissioners. Specifically, there is a Bluefin Tuna Working Group, a Swordfish Working Group, a Billfish Working Group, and a BAYS (Bigeye, Albacore, Yellowfin, and Skipjack) Tunas Working Group. Technical Advisors to the species working groups serve at the pleasure of the U.S. Commissioners; therefore, the Commissioners can choose to alter appointments at any time.

Nominations to the Advisory Committee or to a species working group should include a letter of interest and a resume or curriculum vitae. Letters of recommendation are useful but not required. Self-nominations are acceptable. When making a nomination, please clearly specify which appointment (Advisory Committee member or technical advisor to a species working group) is being sought. Requesting consideration for placement on both the Advisory Committee and a species working group is acceptable. Those interested in a species working group technical advisor appointment should indicate which of the four working groups is preferred. Placement on the requested species working group, however, is not guaranteed.

Dated: August 8, 2002.

**Virginia M. Fay,**

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

[FR Doc. 02–20654 Filed 8–13–02; 8:45 am]

**BILLING CODE 3510–22–S**

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

**[I.D. 080502C]**

### ICCAT Advisory Committee; Public Meetings

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

**ACTION:** Notice of public meetings.

**SUMMARY:** The Advisory Committee to the U.S. Section to the International Commission for the Conservation of Atlantic Tunas (ICCAT), in conjunction with the International Fisheries Division of NMFS, announces the schedule of regional public meetings to be held this fall.

**DATES:** The meetings are scheduled for September 2002. See **SUPPLEMENTARY INFORMATION** for specific dates and times of the meetings.

**ADDRESSES:** The meetings will be held in New Jersey, Massachusetts, South Carolina, and Florida. See **SUPPLEMENTARY INFORMATION** for specific addresses of the meetings.

**FOR FURTHER INFORMATION CONTACT:** Erika Carlsen at 301–713–2276.

**SUPPLEMENTARY INFORMATION:** The regional public meetings are scheduled as follows:

*Tuesday, September 3, 2002, 7 p.m. to 9:30 p.m.* - Atlantic Cape Community College, 5100 Black Horse Pike, Mays Landing, NJ;

*Wednesday, September 4, 2002, 7 p.m. to 9:30 p.m.* - Holiday Inn Boston Logan Airport, 225 McClellan Highway, Boston, MA;

*Tuesday, September 17, 2002, 7 p.m. to 9:30 p.m.* - Town and Country Inn, 2008 Savannah Highway, Charleston, SC;

*Wednesday, September 18, 2002, 7 p.m. to 9:30 p.m.* - Sheraton Biscayne Bay Hotel, 495 Brickell Avenue, Miami, FL.

The following topics may be presented to the public for discussion at the regional meetings:

(1) Background on ICCAT

(2) Information on the Advisory Committee and Commissioners

(3) Status of Highly Migratory Species Managed by ICCAT

(4) Topics for the 2002 ICCAT Annual Meeting

Representatives from the Advisory Committee to the U.S. Section to ICCAT and NMFS will be in attendance at the regional meetings. There will be an opportunity for public comment on each of these international issues. The length of the meetings may be adjusted based on the progress of the discussions.

Additionally, the annual fall meeting of the Advisory Committee will be held on October 14 - 16, 2002, at the Hilton Hotel Silver Spring, 8727 Colesville Road, Silver Spring, MD. There will be opportunity for public comment on international issues on Monday, October 14. The time for public comment period will be announced in a future notice. Domestic issues will not be discussed. An agenda for the annual fall Advisory Committee meeting will be available at a later date.

Please be reminded that NMFS expects members of the public to conduct themselves appropriately for the duration of the meeting. At the beginning of the public comment session, an explanation of the ground rules will be provided (e.g., alcohol in the meeting room is prohibited, speakers will be called to give their comments in the order in which they registered to speak, each speaker will have an equal amount of time to speak, and speakers should not interrupt one another). The session will be structured so that all attending members of the public are able to comment, if they so choose, regardless of the degree of controversy of the subject(s). Those not respecting the ground rules will be asked to leave the meeting.

**Special Accommodations**

The meeting locations are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Erika Carlsen at (301) 713–2276 at least 5 days prior to the meeting date.

Dated: August 8, 2002.

**Virginia M. Fay,**

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

[FR Doc. 02–20658 Filed 8–13–02; 8:45 am]

**BILLING CODE 3510–22–S**

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

**[I.D. 080902B]**

### North Pacific Fishery Management Council; Notice of Committee Meeting

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

**ACTION:** Committee Meeting.

**SUMMARY:** The North Pacific Fishery Management Council's (Council) Improved Retention/Improved Utilization (IR/IU) Technical Committee will meet in Seattle, Washington.

**DATES:** The Committee meeting is scheduled for August 28–29, 2002.

**ADDRESSES:** The meeting location is at the Alaska Fisheries Science Center, 7600 Sand Point Way NE, Bldg. 4, Room 2079, Seattle, Washington 98115.

*Council address*: North Pacific Fishery Management Council, 605 W. 4th Ave., Suite 306, Anchorage, AK 99501–2252.

**FOR FURTHER INFORMATION CONTACT:** Council Staff: 907–271–2809.

**SUPPLEMENTARY INFORMATION:** The Committee will meet from 9–5 p.m. The agenda consists of: A review of June 2002 Council motion, NMFS

Management and Implementation considerations for IR/IU; an industry presentation of bycatch reduction cooperative proposals; a discussion of the selection of bycatch alternatives to be presented to the Council, and the development of work assignments and set the date for next meeting.

Although other issues not contained in this notice may come before the Committee for discussion, in accordance with the Magnuson-Stevens Fishery Conservation and Management Act, those issues may not be the subject of formal action during the meeting. Action will be restricted to those issues specifically identified in this notice.

**Special Accommodations**

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Gail Bendixen, 907–271–2809, at least 5 working days prior to the meeting date.

Dated: August 9, 2002.

**Richard W. Surdi,**

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

[FR Doc. 02–20655 Filed 8–13–02; 8:45 am]

**BILLING CODE 3510–22–S**

## DEPARTMENT OF COMMERCE

## National Oceanic and Atmospheric Administration

**[I.D. 080502I]**

## North Pacific Fishery Management Council; Public Meeting

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

**ACTION:** Notice of committee meeting.

**SUMMARY:** The North Pacific Fishery Management Council's (Council) Improved Retention/Improved Utilization (IR/IU) Technical Committee will meet in Seattle, WA.

**DATES:** The meeting will be held on August 28–29, 2002, from 9 a.m. to 5 p.m. each day.

**ADDRESSES:** The meeting will be held at the Alaska Fishery Science Center, 7600 Sand Point Way NE, Bldg. 4, Room 2079, Seattle, WA 98115.

Council address: North Pacific Fishery Management Council, 605 W. 4th Ave., Suite 306, Anchorage, AK 99501–2252.

**FOR FURTHER INFORMATION CONTACT:** Council Staff: 907–271–2809

**SUPPLEMENTARY INFORMATION:** On Wednesday, August 28th and Thursday, August 29th, the Committee will meet at the Alaska Fishery Science Center. Agenda consists of: Review of June 2002 Council motion, NMFS Management and Implementation considerations for IR/IU; industry presentation of bycatch reduction cooperative proposals; discussion of selection of alternatives to be presented to the Council; develop work assignments of set dates for next meeting.

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the Council's intent to take final action to address the emergency.

**Special Accommodations**

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Gail Bendixen, 907–271–2809, at least 5 working days prior to the meeting date.

Dated: August 9, 2002.

**Richard W. Surdi,**

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

[FR Doc. 02–20659 Filed 8–13–02; 8:45 am]

**BILLING CODE 3510–22–S**

## DEPARTMENT OF COMMERCE

## National Oceanic and Atmospheric Administration

**[I.D. 080502F]**

## Pacific Fishery Management Council; Public Meeting

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

**ACTION:** Notice of public meeting; public scoping meeting.

**SUMMARY:** The Pacific Fishery Management Council's (Council) Ad Hoc Allocation Committee (Committee) will hold a working meeting, which is open to the public.

**DATES:** The Committee meeting will be held Wednesday, August 28, 2002, from 1 p.m. until business for the day is completed. The Committee meeting will reconvene on Thursday, August 29, 2002, from 8 a.m. until business is completed.

**ADDRESSES:** The Committee meeting will be held at the Shilo Inn, 11707 NE Airport Way, Portland, OR 97220; telephone: (503) 252–5800.

Council address: Pacific Fishery Management Council, 7700 NE Ambassador Place, Suite 200, Portland, OR 97220–1384.

**FOR FURTHER INFORMATION CONTACT:** Mr. John DeVore, Groundfish Fishery Management Coordinator; telephone: (503) 820–2280.

**SUPPLEMENTARY INFORMATION:** The purpose of the Committee meeting is to develop options for allocations and other management measures for the 2003 Pacific Coast groundfish fishery. In addition, the Committee will evaluate current catch levels of overfished groundfish species and may propose inseason adjustments. The Committee will discuss the types of provisions that may be necessary to prevent further overfishing, to reduce bycatch of overfished species in the various groundfish fisheries, and to reduce bycatch in non-groundfish fisheries. The Committee will also review a new stock assessment and rebuilding analysis for yelloweye rockfish. No management actions will be decided by the Committee. The Committee's role will be development of recommendations for consideration by the Pacific Fishery Management Council at its September meeting in Portland, OR.

Additionally, the Council will solicit public scoping comments for preparing the 2003 Pacific Coast groundfish annual specifications Environmental Impact Statement at 4 p.m. on

August 28. This will be the Council's primary decision document for recommending harvest specifications and management measures for the 2003 Pacific Coast groundfish fishery.

Although nonemergency issues not contained in the meeting agenda may come before the Committee for discussion, those issues may not be the subject of formal Committee action during this meeting. Committee action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the Committee's intent to take final action to address the emergency.

**Special Accommodations**

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Ms.

Carolyn Porter at (503) 820–2280 at least 5 days prior to the meeting date.

Dated: August 9, 2002.

**Richard W. Surdi,**

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

[FR Doc. 02–20660 Filed 8–13–02; 8:45 am]

**BILLING CODE 3510–22–S**

## COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE AGREEMENTS

### Adjustment of Import Limits for Certain Cotton and Man-Made Fiber Textile Products Produced or Manufactured in Nepal

August 8, 2002.

**AGENCY:** Committee for the Implementation of Textile Agreements (CITA).

**ACTION:** Issuing a directive to the Commissioner of customs adjusting limits.

**EFFECTIVE DATE:** August 14, 2002.

**FOR FURTHER INFORMATION CONTACT:** Roy Unger, International Trade Specialist, Office of Textiles and Apparel, U.S. Department of Commerce, (202) 482–4212. For information on the quota status of these limits, refer to the Quota Status Reports posted on the bulletin boards of each Customs port, call (202) 927–5850, or refer to the U.S. Customs website at http://www.customs.gov. For information on embargoes and quota re-openings, refer to the Office of Textiles and Apparel website at http://otexa.ita.doc.gov.

**SUPPLEMENTARY INFORMATION:**

**Authority:** Section 204 of the Agricultural Act of 1956, as amended (7 U.S.C. 1854); Executive Order 11651 of March 3, 1972, as amended.

The current limits for certain categories are being adjusted for swing, carryover, and special shift.

A description of the textile and apparel categories in terms of HTS numbers is available in the CORRELATION: Textile and Apparel Categories with the Harmonized Tariff Schedule of the United States (see **Federal Register** notice 66 FR 65178, published on December 18, 2001). Also see 66 FR 59581, published on November 29, 2001.

**James C. Leonard III,**

*Chairman, Committee for the Implementation of Textile Agreements.*

**Committee for the Implementation of Textile Agreements**

August 8, 2002.

Commissioner of Customs,

*Department of the Treasury, Washington, DC 20229*

Dear Commissioner: This directive amends, but does not cancel, the directive issued to you on November 23, 2001, by the Chairman, Committee for the Implementation of Textile Agreements. That directive concerns imports of certain cotton and man–made fiber textile products, produced or manufactured in Nepal and exported during the twelve-month period which began on January 1, 2002 and extends through December 31, 2002.

Effective on August 14, 2002, you are directed to adjust the limits for the following categories, as provided for under the terms of the current bilateral textile agreement between the Governments of the United States and Nepal:

| Category | Adjusted twelve-month limit [1] |
|---|---|
| 341 | 1,008,878 dozen. |
| 347/348 | 1,106,244 dozen. |
| 369–S [2] | 1,109,880 kilograms. |
| 641 | 440,664 dozen. |

[1] The limits have not been adjusted to account for any imports exported after December 31, 2001.

[2] Category 369–S: only HTS number 6307.10.2005.

The Committee for the Implementation of Textile Agreements has determined that these actions fall within the foreign affairs exception to the rulemaking provisions of 5 U.S.C. 553(a)(1).

Sincerely,

James C. Leonard III,

*Chairman, Committee for the Implementation of Textile Agreements.*

[FR Doc. 02–20578 Filed 8–13–02; 8:45 am]

**BILLING CODE 3510–DR–S**

## DEPARTMENT OF DEFENSE

### Office of the Secretary

### Revised Non-Foreign Overseas Per Diem Rates

**AGENCY:** DoD, Per Diem, Travel and Transportation Allowance Committee.

**ACTION:** Notice of revised non-foreign overseas per diem rates.

**SUMMARY:** The Per Diem, Travel and Transportation Allowance Committee is publishing Civilian Personnel Per Diem Bulletin Number 227. This bulletin lists revisions in the per diem rates prescribed for U.S. Government employees for official travel in Alaska, Hawaii, Puerto Rico, the Northern Mariana Islands and Possessions of the United States. AEA changes announced in Bulletin Number 194 remain in effect. Bulletin Number 227 is being published in the Federal Register to assure that travelers are paid per diem at the most current rates.

**EFFECTIVE DATE:** September 1, 2002.

**SUPPLEMENTARY INFORMATION:** This document gives notice of revisions in per diem rates prescribed by the Per Diem Travel and Transportation Allowance Committee for non-foreign areas outside the continental United States. It supersedes Civilian Personnel Per Diem Bulletin Number 226. Distribution of Civilian Personnel Per Diem Bulletins by mail was discontinued. Per Diem Bulletins published periodically in the Federal Register now constitute the only notification of revisions in per diem rates to agencies and establishments outside the Department of Defense. For more information or questions about per diem rates, please contact your local travel office. The text of the Bulletin follows:

Dated: August 8, 2002.

**Patricia L. Toppings,**

*Alternate OSD Federal Register Liaison Officer, Department of Defense.*

**BILLING CODE 5001–08–M**

Maximum Per Diem Rates for official travel in Alaska, Hawaii, the Commonwealths of Puerto Rico and the Northern Mariana Islands and Possessions of the United States by Federal Government civilian employees.

| LOCALITY | MAXIMUM LODGING AMOUNT (A) + | M&IE RATE (B) = | MAXIMUM PER DIEM RATE (C) | EFFECTIVE DATE |
|---|---|---|---|---|
| THE ONLY CHANGES IN CIVILIAN BULLETIN 227 ARE UPDATES TO RATES FOR GUAM; ROTA, SAIPAN, AND TINIAN, NORTHERN MARIANA ISLANDS. THE FOLLOWING LOCATIONS WERE ADDED MOLOKAI AND LANAI, HAWAII. | | | | |
| ALASKA | | | | |
| ANCHORAGE [INCL NAV RES] | | | | |
| 05/01 - 09/15 | 161 | 85 | 246 | 05/01/2002 |
| 09/16 - 04/30 | 85 | 77 | 162 | 05/01/2002 |
| BARROW | 159 | 95 | 254 | 05/01/2002 |
| BETHEL | 129 | 66 | 195 | 05/01/2002 |
| CLEAR AB | 80 | 55 | 135 | 09/01/2001 |
| COLD BAY | 90 | 73 | 163 | 05/01/2002 |
| COLDFOOT | 135 | 71 | 206 | 10/01/1999 |
| COPPER CENTER | 99 | 63 | 162 | 05/01/2002 |
| CORDOVA | 105 | 89 | 194 | 05/01/2002 |
| CRAIG | 75 | 57 | 132 | 05/01/2002 |
| DEADHORSE | 95 | 67 | 162 | 05/01/2002 |
| DELTA JUNCTION | 79 | 58 | 137 | 05/01/2002 |
| DENALI NATIONAL PARK | | | | |
| 06/01 - 08/31 | 125 | 66 | 191 | 09/01/2001 |
| 09/01 - 05/31 | 90 | 63 | 153 | 09/01/2001 |
| DILLINGHAM | 95 | 69 | 164 | 05/01/2002 |
| DUTCH HARBOR-UNALASKA | 120 | 78 | 198 | 05/01/2002 |
| EARECKSON AIR STATION | 80 | 55 | 135 | 09/01/2001 |
| EIELSON AFB | | | | |
| 05/01 - 09/15 | 149 | 78 | 227 | 05/01/2002 |
| 09/16 - 04/30 | 75 | 70 | 145 | 05/01/2002 |
| ELMENDORF AFB | | | | |
| 05/01 - 09/15 | 161 | 85 | 246 | 05/01/2002 |
| 09/16 - 04/30 | 85 | 77 | 162 | 05/01/2002 |
| FAIRBANKS | | | | |
| 05/01 - 09/15 | 149 | 78 | 227 | 05/01/2002 |
| 09/16 - 04/30 | 75 | 70 | 145 | 05/01/2002 |
| FOOTLOOSE | 175 | 18 | 193 | 06/01/2002 |
| FT. GREELY | 79 | 58 | 137 | 05/01/2002 |
| FT. RICHARDSON | | | | |
| 05/01 - 09/15 | 161 | 85 | 246 | 05/01/2002 |
| 09/16 - 04/30 | 85 | 77 | 162 | 05/01/2002 |
| FT. WAINWRIGHT | | | | |
| 05/01 - 09/15 | 149 | 78 | 227 | 05/01/2002 |
| 09/16 - 04/30 | 75 | 70 | 145 | 05/01/2002 |
| GLENNALLEN | | | | |
| 05/01 - 09/30 | 137 | 61 | 198 | 09/01/2001 |
| 10/01 - 04/30 | 89 | 56 | 145 | 09/01/2001 |
| HEALY | | | | |
| 06/01 - 08/31 | 125 | 66 | 191 | 09/01/2001 |
| 09/01 - 05/31 | 90 | 63 | 153 | 09/01/2001 |
| HOMER | | | | |
| 05/15 - 09/15 | 109 | 76 | 185 | 06/01/2002 |
| 09/16 - 05/14 | 76 | 72 | 148 | 06/01/2002 |

Maximum Per Diem Rates for official travel in Alaska, Hawaii, the Commonwealths of Puerto Rico and the Northern Mariana Islands and Possessions of the United States by Federal Government civilian employees.

| LOCALITY | MAXIMUM LODGING AMOUNT (A) + | M&IE RATE (B) = | MAXIMUM PER DIEM RATE (C) | EFFECTIVE DATE |
|---|---|---|---|---|
| JUNEAU | 119 | 83 | 202 | 05/01/2002 |
| KAKTOVIK | 165 | 86 | 251 | 05/01/2002 |
| KAVIK CAMP | 150 | 69 | 219 | 05/01/2002 |
| KENAI-SOLDOTNA | | | | |
| 04/01 - 10/31 | 95 | 76 | 171 | 05/01/2002 |
| 11/01 - 03/31 | 60 | 71 | 131 | 05/01/2002 |
| KENNICOTT | 159 | 77 | 236 | 05/01/2002 |
| KETCHIKAN | | | | |
| 05/01 - 09/30 | 130 | 80 | 210 | 05/01/2002 |
| 10/01 - 04/30 | 100 | 80 | 180 | 05/01/2002 |
| KING SALMON | | | | |
| 05/01 - 10/01 | 225 | 91 | 316 | 05/01/2002 |
| 10/02 - 04/30 | 125 | 81 | 206 | 05/01/2002 |
| KLAWOCK | 75 | 57 | 132 | 05/01/2002 |
| KODIAK | 105 | 81 | 186 | 05/01/2002 |
| KOTZEBUE | | | | |
| 05/01 - 08/31 | 167 | 99 | 266 | 06/01/2002 |
| 09/01 - 04/30 | 136 | 96 | 232 | 06/01/2002 |
| KULIS AGS | | | | |
| 05/01 - 09/15 | 161 | 85 | 246 | 05/01/2002 |
| 09/16 - 04/30 | 85 | 77 | 162 | 05/01/2002 |
| MCCARTHY | 159 | 77 | 236 | 05/01/2002 |
| METLAKATLA | | | | |
| 05/30 - 10/01 | 98 | 48 | 146 | 05/01/2002 |
| 10/02 - 05/29 | 78 | 47 | 125 | 05/01/2002 |
| MURPHY DOME | | | | |
| 05/01 - 09/15 | 149 | 78 | 227 | 05/01/2002 |
| 09/16 - 04/30 | 75 | 70 | 145 | 05/01/2002 |
| NOME | 120 | 103 | 223 | 07/01/2002 |
| NUIQSUT | 180 | 53 | 233 | 05/01/2002 |
| POINT HOPE | 130 | 70 | 200 | 03/01/1999 |
| POINT LAY | 105 | 67 | 172 | 03/01/1999 |
| PORT ALSWORTH | 135 | 88 | 223 | 05/01/2002 |
| PRUDHOE BAY | 95 | 67 | 162 | 05/01/2002 |
| SEWARD | | | | |
| 05/31 - 09/30 | 174 | 105 | 279 | 07/01/2002 |
| 10/01 - 05/30 | 79 | 96 | 175 | 07/01/2002 |
| SITKA-MT. EDGECUMBE | | | | |
| 05/16 - 09/16 | 159 | 98 | 257 | 05/01/2002 |
| 09/17 - 05/15 | 139 | 97 | 236 | 05/01/2002 |
| SKAGWAY | | | | |
| 05/01 - 09/30 | 130 | 80 | 210 | 05/01/2002 |
| 10/01 - 04/30 | 100 | 80 | 180 | 05/01/2002 |
| SPRUCE CAPE | 105 | 81 | 186 | 05/01/2002 |
| ST. GEORGE | 105 | 39 | 144 | 07/01/2002 |
| TALKEETNA | 100 | 89 | 189 | 07/01/2002 |
| TANANA | 120 | 103 | 223 | 07/01/2002 |
| TOGIAK | 100 | 39 | 139 | 07/01/2002 |
| UMIAT | 200 | 20 | 220 | 05/01/2002 |
| VALDEZ | | | | |

Maximum Per Diem Rates for official travel in Alaska, Hawaii, the Commonwealths of Puerto Rico and the Northern Mariana Islands and Possessions of the United States by Federal Government civilian employees.

| LOCALITY | MAXIMUM LODGING AMOUNT (A) + | M&IE RATE (B) = | MAXIMUM PER DIEM RATE (C) | EFFECTIVE DATE |
|---|---|---|---|---|
| 05/01 - 10/01 | 124 | 71 | 195 | 05/01/2002 |
| 10/02 - 04/30 | 69 | 66 | 135 | 05/01/2002 |
| WAINWRIGHT | 120 | 83 | 203 | 05/01/2002 |
| WASILLA | 95 | 60 | 155 | 01/01/2000 |
| WRANGELL | | | | |
| 05/01 - 09/30 | 130 | 80 | 210 | 05/01/2002 |
| 10/01 - 04/30 | 100 | 80 | 180 | 05/01/2002 |
| YAKUTAT | 110 | 68 | 178 | 03/01/1999 |
| [OTHER] | 80 | 55 | 135 | 09/01/2001 |
| AMERICAN SAMOA | | | | |
| AMERICAN SAMOA | 85 | 67 | 152 | 03/01/2000 |
| GUAM | | | | |
| GUAM (INCL ALL MIL INSTAL) | 135 | 76 | 211 | 09/01/2002 |
| HAWAII | | | | |
| CAMP H M SMITH | 112 | 72 | 184 | 06/01/2002 |
| EASTPAC NAVAL COMP TELE AREA | 112 | 72 | 184 | 06/01/2002 |
| FT. DERUSSEY | 112 | 72 | 184 | 06/01/2002 |
| FT. SHAFTER | 112 | 72 | 184 | 06/01/2002 |
| HICKAM AFB | 112 | 72 | 184 | 06/01/2002 |
| HONOLULU (INCL NAV & MC RES CTR) | 112 | 72 | 184 | 06/01/2002 |
| ISLE OF HAWAII: HILO | 108 | 69 | 177 | 06/01/2002 |
| ISLE OF HAWAII: OTHER | 89 | 54 | 143 | 05/01/2000 |
| ISLE OF KAUAI | | | | |
| 05/01 - 11/30 | 158 | 88 | 246 | 06/01/2002 |
| 12/01 - 04/30 | 203 | 93 | 296 | 06/01/2002 |
| ISLE OF KURE | 65 | 41 | 106 | 05/01/1999 |
| ISLE OF MAUI | 159 | 89 | 248 | 06/01/2002 |
| ISLE OF OAHU | 112 | 72 | 184 | 06/01/2002 |
| KEKAHA PACIFIC MISSILE RANGE FAC | | | | |
| 05/01 - 11/30 | 158 | 88 | 246 | 06/01/2002 |
| 12/01 - 04/30 | 203 | 93 | 296 | 06/01/2002 |
| KILAUEA MILITARY CAMP | 108 | 69 | 177 | 06/01/2002 |
| LANAI | 299 | 138 | 437 | 09/01/2002 |
| LUALUALEI NAVAL MAGAZINE | 112 | 72 | 184 | 06/01/2002 |
| MCB HAWAII | 112 | 72 | 184 | 06/01/2002 |
| MOLOKAI | 195 | 111 | 306 | 09/01/2002 |
| NAS BARBERS POINT | 112 | 72 | 184 | 06/01/2002 |
| PEARL HARBOR [INCL ALL MILITARY] | 112 | 72 | 184 | 06/01/2002 |
| SCHOFIELD BARRACKS | 112 | 72 | 184 | 06/01/2002 |
| WHEELER ARMY AIRFIELD | 112 | 72 | 184 | 06/01/2002 |
| [OTHER] | 72 | 61 | 133 | 01/01/2000 |
| JOHNSTON ATOLL | | | | |
| JOHNSTON ATOLL | 0 | 14 | 14 | 05/01/2002 |
| MIDWAY ISLANDS | | | | |
| MIDWAY ISLANDS [INCL ALL MILITAR | 150 | 47 | 197 | 02/01/2000 |
| NORTHERN MARIANA ISLANDS | | | | |
| ROTA | 129 | 88 | 217 | 09/01/2002 |
| SAIPAN | 152 | 120 | 272 | 09/01/2002 |
| TINIAN | 66 | 72 | 138 | 09/01/2002 |
| [OTHER] | 55 | 72 | 127 | 04/01/2000 |

Maximum Per Diem Rates for official travel in Alaska, Hawaii, the Commonwealths of Puerto Rico and the Northern Mariana Islands and Possessions of the United States by Federal Government civilian employees.

| LOCALITY | MAXIMUM LODGING AMOUNT (A) + | M&IE RATE (B) = | MAXIMUM PER DIEM RATE (C) | EFFECTIVE DATE |
|---|---|---|---|---|
| PUERTO RICO | | | | |
| BAYAMON | | | | |
| 04/11 - 12/23 | 155 | 71 | 226 | 01/01/2000 |
| 12/24 - 04/10 | 195 | 75 | 270 | 01/01/2000 |
| CAROLINA | | | | |
| 04/11 - 12/23 | 155 | 71 | 226 | 01/01/2000 |
| 12/24 - 04/10 | 195 | 75 | 270 | 01/01/2000 |
| FAJARDO [INCL CEIBA & LUQUILLO] | 82 | 54 | 136 | 01/01/2000 |
| FT. BUCHANAN [INCL GSA SVC CTR, | | | | |
| 04/11 - 12/23 | 155 | 71 | 226 | 01/01/2000 |
| 12/24 - 04/10 | 195 | 75 | 270 | 01/01/2000 |
| HUMACAO | 82 | 54 | 136 | 01/01/2000 |
| LUIS MUNOZ MARIN IAP AGS | | | | |
| 04/11 - 12/23 | 155 | 71 | 226 | 01/01/2000 |
| 12/24 - 04/10 | 195 | 75 | 270 | 01/01/2000 |
| MAYAGUEZ | 85 | 59 | 144 | 01/01/2000 |
| PONCE | 96 | 69 | 165 | 01/01/2000 |
| ROOSEVELT RDS & NAV STA | 82 | 54 | 136 | 01/01/2000 |
| SABANA SECA [INCL ALL MILITARY] | | | | |
| 04/11 - 12/23 | 155 | 71 | 226 | 01/01/2000 |
| 12/24 - 04/10 | 195 | 75 | 270 | 01/01/2000 |
| SAN JUAN & NAV RES STA | | | | |
| 04/11 - 12/23 | 155 | 71 | 226 | 01/01/2000 |
| 12/24 - 04/10 | 195 | 75 | 270 | 01/01/2000 |
| [OTHER] | 62 | 57 | 119 | 01/01/2000 |
| VIRGIN ISLANDS (U.S.) | | | | |
| ST. CROIX | | | | |
| 04/15 - 12/14 | 93 | 72 | 165 | 01/01/2000 |
| 12/15 - 04/14 | 129 | 76 | 205 | 01/01/2000 |
| ST. JOHN | | | | |
| 04/15 - 12/14 | 219 | 84 | 303 | 01/01/2000 |
| 12/15 - 04/14 | 382 | 100 | 482 | 01/01/2000 |
| ST. THOMAS | | | | |
| 04/15 - 12/14 | 163 | 73 | 236 | 01/01/2000 |
| 12/15 - 04/14 | 288 | 86 | 374 | 01/01/2000 |
| WAKE ISLAND | | | | |
| WAKE ISLAND | 60 | 32 | 92 | 09/01/1998 |

[FR Doc. 02–20503 Filed 8–13–02; 8:45 am]
BILLING CODE 5001–08–C

## DEPARTMENT OF DEFENSE

### Department of the Army

### Armed Forces Epidemiological Board; Meeting

**AGENCY:** Department of the Army, DoD.

**ACTION:** Notice of open meeting.

**SUMMARY:** In accordance with section 10(a)(2) of Public Law 92–463, The Federal Advisory Committee Act, announcement is made of the following meeting:

*Name of Committee:* Armed Forces Epidemiological Board (AFEB).

*Dates:* September 17–18, 2002.

*Time:* 7:30 a.m.–5:30 p.m. (September 17, 2002). 7:00 a.m.–5:20 p.m. (September 18, 2002).

*Location:* The Thayer Hotel, 674 Thayer Road, West Point Military Academy, West Point, NY 10996.

*Agenda:* The purpose of the meeting is to address pending and new Board issues, provide briefings for Board members on topics related to ongoing and new Board issues, conduct subcommittee meetings, and conduct an executive working session.

**FOR FURTHER INFORMATION CONTACT:** Colonel James R. Riddle, Executive Secretary, Armed Forces Epidemiological Board, Skyline Six, 5109 Leesburg Pike, Room 682, Falls Church, Va 22041–3258, (703) 681–8012/3.

**SUPPLEMENTARY INFORMATION:** Open sessions of the meeting will be limited by space accommodations. The meeting will be open to the public in accordance with Section 552b(c) of Title 5, U.S.C., specifically subparagraph (1) thereof and Title 5, U.S.C., appendix 1, subsection 10(d). Any interested person may attend, appear before or file statements with the committee at the time and in the manner permitted by the committee.

**Luz D. Ortiz,**

*Army Federal Register Liaison Officer.*

[FR Doc. 02–20647 Filed 8–13–02; 8:45 am]
BILLING CODE 3710–08–M

## DEPARTMENT OF DEFENSE

### Department of the Army; Corps of Engineers

### Intent to Prepare a Supplemental Environmental Impact Statement for the Lower Mud River Watershed Project, Milton, Cabell County, WV

**AGENCY:** Department of the Army, U.S. Army Corps of Engineers, DoD.

**ACTION:** Notice of intent.

**SUMMARY:** Pursuant to the National Environmental Policy Act (NEPA), the U.S. Army Corps of Engineers (Corps), Huntington District will prepare a Supplemental Environmental Impact Statement (SEIS). The SEIS will evaluate potential impacts to the natural, physical, and human environment as a result of the proposed flood damage reduction measures for the area at the City of Milton, Cabell County, West Virginia (Lower Mud River Project). The Corps is soliciting public concerns/issues to be evaluated during the study process.

**ADDRESSES:** Send written comments and suggestions concerning this proposed project to S. Michael Worley PM–PD, U.S. Army Corps of Engineers, Huntington District, 502 Eighth Street, Huntington, WV 25701–2070. Telephone: (304) 529–5712. Electronic mail: *Stephen.M.Worley @Lrh01.usace.army.mil.* Requests to be placed on the mailing list should also be sent to this address.

**FOR FURTHER INFORMATION CONTACT:** Mr. Louis E. Aspey PM–P, U.S. Army Corps of Engineers, Huntington District, 502 Eighth Street, Huntington, WV, 25701–2070. Telephone: (304) 528–7446. Electronic mail: *louisa@Lrh01.usace.army.mil.*

**SUPPLEMENTARY INFORMATION:**

1. *Authority:* The proposed project is authorized under Section 580 of the Water Resources Development Act (WRDA) of 1996, which provides the Corps authority ''* * * to conduct a limited reevaluation of the watershed plan and environmental impact statement prepared for the Lower Mud River, Milton, W.V., by the Natural Resources Conservation Service, pursuant to the Watershed Protection and Flood Prevention Act (16 U.S.C. 1001 *et seq.*) and may carry out the project,'' and Section 340 of the WRDA of 2000, which reads: ''Modifies Lower Mud River project at Milton authority (Sec 580 of WRDA of 1996) to direct the COE to construct the project as selected in the COE reevaluation report.''

2. *Background:* Under authority of the Watershed Protection and Flood Prevention Act (Pub. L. 83–566), the Natural Resources Conservation Service (NRCS) began an investigation of land and water resource problems, including flooding, in the Lower Mud River watershed in 1972. This early investigation culminated with completion of the Lower Mud River Watershed Plan and Environmental Impact Statement (EIS) in May 1993, in which a channel modification project on the Mud River in the vicinity of Milton was recommended. Section 580 of WRDA 1996 provided the Corps authority to re-evaluate that study and construct a project.

Alternatives being initially considered include the NRCS recommended plan (channel modification); four levee alternatives; a diversion alternative; non-structural alternatives; and the no action. The levee alternatives include a levee providing low-level of protection, two levees that would provide protection from 100-year floods, and a levee that would protect Milton to a 500-year flood level. Alternatives to be evaluated in detail in the SEIS will be selected from the those described above.

3. *Public Participation:* The Corps invites full public participation to promote open communication and better decision-making. All persons and organizations that have an interest in the Lower Mud River flooding problems as they affect the community of Milton, West Virginia and the environment are urged to participate in this NEPA environmental analysis process. Assistance will be provided upon request to anyone having difficulty with learning how to participate.

Public comments are welcomed anytime throughout the NEPA process. Formal opportunities for public participation include: (1) Public meetings to be held near the community of Milton; (2) Anytime during the NEPA process via mail, telephone or e-mail; (3) During Review and Comment on the Draft EIS—approximately January 2003; and, (4) Review of the Final EIS–Spring 2003. Schedules and locations will be announced in local news media. Interested parties should submit contact information to be included on the mailing list for public distribution of meeting announcements and documents (*See* **ADDRESSES**).

**Luz D. Ortiz,**

*Army Federal Register Liaison Officer.*

[FR Doc. 02–20650 Filed 8–13–02; 8:45 am]
BILLING CODE 3710–GM–M

## DEPARTMENT OF DEFENSE

### Department of the Army; Corps of Engineers

### Coastal Engineering Research Board

**AGENCY:** Department of the Army, DoD.

**ACTION:** Notice of open meeting.

**SUMMARY:** In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), announcement is made of the following committee meeting:

*Name of Committee:* Coastal Engineering Research Board (CERB).

*Date of Meeting:* September 10–11, 2002.

*Place:* The Sanderling, Duck, North Carolina.

*Time:* 8 a.m. to 3:45 p.m. (September 10, 2002), 8 a.m. to 4 p.m. (September 11, 2002).

**FOR FURTHER INFORMATION CONTACT:** Inquiries and notice of intent to attend the meeting may be addressed to Colonel John W. Morris III, Executive Secretary, U.S. Army Engineer Research and Development Center, Waterways Experiment Station, 3909 Halls Ferry Road, Vicksburg, Mississippi 39180–6199.

**SUPPLEMENTARY INFORMATION:**

*Proposed Agenda:* The theme of the meeting is ''Field Data Collection.'' On Tuesday, September 10, the morning session will consist of presentations dealing with the ''National Shoreline Management Study,'' ''National Regional Sediment Management (RSM) Demonstration Program,'' ''Section 227 Report and Coastal Engineering Manual—Status and Maintenance,'' ''Coastal Louisiana Study,'' and panel presentations concerning ''Agency Approaches to Regional Coastal Mapping.'' The afternoon session will consist of panel presentations concerning ''Beach-Fill Monitoring Performance Analysis.'' On the evening of September 10, a tour of the Field Research Facility is scheduled. On Wednesday, September 11, there will be panel presentations concerning ''The Integrated Ocean Observing System—National Program'' and ''The Integrated Ocean Observing System—Corps Activities,'' followed by an Executive Working Session. An optional field trip is planned for the afternoon on September 11.

These meetings are open to the public; participation by the public is scheduled for 11:15 a.m. on September 11.

The entire meeting is open to the public, but since seating capacity of the meeting room is limited, advance notice of intent to attend, although not required, is requested in order to assure adequate arrangements. Oral participation by public attendees is encouraged during the time scheduled on the agenda; written statements may be submitted prior to the meeting or up to 30 days after the meeting.

**John W. Morris III,**

*Colonel, Corps of Engineers, Executive Secretary.*

[FR Doc. 02–20649 Filed 8–13–02; 8:45 am]

**BILLING CODE 3710–61–M**

## DEPARTMENT OF DEFENSE

### Department of the Army; Corps of Engineers

### Estuary Habitat Restoration Council; Meeting

**AGENCY:** Department of the Army, U.S. Army Corps of Engineers, DoD.

**ACTION:** Notice of open meeting.

**SUMMARY:** In accordance with Section 105(h) of the Estuary Restoration Act of 2000, (Title I, Pub. L. 106–457), announcement is made of the forthcoming meeting of the Estuary Habitat Restoration Council. The meeting is open to the public.

*Date:* August 28, 2002, from 10 a.m. to 12 p.m.

*Location:* 441 G Street, NW., Room 3M60/70, Washington, DC

**FOR FURTHER INFORMATION CONTACT:** Ms. Ellen Cummings, Headquarters, U.S. Army Corps of Engineers, Washington, DC 20314–1000, (202) 761–4558; or Ms. Cynthia Garman-Squier, Office of the Assistant Secretary of the Army (Civil Works), Washington, DC, (703) 695–6791.

**SUPPLEMENTARY INFORMATION:** The Estuary Habitat Restoration Council consists of representatives of five agencies. These are the National Oceanic and Atmospheric Administration, Environmental Protection Agency, U.S. Fish and Wildlife Service, Department of Agriculture, and Army. Among the duties of the Council is development of a national estuary restoration strategy designed in part to meet the goal of restoring one million acres by 2010.

Items the Council will consider at this meeting include the nature of the comments received on the draft Estuary Habitat Restoration Strategy, general extent and nature of proposed revisions, and the guidelines for submission of estuary restoration project proposals. There will be an informational presentation on the National Estuary Program by a representative of the Environmental Protection Agency.

Current security measures require that persons interested in attending the meeting must pre-register with us before 2 p.m. August 26, 2002. Please contact Ellen Cummings at 202–761–4558 to pre-register. When leaving a voice mail message please provide the name of the individual attending, the company or agency represented, and a telephone number, in case there are any questions. The public should enter on the ''G'' Street side of the GAO building. All attendees are required to show photo identification and must be escorted to the meeting room by Corps personnel. Attendee's bags and other possessions are subject to being searched. All attendees arriving between one-half hour before and one-half hour after 10 a.m. will be escorted to the hearing. Those that are not pre-registered and/or arriving later than the allotted time will be unable to attend the public hearing.

**Luz D. Ortiz,**

*Army Federal Register Liaison Officer.*

[FR Doc. 02–20648 Filed 8–13–02; 8:45 am]

**BILLING CODE 3710–02–M**

## DEPARTMENT OF EDUCATION

### Notice of Proposed Information Collection Requests

**AGENCY:** Department of Education.

**SUMMARY:** The Leader, Regulatory Information Management Group, Office of the Chief Information Officer, invites comments on the proposed information collection requests as required by the Paperwork Reduction Act of 1995.

**DATES:** Interested persons are invited to submit comments on or before October 15, 2002.

**SUPPLEMENTARY INFORMATION:** Section 3506 of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35) requires that the Office of Management and Budget (OMB) provide interested Federal agencies and the public an early opportunity to comment on information collection requests. OMB may amend or waive the requirement for public consultation to the extent that public participation in the approval process would defeat the purpose of the information collection, violate State or Federal law, or substantially interfere with any agency's ability to perform its statutory obligations. The Leader, Regulatory Information Management Group, Office of the Chief Information Officer, publishes that notice containing proposed information collection requests prior to submission of these requests to OMB. Each proposed

information collection, grouped by office, contains the following: (1) Type of review requested, *e.g.* new, revision, extension, existing or reinstatement; (2) title; (3) summary of the collection; (4) description of the need for, and proposed use of, the information; (5) respondents and frequency of collection; and (6) reporting and/or recordkeeping burden. OMB invites public comment. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology.

Dated: August 9, 2002.

**John D. Tressler,**

*Leader, Regulatory Information Management Group, Office of the Chief Information Officer.*

**Office of Educational Research and Improvement**

*Type of Review:* Revision.

*Title:* Education Longitudinal Study (ELS) of 2002, First Followup.

*Frequency:* One time.

*Affected Public:* Individuals or household; Not-for-profit institutions; State, Local, or Tribal Gov't, SEAs or LEAs.

*Reporting and Recordkeeping Hour Burden:*

*Responses:* 1,270.

*Burden Hours:* 941.

*Abstract:* The ELS:2002 first followup is the second time this cohort of students, who were in 10th grade in 2002, will be interviewed and assessed. The field test for this survey will be conducted in spring 2003 with 53 schools in five states. Data will be collected from students, dropouts, and school administrators. The full scale study will be conducted in spring 2004 in 754 schools in all 50 states and the District of Columbia. This longitudinal study is intended to measure school effectiveness and impact on postsecondary and labor market outcomes.

Requests for copies of the proposed information collection request may be accessed from *http://edicsweb.ed.gov,* by selecting the ''Browse Pending Collections'' link and by clicking on link number 2064. When you access the information collection, click on ''Download Attachments ''to view. Written requests for information should be addressed to Vivian Reese, Department of Education, 400 Maryland Avenue, SW, Room 4050, Regional Office Building 3, Washington, DC 20202–4651 or to the e-mail address *Vivian.Reese@ed.gov.* Requests may also be electronically mailed to the Internet address *OCIO__RIMG@ed.gov* or faxed to 202–708–9346. Please specify the complete title of the information collection when making your request.

Comments regarding burden and/or the collection activity requirements should be directed to Kathy Axt at *Kathy.Axt@ed.gov.* Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339.

[FR Doc. 02–20664 Filed 8–13–02; 8:45 am]

**BILLING CODE 4000–01–P**

## DEPARTMENT OF EDUCATION

### Submission for OMB Review; Comment Request

**AGENCY:** Department of Education

**SUMMARY:** The Leader, Regulatory Information Management Group, Office of the Chief Information Officer invites comments on the submission for OMB review as required by the Paperwork Reduction Act of 1995.

**DATES:** Interested persons are invited to submit comments on or before September 13, 2002.

**ADDRESSES:** Written comments should be addressed to the Office of Information and Regulatory Affairs, Attention: Karen Lee, Desk Officer, Department of Education, Office of Management and Budget, 725 17th Street, N.W., Room 10202, New Executive Office Building, Washington, DC 20503 or should be electronically mailed to the Internet address *Karen_F._Lee@omb.eop.gov.*

**SUPPLEMENTARY INFORMATION:** Section 3506 of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35) requires that the Office of Management and Budget (OMB) provide interested Federal agencies and the public an early opportunity to comment on information collection requests. OMB may amend or waive the requirement for public consultation to the extent that public participation in the approval process would defeat the purpose of the information collection, violate State or Federal law, or substantially interfere with any agency's ability to perform its statutory obligations. The Leader, Regulatory Information Management Group, Office of the Chief Information Officer, publishes that notice containing proposed information collection requests prior to submission of these requests to OMB. Each proposed information collection, grouped by office, contains the following: (1) Type of review requested, e.g. new, revision, extension, existing or reinstatement; (2) Title; (3) Summary of the collection; (4) Description of the need for, and proposed use of, the information; (5) Respondents and frequency of collection; and (6) Reporting and/or Recordkeeping burden. OMB invites public comment.

Dated: August 8, 2002.

**John D. Tressler,**

*Leader, Regulatory Information Management, Office of the Chief Information Officer.*

*Office of Educational Research and Improvement*

*Type of Review:* Revision.

*Title:* International Adult Literacy and Lifeskills Survey.

*Frequency:* One time.

*Affected Public:* Individuals or household; Not-for-profit institutions; State, Local, or Tribal Gov't, SEAs or LEAs.

*Reporting and Recordkeeping Hour Burden:* Responses: 9,740. Burden Hours: 6,731.

*Abstract:* The International Adult Literacy and Lifeskills Survey (IALLS) will collect internationally comparable information on the literacy and numberacy performancy of adults from around the world. The IALLS will be administered in the general household population aged 16–65 and in selected federally-funded adult education programs. The IALLS household assessment will provide a detailed picture of the literacy and numeracy skills of U.S. adults compared to adults in other countries. The IALLS adult education program assessment will show the literacy skills of the adults enrolled in adult education programs and how they differ from the U.S. general population and international populations.

Requests for copies of the submission for OMB review; comment request may be accessed from *http://edicsweb.ed.gov*, by selecting the ''Browse Pending Collections'' link and by clicking on link number 2063. When you access the information collection, click on ''Download Attachments '' to view. Written requests for information should be addressed to Vivian Reese, Department of Education, 400 Maryland Avenue, SW., Room 4050, Regional Office Building 3, Washington, DC 20202–4651 or to the e-mail address *vivan.reese@ed.gov.* Requests may also

be electronically mailed to the Internet address *OCIO__RIMG@ed.gov* or faxed to 202–708–9346. Please specify the complete title of the information collection when making your request.

Comments regarding burden and/or the collection activity requirements should be directed to Katrina Ingalls at her e-mail address *Katrina.Ingalls@ed.gov.* Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339.

[FR Doc. 02–20504 Filed 8–13–02; 8:45 am]

**BILLING CODE 4000–01–P**

## DEPARTMENT OF EDUCATION

### Secretary of Education's Commission on Opportunity in Athletics; Meeting

**AGENCY:** Secretary of Education's Commission on Opportunity in Athletics; Department of Education.

**ACTION:** Notice of open meeting.

**SUMMARY:** This notice sets forth the schedule and proposed agenda of a forthcoming public meeting of the Secretary of Education's Commission on Opportunity in Athletics (the Commission). The Commission invites comments from the public regarding the application of current Federal standards for ensuring equal opportunity for men and women and boys and girls to participate in athletics under Title IX of the Education Amendments of 1972 (''Title IX''). The meeting will take place in Atlanta, Georgia. Individuals who will need accommodations for a disability in order to attend the meetings should notify the Commission office no later than Thursday, August 22, 2002.

We will attempt to meet requests after this date, but cannot guarantee availability of the requested accommodation. The meeting site is accessible to individuals with disabilities.

Notice of this meeting is required under Section 10(a)(2) of the Federal Advisory Committee Act.

**DATES:** August 27–28, 2002.

*Location:* Wyndham Downtown Hotel, 160 Spring St., NW., Atlanta, Georgia, 30309.

*Times:* August 27: 9 a.m.–12:30 p.m., 2 p.m.–5 p.m. August 28: 9 a.m.–1 p.m.:

*Meeting Format:* This meeting will be held according to the following schedule:

1. *Date:* August 27, 2002, Time: 9 a.m. to 12:30 p.m., 2 p.m.–5p.m.

2. *Date:* August 28, 2002, Time: 9 a.m. to 1 p.m.

*Attendees:* If you would like to attend any or all of the above listed meetings, we ask that you register with the Commission office by email or fax to the address listed under **ADDRESSES**. Please provide us with your name and contact information.

*Participants:* The meeting scheduled for August 27, 2002 will begin with presentations from panels of invited speakers. After the presentations by invited speakers, there will be time reserved for comments from the public. This period for public comment will continue on August 28.

If you are interested in participating in the public comment period to present comments on the Federal standards for ensuring equal opportunity for men and women to participate in athletics under Title IX at this meeting, you are requested to reserve time on the agenda of the meeting by contacting the Commission office by email or fax.

We request that you submit a request to the Commission office by email or fax. Please include your name, the organization you represent if appropriate, and a brief description of the issue you would like to present. Participants will be allowed approximately 3 to 5 minutes to present their comments, depending on the number of individuals who reserve time on the agenda. At the meeting, participants are also encouraged to submit two written copies of their comments. Persons interested in making comments are encouraged to address the issues and questions discussed under **SUPPLEMENTARY INFORMATION.**

Given the expected number of individuals interested in providing comments at the meetings, reservations for presenting comments should be made as soon as possible. Persons who are unable to obtain reservations to speak during the meetings are encouraged to submit written comments. Written comments will be accepted at each meeting site or may be mailed to the Commission at the address listed under **ADDRESSES**.

In addition to making reservations, individuals attending the public meetings, for security purposes, must be prepared to show photo identification in order to enter the meeting location.

*Request for Written Comments:* In addition to soliciting input during the public meetings, we invited the public to submit written comments relevant to the Commission.

**DATES:** We would like to receive your written comments on the Act by November 29, 2002.

**ADDRESSES:** Submit all comments to the Commission using one of the following methods:

1. *Internet:* We encourage you to send your comments through the Internet to the following address: *OpportunityinAthletics@ed.gov*

2. *Mail.* You may submit your comments to The Secretary of Education's Commission on Opportunity in Athletics, 400 Maryland Avenue, SW., ROB–3 Room 3060, Washington, DC 20202. Due to delays in mail delivery caused by heightened security, please allow adequate time for the mail to be received.

3. *Facsimile.* You may submit comments by facsimile at (202) 260–4560.

**FOR FURTHER INFORMATION CONTACT:** See the Commission address under the **ADDRESSES** section of the notice. View the Commission's Web site at: *http://www.ed.gov/inits/commissionsboards/athletics.* The Commission office number is 202–708–7417.

**SUPPLEMENTARY INFORMATION:** The nation is commemorating the 30th anniversary of the passage of Title IX, the landmark legislation prohibiting recipients of Federal funds from discriminating on the basis of sex. Since this legislation was enacted, there has been a dramatic increase in the number of women participating in athletics at the high school and college levels. The Secretary of Education has determined that this anniversary provides an appropriate time to review the application of Title IX to educational institutions' efforts to provide equal opportunity in athletics to women and men. In order to do so, the Secretary established the Commission on Opportunity in Athletics. The Commission will produce a report no later than January 31, 2002, outlining its findings relative to the opportunities for men and women in athletics in order to improve the effectiveness of Title IX.

Comments are encouraged on the following priority areas:

1. Are Title IX standards for assessing equal opportunity in athletics working to promote opportunities for male and female athletes?

2. Is there adequate Title IX guidance that enables colleges and school districts to know what is expected of them and to plan for an athletic program that effectively meets the needs and interests of their students?

3. Is further guidance or are other steps need at the junior and senior high school levels where the availability or absence of opportunities will critically affect the prospective interests and abilities of student athletes when they reach college age?

4. How should activities such as cheerleading or bowling factor into the analysis of equitable opportunities?

5. How do revenue producing and large-roster teams affect the provision of equal athletic opportunities? The Department has heard from some parties that whereas some men athletes will ''walk-on'' to intercollegiate teams—without athletic financial aid and without having been recruited—women rarely do this. Is this accurate and, if so, what are its implications for Title IX analysis?

6. In what ways do opportunities in other sports venues, such as the Olympics, professional leagues, and community recreation programs, interact with the obligations of colleges and school districts to provide equal athletic opportunity? What are the implications for Title IX?

7. Apart from Title IX enforcement, are there other efforts to promote athletic opportunities for male and female students that the Department might support, such as public-private partnerships to support the efforts of schools and colleges in this area?

**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 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: August 9, 2002.

**Deborah Price,**

*Executive Director, the Secretary of Education's Commission on Opportunity in Athletics.*

[FR Doc. 02–20675 Filed 8–9–02; 5:06 pm]

BILLING CODE 4000–01–M

## DEPARTMENT OF ENERGY

### Office of Fossil Energy

**[FE Docket Nos. 02–44–NG, 00–23–NG, 02–48–NG, 02–47–NG, 02–49–NG, 01–87–NG, 02–50–NG, 02–52–NG, 02–51–NG, 02–53–NG]**

### BP West Coast Products, LLC, et al.; Orders Granting, Amending and Vacating Authority To Import and Export Natural Gas, Including Liquefied Natural Gas

**AGENCY:** Office of Fossil Energy, DOE.

**ACTION:** Notice of Orders.

**SUMMARY:** The Office of Fossil Energy (FE) of the Department of Energy gives notice that during July 2002, it issued Orders granting, amending and vacating authority to import and export natural gas, including liquefied natural gas. These Orders are summarized in the attached appendix and may be found on the FE Web site at *http://www.fe.doe.gov* (select gas regulation), or on the electronic bulletin board at (202) 586–7853. They are also available for inspection and copying in the Office of Natural Gas & Petroleum Import & Export Activities, Docket Room 3E–033, Forrestal Building, 1000 Independence Avenue, SW., Washington, DC 20585, (202) 586–9478. The Docket Room is open between the hours of 8 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays.

Issued in Washington, DC, on August 6, 2002.

**Clifford P. Tomaszewski,**

*Manager, Natural Gas Regulation, Office of Natural Gas & Petroleum Import & Export Activities, Office of Fossil Energy.*

**Appendix; Orders Granting, Amending and Vacating Import/Export Authorizations**

DOE/FE AUTHORITY

| Order No. | Date issued | Importer/exporter FE docket No. | Import volume | Export volume | Comments |
|---|---|---|---|---|---|
| 1794 | 7–2–02 | BP West Coast Products, LLC, 02–44–NG. | 25 Bcf | 25 Bcf | Import and export natural gas from and to Canada, beginning on July 2, 2002, and extending through July 1, 2004. |
| 1794 | 7–2–02 | ARCO Products Company, 00–23–NG .... | ..... | ..... | Vacate of blanket authority. |
| 1795 | 7–2–02 | Sempra Energy Trading Corp., 02–48–NG. | 300 Bcf<br>300 Bcf<br>300 Bcf | 300 Bcf<br>300 Bcf | Import and export natural gas from and to Canada, and to import and export from and to Mexico, and to import LNG from various international sources beginning on June 16, 2001, and extending through June 15, 2003. |
| 1796 | 7–3–02 | Conoco Canada Limited, 02–47–NG ..... | 100 Bcf | | Import and export a combined total of natural gas from and to Canada, beginning on June 1, 2002, and extending through May 31, 2004. |
| 1797 | 7–3–02 | Union Gas Limited, 02–49–NG ..... | 216 Bcf | | Import and export a combined total of natural gas from and to Canada, beginning on August 15, 2002, and extending through August 14, 2004. |
| 1751–A | 7–23–02 | Sunoco Inc., 01–87–NG ..... | ..... | ..... | Vacate of blanket authority. |
| 1798 | 7–23–02 | Marathon Oil Company, 02–50–NG ..... | 100 Bcf | | Import and export a combined total of natural gas from and to Canada and Mexico, beginning on August 1, 2002, and extending through July 31, 2004. |
| 1799 | 7–29–02 | IGI Resources, Inc., 02–52–NG ..... | 400 Bcf | ..... | Import natural gas from Canada, beginning on August 1, 2002, and extending through July 31, 2004. |
| 1800 | 7–31–02 | Superior Energy Management, 02–51–NG. | 200 Bcf | 200 Bcf | Import and export natural gas from and to Canada, beginning on October 1, 2002, and extending through September 30, 2004. |

DOE/FE AUTHORITY—Continued

| Order No. | Date issued | Importer/exporter FE docket No. | Import volume | Export volume | Comments |
|---|---|---|---|---|---|
| 1801 | 7–31–02 | Emera Energy Services Inc., 02–53–NG | 200 Bcf | | Import and export a combined total of natural gas from and to Canada, beginning on August 1, 2002, and extending through July 31, 2004. |

[FR Doc. 02–20569 Filed 8–13–02; 8:45 am]

**BILLING CODE 6450–01–P**

## DEPARTMENT OF ENERGY

### Office of Energy Efficiency and Renewable Energy

### Biomass Research and Development Technical Advisory Committee

**AGENCY:** Office of Energy Efficiency and Renewable Energy, Department of Energy.

**ACTION:** Notice of open meeting.

**SUMMARY:** This notice announces an open meeting of the Biomass Research and Development Technical Advisory Committee under the Biomass Research and Development Act of 2000. The Federal Advisory Committee Act (Pub. L. 92–463, 86 Stat. 770) requires that agencies publish these notices in the Federal Register to allow for public participation. This notice announces the meeting of the Biomass Research and Development Technical Advisory Committee.

*Date:* September 4 and 5, 2002.

*Time:* 8:30 a.m.

*Address:* Hilton Crystal City Hotel at National Airport, Crystal Room, 2399 Jefferson Davis Highway, Arlington, VA 22202.

**FOR FURTHER INFORMATION CONTACT:** Douglas E. Kaempf, Designated Federal Officer for the Committee, Office of Energy Efficiency and Renewable Energy, U.S. Department of Energy, 1000 Independence Avenue, SW., Washington, DC 20585; (202) 586–7766.

**SUPPLEMENTARY INFORMATION:**

*Purpose of Meeting:* To provide advice and guidance that promotes research and development leading to the production of biobased industrial products.

*Tentative Agenda:* Agenda will include discussions on the following:

• Full committee discussion on the development of a Vision and a Roadmap document for federal biomass research and development programs.

*Public Participation:* In keeping with procedures, members of the public are welcome to observe the business of the Biomass Research and Development Technical Advisory Committee. To attend the meeting and/or to make oral statements regarding any of the items on the agenda, you should contact Douglas E. Kaempf at 202–586–7766 or *Bioenergy @ee.doe.gov* (e-mail). You must make your request for an oral statement at least 5 business days before the meeting. Members of the public will be heard in the order in which they sign up at the beginning of the meeting. Reasonable provision will be made to include the scheduled oral statements on the agenda. The Chair of the Committee will make every effort to hear the views of all interested parties. If you would like to file a written statement with the Committee, you may do so either before or after the meeting. The Chair will conduct the meeting to facilitate the orderly conduct of business.

*Minutes:* The minutes of the meeting will be available for public review and copying within 60 days at the Freedom of Information Public Reading Room; Room 1E–190; Forrestal Building; 1000 Independence Avenue, SW., Washington, DC, between 9 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

Issued at Washington, DC, on August 7, 2002.

**Rachel Samuel,**

*Deputy Advisory Committee Management Officer.*

[FR Doc. 02–20568 Filed 8–13–02; 8:45 am]

**BILLING CODE 6450–01–P**

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

**[Docket No. ER02–2120–000]**

### FPLE Rhode Island State Energy, L.P.; Notice of Issuance of Order

August 7, 2002.

FPLE Rhode Island State Energy, LP (FPLE) submitted for filing an application for authorization to sell energy, capacity and certain ancillary services at market-based rates. FPLE also requested waiver of various Commission regulations. In particular, FPLE requested that the Commission grant blanket approval under 18 CFR Part 34 of all future issuances of securities and assumptions of liability by FPLE.

On July 29, 2002, pursuant to delegated authority, the Director, Office of Markets, Tariffs and Rates-East, granted requests for blanket approval under Part 34, subject to the following:

Any person desiring to be heard or to protest the blanket approval of issuances of securities or assumptions of liability by FPLE should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with rules 211 and 214 of the Commission's rules of practice and procedure (18 CFR 385.211 and 385.214).

Absent a request to be heard in opposition within this period, FPLE is authorized to issue securities and assume obligations or liabilities as a guarantor, indorser, surety, or otherwise in respect of any security of another person; provided that such issuance or assumption is for some lawful object within the corporate purposes of FPLE, compatible with the public interest, and is reasonably necessary or appropriate for such purposes.

The Commission reserves the right to require a further showing that neither public nor private interests will be adversely affected by continued approval of FPLE's issuances of securities or assumptions of liability.

Notice is hereby given that the deadline for filing motions to intervene or protests, as set forth above, is August 28, 2002.

Copies of the full text of the Order are available from the Commission's Public Reference Branch, 888 First Street, NE., Washington, DC 20426. The Order may also be viewed on the Internet at *http://www.ferc.fed.us/online/rims.htm* (call 202–208–2222 for assistance). Comments, protests, and interventions may be filed electronically via the internet in lieu of paper. *See*, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site at *http://www.ferc.fed.us/efi/doorbell.htm*.

**Linwood A. Watson, Jr.,**

*Deputy Secretary.*

[FR Doc. 02–20544 Filed 8–13–02; 8:45 am]

**BILLING CODE 6717–01–P**

## DEPARTMENT OF ENERGY

## Federal Energy Regulatory Commission

**[Docket No. EL00–95–000, EL00–98–000 and ER02–1656–000]**

## San Diego Gas & Electric Company, Complainant, v. Sellers of Energy and Ancillary Services Into Markets Operated by the California Independent System Operator and the California Power Exchange, Respondents, Investigation of Practices of the California Independent System Operator and the California Power Exchange, and California Independent System Operator (MD02); Amended Notice of Technical Conference and Agenda

August 8, 2002.

The Federal Energy Regulatory Commission Staff is convening a technical conference to facilitate continued discussions between the California Independent System Operator Corporation (CAISO), market participants, state agencies and other interested participants on the development of a revised market design for the CAISO. Attached is the proposed agenda for the conference. The conference will be held in San Francisco, California, at the Renaissance Parc 55 Hotel, 55 Cyril Magnin Street, San Francisco, CA, on August 13, 14 and 15, 2002, beginning at 9 a.m.

For additional information concerning the conference, interested persons may contact Susan G. Pollonais at (202) 502–6011 or by electronic mail at ''*susan.pollonais@ferc.gov*.'' No telephone communication bridge will be provided at this technical conference.

**Linwood A. Watson, Jr.,**

*Deputy Secretary.*

**Discussion Issues for FERC Technical Conference on California Market Design (MD02), August 13–15, 2002**

1. Introduction and Statement of Goals for Technical Conference
2. Overview and Discussion on Forthcoming Process
   a. Short-term Issues—Process for Resolving Issues Related to Phase II
   b. Long-term Issues—Process for Resolving Issues Related to Phase III
3. Standard Market Design (SMD) Overview
   a. Market Power Mitigation b. Day-Ahead and Real-Time Markets
   c. Resource Adequacy
   d. Congestion Revenue Rights (CRRs)
4. Implementation Issues and Milestones
   a. Introduction—Overview of FERC Directives
   b. Phase IA
   i. Status Report on Development of Automatic Mitigation Procedures(AMP)
   ii. Status Report on RFP for Independent Entity to Develop AMP Reference Prices
   c. Phase IB
   i. Status Report on Implementation of Real-Time EconomicDispatch/Deviation Penalties (enhanced Scheduling Logging for the ISO of California (SLIC))
   d. Phase 2
   i. Update on Implementation Requirements and Timeline
   ii. Issues:
   - Integrated Forward Markets and Simultaneous Optimization
   - Residual Unit Commitment
   - Financial v. Physical Forward Schedules

   e. Phase III (including Locational Marginal Pricing (LMP) and CRRs)
   i. Update on Implementation Timeline
   ii. Issues:
   - Network Model and State Estimator MP and Optimal Power Flow (OPF)
   - CRRs
   - Financial v. Physical Foward Schedules

5. California ISO Market Surveillance Committee—Opinion and Comment
6. Next Steps/Future Conferences

[FR Doc. 02–20543 Filed 8–13–02; 8:45 am]

**BILLING CODE 6717–01–P**

## DEPARTMENT OF ENERGY

## Federal Energy Regulatory Commission

**[Docket No. CP02–416–000]**

## Williams Gas Pipelines Central, Inc.; Notice of Application

August 8, 2002.

On July 31, 2002, Williams Gas Pipelines Central, Inc. (Williams), 3800 Frederica Street, Owensboro, Kentucky 42301, filed an application pursuant to Section 7(c) of the Natural Gas Act (NGA), as amended, and the Federal Energy Regulatory Commission's (Commission) Rules and Regulations thereunder. Williams requests authorization to: construct 15.67 miles of pipeline; and, perform piping upgrades at a compressor station. The facilities are necessary to provide additional incremental firm transportation service of 66,800 Decatherms per Day(Dth/d) for electric power generation expansion and LDC load growth, all as more fully set forth in the application which is on file with the Commission and open to public inspection. 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, call (202) 502–8222 or for TTY, (202) 208–1659. Following its open season, Williams received binding requests from Empire District Electric Co.(63,800 Dth/d) and Kansas Gas Service(3,000 Dth/d) for 15 years of firm transportation service.

Williams requests authority to: (1) Construct approximately 15.67 miles of 20-inch pipeline from the Southern Trunk 20-inch Loop Line ''FR'' in Cherokee County, Kansas to Jasper County, Missouri; and, (2) install piping upgrades at the Saginaw compressor station in Newton County, Missouri to increase maximum allowable operating pressure from 820 psig to 900 psig. The cost of these modifications is estimated to be approximately $10,500,000. Further, Williams requests that the Commission determine that costs of the proposed facilities should be rolled-in with existing facility costs in their next general rate case.

Questions regarding the application may be directed to David N. Roberts, Manager of Certificates and Tariffs, P.O. Box 20008, Owensboro, Kentucky 42304, or call (270) 688–6712.

There are two ways to become involved in the Commission's review of this project. First, any person wishing to obtain legal status by becoming a party to the proceedings for this project should, on or before August 28, 2002, file with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, a motion to intervene in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the NGA (18 CFR 157.10). A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies of all documents filed by the applicant and by all other parties. A party must submit 14 copies of filings made with the Commission and must mail a copy to the applicant and to every other party in the proceeding. Only parties to the proceeding can ask for court review of Commission orders in the proceeding.

However, a person does not have to intervene in order to have comments considered. The second way to participate is by filing with the Secretary of the Commission, as soon as possible, an original and two copies of comments in support of or in opposition to this project. The Commission will consider these comments in determining the appropriate action to be taken, but the filing of a comment alone will not serve to make the filer a party to the proceeding. The Commission's rules require that persons filing comments in opposition to the project provide copies of their protests only to

the party or parties directly involved in the protest.

Persons who wish to comment only on the environmental review of this project should submit an original and two copies of their comments to the Secretary of the Commission. Environmental commenters will be placed on the Commission's environmental mailing list, will receive copies of the environmental documents, and will be notified of meetings associated with the Commission's environmental review process. Environmental commenters will not be required to serve copies of filed documents on all other parties. However, the nonparty commenters will not receive copies of all documents filed by other parties or issued by the Commission (except for the mailing of environmental documents issued by the Commission) and will not have the right to seek court review of the Commission's final order.

If the Commission decides to set the application for a formal hearing before an Administrative Law Judge, the Commission will issue another notice describing that process. At the end of the Commission's review process, a final Commission order approving or denying a certificate will be issued.

Comments, protests and interventions 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 under the ''e-Filing'' link. The Commission strongly encourages electronic filings.

**Linwood A. Watson, Jr.,**

*Deputy Secretary.*

[FR Doc. 02–20533 Filed 8–13–02; 8:45 am]

**BILLING CODE 6717–01–P**

## DEPARTMENT OF ENERGY

## Federal Energy Regulatory Commission

**[Docket No. EG02–159–000, *et al.*]**

## Delaware Mountain Wind Farm, LP, *et al.*; Electric Rate and Corporate Regulation Filings

August 8, 2002.

The following filings have been made with the Commission. The filings are listed in ascending order within each docket classification.

### 1. Delaware Mountain Wind Farm, LP

[Docket No. EG02–159–000]

Take notice that on August 6, 2002, Delaware Mountain Wind Farm, LP (Applicant), filed with the Federal Energy Regulatory Commission (Commission) an amendment to its June 26, 2002 application for determination of exempt wholesale generator status pursuant to Part 365 of the Commission's regulations.

Applicant states that it is a Delaware limited partnership engaged directly and exclusively in the business of owning and operating an approximately 30 MW wind-powered generation facility located in Culberson County, Texas. Electric energy produced by the facility will be sold at wholesale.

*Comment Date:* August 29, 2002.

### 2. Williams Generating Memphis, L.L.C.

[Docket No. EG02–176–000]

Take notice that on August 5, 2002, Williams Generating Memphis, L.L.C. (WGM) tendered for filing pursuant to Part 365 of the Federal Energy Regulatory Commission's Regulations, 18 CFR part 365, its application for determination of exempt wholesale generator status.

WGM, a wholly-owned subsidiary of Williams Refining & Marketing, L.L.C., will own a natural gas-fired electric generating facility with a capacity of approximately 75 MW net in summer ambient conditions and 80 MW net in winter conditions.

*Comment Date:* August 29, 2002.

### 3. LMB Funding, Limited Partnership

[Docket No. EG02–177–000]

Take notice that on August 5, 2002, LMB Funding, Limited Partnership (LMB), filed with the Federal Energy Regulatory Commission (Commission) an Application for Determination of Exempt Wholesale Generator Status pursuant to Part 365 of the Commission's Regulations and section 32 of the Public Utility Holding Company Act, as amended (the Application).

The Application seeks a determination that LMB qualifies for Exempt Wholesale Generator status. LMB is a Delaware limited partnership that will own, but not operate a gas-fired combined cycle electric generating facility rated at approximately 600 MW capacity. The facility will be used for the generation of electricity exclusively for sale at wholesale. Copies of this application have been served upon the Securities and Exchange Commission and the Pennsylvania Utility Commission.

*Comment Date:* August 28, 2002.

### 4. Cargill-Alliant, LLC v. New York Independent System Operator, Inc.

[Docket No. EL02–116–000]

Take notice that on August 6, 2002, Cargill-Alliant, LLC (Cargill-Alliant), filed a complaint against New York Independent System Operator, Inc (NYISO). Cargill-Alliant alleges that the NYISO, in violation of its tariff, has unlawfully withheld interest on Cargill-Alliant's cash deposit held in escrow by the NYISO.

*Comments and Answers*: August 28, 2002.

### 5. Commonwealth Edison Company

[Docket No. ER01–2985–002]

Take notice that on August 5, 2002, Commonwealth Edison Company (Com Ed) submitted for filing, in compliance with the Commission's letter order dated February 13, 2002 in Docket Nos. ER01–2985–000 and -001, an executed copy of the Interconnection Agreement between Com Ed and Zion Energy LLC (Zion).

ComEd states that a copy of this filing has been served on Zion and the Illinois Commerce Commission.

*Comment Date:* August 26, 2002.

### 6. Arizona Public Service Company

[Docket No. ER02–2417–000]

Take notice that on August 5, 2002, Arizona Public Service Company tendered for filing Service Agreement No. 147 under FERC Electric Tariff, Eleventh Revised Volume No. 2, effective date January 1, 2001 and filed with the Federal Energy Regulatory Commission by Arizona Public Service Company is to be cancel effective June 30, 2002.

*Comment Date:* August 26, 2002.

### 7. Northeast Utilities Service Companies

[Docket No. ER02–2418–000]

Take notice that on August 5, 2002, the Northeast Utilities Service Company (NUSCO), on behalf of The Connecticut Light and Power Company, Western Massachusetts Electric Company, Holyoke Water Power Company, and Holyoke Power and Electric Company, submitted pursuant to section 205 of the Federal Power Act and Part 35 of the Federal Energy Regulatory Commission's (Commission) regulations, rate schedule changes to modify the Northeast Utilities Companies' existing transmission arrangement with the Connecticut Municipal Electric Energy Cooperative (CMEEC) to provide for the delivery of firm power to the Fort Hill Farms substation at the Mohegan Trust Land Border.

A May 1, 2002 effective date has been requested. NUSCO states that copies of these materials were sent to CMEEC and the regulatory commission for the State of Connecticut.

*Comment Date:* August 29, 2002.

**8. PPL Electric Utilities Corporation**

[Docket No. ER02–2419–000]

Take notice that on August 5, 2002, PPL Electric Utilities Corporation (PPL Electric Utilities) tendered for filing an Interconnection Agreement between PPL Electric Utilities and Bloomsburg Hospital.

*Comment Date:* August 26, 2002.

**9. Midwest Independent Transmission System Operator, Inc.**

[Docket No. ER02–2420–000]

Take notice that on August 2, 2002, the Midwest Independent Transmission System Operator, Inc. (Midwest ISO) submitted modifications to amend the energy imbalance provisions set forth in Schedule 4A of its Joint Open Access Transmission Tariff of the Midwest Independent Transmission System Operator, Inc. for the Transmission System (Michigan) (Midwest ISO JOATT).

The Midwest ISO has requested an effective date of May 1, 2002. The Midwest ISO has electronically served a copy of this filing upon all Midwest ISO Members, Member representatives of Transmission Owners and Non-Transmission Owners, the Midwest ISO Advisory Committee participants, Policy Subcommittee participants, as well as all state commissions within the region. In addition, the filing has been electronically posted on the Midwest ISO's Web site at *www.midwestiso.org* under the heading ''Filings to FERC'' for other interested parties in this matter. The Midwest ISO will provide hard copies to any interested parties upon request.

*Comment Date*: August 23, 2002.

**10. Williams Generating Memphis, L.L.C.**

[Docket No. ER02–2421–000]

Take notice that on August 5, 2002, Williams Generating Memphis, L.L.C. (WGM) tendered for filing pursuant to section 205 of the Commission's Rules of Practice and Procedure, 18 CFR 385.205, its application for waivers and blanket approvals under various regulations of the Commission and for an order accepting its Electric Rate Schedule FERC No. 1.

*Comment Date*: August 26, 2002.

**11. Progress Energy on Behalf of Carolina Power & Light Company**

[Docket No. ER02–2422–000]

Take notice that on August 6, 2002, Carolina Power & Light Company (CP&L) tendered for filing Service Agreements for Non-Firm and Short-Term Firm Point-to-Point Transmission Service with Allegheny Energy Supply Company, LLC. Service to this Eligible Customer will be in accordance with the terms and conditions of the Open Access Transmission Tariff filed on behalf of CP&L.

CP&L is requesting an effective date of July 15, 2002 for these Service Agreements. A copy of the filing was served upon the North Carolina Utilities Commission and the South Carolina Public Service Commission.

*Comment Date*: August 27, 2002.

**12. Southern California Edison Company**

[Docket No. ER02–2423–000]

Take notice that on August 6, 2002, effective the First day of January 2002, Rate Schedule FERC No. 214 and all supplements thereto and Rate Schedule FERC No. 442, filed with the Federal Energy Regulatory Commission by Southern California Edison Company, are to be canceled.

Notice of the proposed cancellation has been served upon the Public Utilities Commission of the State of California and PacifiCorp.

*Comment Date*: August 27, 2002.

**13. New England Power Company**

[Docket No. ER02–2424–000]

Take notice that on August 6, 2002, New England Power Company (NEP) submitted for filing Second Revised Service Agreement No. 86 between NEP and Green Mountain Power Corporation under NEP's FERC Electric Tariff, Second Revised Volume No. 9.

*Comment Date*: August 27, 2002.

**14. New England Power Company**

[Docket No. ER02–2425–000]

Take notice that on August 6, 2002, New England Power Company (NEP) submitted for filing Third Revised Service Agreement No. 7 between NEP and Green Mountain Power Corporation under NEP's FERC Electric Tariff, Original Volume No. 1.

*Comment Date*: August 27, 2002.

**15. PJM Interconnection, L.L.C. and Allegheny Power**

[Docket No. RT01–98–008]

Take notice that on August 5, 2002, PJM Interconnection, L.L.C. (PJM) in compliance with the Federal Energy Regulatory Commission's (Commission) July 23, 2002 order in these proceedings, submitted for filing revised tariff sheets to implement the approved rate settlement in this proceeding. PJM states that, consistent with the settlement and the Commission's order, the revised tariff sheets, which effect a rate reduction, have an effective date of April 1, 2002.

PJM states that it served a copy of its filing on all PJM members, and each of the state electric regulatory commissions within the PJM region.

*Comment Date*: September 9, 2002.

**Standard Paragraph**

E. Any person desiring to intervene or to protest this filing should file with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. All such motions or protests should be filed on or before the comment date, and, to the extent applicable, must be served on the applicant and on any other person designated on the official service list. This filing is available for review at the Commission or may be viewed on the Commission's Web site at *http://www.ferc.gov* using the ''RIMS'' link, select ''Docket #'' and follow the instructions (call 202–208–2222 for assistance). Protests and interventions may be filed electronically via the Internet in lieu of paper; see 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the ''e-Filing'' link.

**Linwood A. Watson, Jr.,**

*Deputy Secretary.*

[FR Doc. 02–20565 Filed 8–13–02; 8:45 am]

**BILLING CODE 6717–01–P**

## DEPARTMENT OF ENERGY

## Federal Energy Regulatory Commission

**[Docket No. CP02–031–000]**

## Iroquois Gas Transmission System, L.P.; Notice of Availability of the Environmental Assessment for the Proposed Brookfield Expansion Project

August 8, 2002.

The staff of the Federal Energy Regulatory Commission (FERC or

Commission) has prepared an environmental assessment (EA) on the natural gas pipeline facilities proposed by Iroquois Gas Transmission System, L.P. (Iroquois) in the above-referenced docket.

The EA was prepared to satisfy the requirements of the National Environmental Policy Act. The staff concludes that approval of the proposed project, with appropriate mitigating measures, would not constitute a major Federal action significantly affecting the quality of the human environment.

The EA assesses the potential environmental effects of the construction and operation of the proposed compressor station, including:

- A new 10,000 horsepower compressor;
- A turbo-compressor building and three additional control/monitoring/maintenance buildings;
- A 500-foot-long access road;
- A security fence; and
- Water well and septic system.

The purpose of the proposed facilities would be to allow for the delivery of natural gas to customers in Queens and Long Island, New York. Iroquois states that both the City of New York and Long Island are experiencing a substantial increase in the demand for gas fired electric generation, which is directly tied to the growth in population and demand in this particular region of the Northeast.

We are currently reviewing a fifth alternative site proposed by the Town of Brookfield and the Brookfield Board of Education. This site is located on Vail Road approximately one mile west of the proposed project site. We are continuing to evaluate in greater detail this site alternative and specifically request reviewers to comment on the merits of this alternative versus Iroquois' proposed site. This site alternative is described more fully in section C.4. of the EA.

The EA has been placed in the public files of the FERC. A limited number of copies of the EA are available for distribution and public inspection at: Federal Energy Regulatory Commission, Public Reference and Files Maintenance Branch, 888 First Street, NE., Room 2A, Washington, DC 20426, (202) 208–1371.

Copies of the EA have been mailed to Federal, state and local agencies, public interest groups, interested individuals, newspapers, and parties to this proceeding.

Any person wishing to comment on the EA may do so. To ensure consideration prior to a Commission decision on the proposal, it is important that we receive your comments before the date specified below. Please carefully follow these instructions to ensure that your comments are received in time and properly recorded:

- Send two copies of your comments to: Secretary, Federal Energy Regulatory Commission, 888 First St., NE., Room 1A, Washington, DC 20426;
- Reference Docket No. CP02–031–000; and
- Mail your comments so that they will be received in Washington, DC on or before September 9, 2002.

Please note that we are continuing to experience delays in mail deliveries from the U.S. Postal Service. As a result, we will include all comments that we receive within a reasonable time frame in our final order. However, the Commission strongly encourages electronic filing of any comments or interventions or protests to this proceeding. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site at *http://www.ferc.gov* under the ''e-Filing'' link and the link to the User's Guide. Before you can file comments you will need to create a free account which can be created by clicking on ''Login to File'' and then ''New User Account.''

Comments will be considered by the Commission but will not serve to make the commentor a party to the proceeding. Any person seeking to become a party to the proceeding must file a motion to intervene pursuant to Rule 214 of the Commission's rules of practice and procedures (18 CFR 385.214).[1] Only intervenors have the right to seek rehearing of the Commission's decision.

Affected landowners and parties with environmental concerns may be granted intervenor status upon showing good cause by stating that they have a clear and direct interest in this proceeding which would not be adequately represented by any other parties. You do not need intervenor status to have your comments considered.

Additional information about the proposed project is available from the Commission's Office of External Affairs, at 1–866–208–FERC or on the FERC Internet Web site (*http://www.ferc.gov*) using the FERRIS link. Click on the FERRIS link, enter the docket number excluding the last three digits in the Docket Number field. Be sure you have selected an appropriate date range. For assistance with FERRIS, the FERRIS helpline can be reached at (202) 502–8222, TTY (202) 208–1659. The FERRIS link on the FERC Internet Web site also provides access to the texts of formal documents issued by the Commission, such as orders, notices, and rulemakings.

[1] Interventions may also be filed electronically via the Internet in lieu of paper. See the previous discussion on filing comments electronically.

**Linwood A. Watson, Jr.,**

*Deputy Secretary.*

[FR Doc. 02–20527 Filed 8–13–02; 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, Protests, and Comments

August 8, 2002.

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Type of Application:* Preliminary Permit.

b. *Project No.:* 12186–000.

c. *Date filed:* June 4, 2002.

d. *Applicant:* Calero Hydro, LLC.

e. *Name of Project:* Calero Dam Project.

f. *Location:* On Calero Creek and the Guadalupe River, Santa Clara County, California utilizing the Calero Dam. The Calero Dam is owned by the Santa Clara Valley Water District.

g. *Filed Pursuant to:* Federal Power Act, 16 USC §§ 791(a)–825(r).

h. Mr. Brent L. Smith, President, Northwest Power Services, Inc., P.O. Box 535, Rigby, ID 83442, (208)745–0834, E-mail *npsi@nwpwrservices.com*.

i. *FERC Contact:* Robert Bell, (202) 219–2806.

j. *Deadline for filing motions to intervene, protests and comments:* 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 electronically filed via the Internet in lieu of paper. *See* 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site at *http://www.ferc.fed.us/efi/doorbell.htm*. Please include the project number (P–12186–000) on any comments or motions filed.

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 in 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.

k. *Description of Project:* The proposed project would consist of: (1) An existing 840-foot-long, 90-foot-high concrete dam, (2) an existing reservoir having a surface area of 337 acres with storage capacity of 9,850 acre-feet and normal water surface elevation of 485 feet msl, (3) a proposed 200-foot-long,72-inch-diameter steel penstock, (4) a proposed powerhouse containing one generating unit having an installed capacity of 1.5 MW, (5) a proposed 1-mile-long, 15 kV transmission line, and (6) appurtenant facilities.

Applicant estimates that the average annual generation would be 12 GWh and would be sold to a local utility.

l. A copy of the application is available for inspection and reproduction at the Commission's Public Reference Room, located at 888 First Street, NE, Room 2A, Washington, DC 20426, or by calling (202) 208–1371. The application may be viewed on *http://www.ferc.gov* using the ''FERRIS'' link. Enter the docket number excluding the last three digits in the docket number to access the document. For assistance call (202) 502–8222 or for TTY, (202) 208–1659. A copy is also available for inspection and reproduction at the address in item h above.

Comments, protests and interventions may be filed electronically via the Internet in lieu of paper; see 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the ''e-Filing'' link.

m. Preliminary Permit—Anyone desiring to file a competing application for preliminary permit for a proposed project must submit the competing application itself, or a notice of intent to file such an application, to the Commission on or before the specified comment date for the particular application (see 18 CFR 4.36). Submission of a timely notice of intent allows an interested person to file the competing preliminary permit application no later than 30 days after the specified comment date for the particular application. A competing preliminary permit application must conform with 18 CFR 4.30(b) and 4.36.

n. Preliminary Permit—Any qualified development applicant desiring to file a competing development application must submit to the Commission, on or before a specified comment date for the particular application, either a competing development application or a notice of intent to file such an application. Submission of a timely notice of intent to file a development application allows an interested person to file the competing application no later than 120 days after the specified comment date for the particular application. A competing license application must conform with 18 CFR 4.30(b) and 4.36.

o. Notice of Intent—A notice of intent must specify the exact name, business address, and telephone number of the prospective applicant, and must include an unequivocal statement of intent to submit, if such an application may be filed, either a preliminary permit application or a development application (specify which type of application). A notice of intent must be served on the applicant(s) named in this public notice.

p. Proposed Scope of Studies under Permit—A preliminary permit, if issued, does not authorize construction. The term of the proposed preliminary permit would be 36 months. The work proposed under the preliminary permit would include economic analysis, preparation of preliminary engineering plans, and a study of environmental impacts. Based on the results of these studies, the Applicant would decide whether to proceed with the preparation of a development application to construct and operate the project.

q. Comments, Protests, or Motions to Intervene—Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

r. Filing and Service of Responsive Documents—Any filings must bear in all capital letters the title ''COMMENTS'', ''NOTICE OF INTENT TO FILE COMPETING APPLICATION'', ''COMPETING APPLICATION'', ''PROTEST'', ''MOTION TO INTERVENE'', as applicable, and the Project Number of the particular application to which the filing refers. Any of the above-named documents must be filed by providing the original and the number of copies provided by the Commission's regulations to: The Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. An additional copy must be sent to Director, Division of Hydropower Administration and Compliance, Federal Energy Regulatory Commission, at the above-mentioned address. A copy of any notice of intent, competing application or motion to intervene must also be served upon each representative of the Applicant specified in the particular application.

s. Agency Comments—Federal, state, and local agencies are invited to file comments on the described application. A copy of the application may be obtained by agencies directly from the Applicant. If an agency does not file comments within the time specified for filing comments, it will be presumed to have no comments. One copy of an agency's comments must also be sent to the Applicant's representatives.

**Linwood A. Watson, Jr.,**

*Deputy Secretary.*

[FR Doc. 02–20528 Filed 8–13–02; 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, Protests, and Comments

August 8, 2002.

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Type of Application:* Preliminary Permit.

b. *Project No.:* 12241–000.

c. *Date filed:* June 17, 2002.

d. *Applicant:* Rock Creek Hydro, LLC.

e. *Name of Project:* Rock Creek Lake Dam Project.

f. *Location:* On Rock Creek, in Powell County, Montana utilizing the Rock Creek Lake Dam owned by Castle Mountain Ranch, Inc.

g. *Filed Pursuant to:* Federal Power Act, 16 USC §§ 791(a)–825(r).

h. *Applicant Contact:* Mr. Brent L. Smith, President, Northwest Power Services, Inc., P.O. Box 535, Rigby, ID 83442, (208)745–0834, E-mail *npsi@nwpwrservices.com*.

i. *FERC Contact:* Robert Bell, (202) 219–2806.

j. *Deadline for filing motions to intervene, protests and comments:* 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 electronically filed via the Internet in lieu of paper. *See* 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site at *http://www.ferc.fed.us/efi/doorbell.htm*. Please include the project number (P–12241–000) on any comments or motions filed.

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 in 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.

k. *Description of Project:* The proposed project would consist of: (1) An existing 320-foot-long, 30-foot-high concrete dam, (2) an existing reservoir having a surface area of 177 acres with storage capacity of 2,552 acre-feet and normal water surface elevation of 5,844 feet msl, (3) a proposed 500-foot-long, 84-inch-diameter steel penstock, (4) a proposed powerhouse containing one generating unit having an installed capacity of 1.5 MW, (5) a proposed 5-mile-long, 25 kV transmission line, and (6) appurtenant facilities.

Applicant estimates that the average annual generation would be 6.3 GWh and would be sold to a local utility.

l. A copy of the application is available for inspection and reproduction at the Commission's Public Reference Room, located at 888 First Street, NE, Room 2A, Washington, DC 20426, or by calling (202) 208–1371. The application may be viewed on *http://www.ferc.gov* using the ''FERRIS'' link. Enter the docket number excluding the last three digits in the docket number to access the document. For assistance call (202) 502–8222 or for TTY, (202) 208–1659. A copy is also available for inspection and reproduction at the address in item h above.

Comments, protests and interventions may be filed electronically via the Internet in lieu of paper; *see* 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the ''e-Filing'' link.

m. Preliminary Permit—Anyone desiring to file a competing application for preliminary permit for a proposed project must submit the competing application itself, or a notice of intent to file such an application, to the Commission on or before the specified comment date for the particular application (*see* 18 CFR 4.36). Submission of a timely notice of intent allows an interested person to file the competing preliminary permit application no later than 30 days after the specified comment date for the particular application. A competing preliminary permit application must conform with 18 CFR 4.30(b) and 4.36.

n. Preliminary Permit—Any qualified development applicant desiring to file a competing development application must submit to the Commission, on or before a specified comment date for the particular application, either a competing development application or a notice of intent to file such an application. Submission of a timely notice of intent to file a development application allows an interested person to file the competing application no later than 120 days after the specified comment date for the particular application. A competing license application must conform with 18 CFR 4.30(b) and 4.36.

o. Notice of Intent—A notice of intent must specify the exact name, business address, and telephone number of the prospective applicant, and must include an unequivocal statement of intent to submit, if such an application may be filed, either a preliminary permit application or a development application (specify which type of application). A notice of intent must be served on the applicant(s) named in this public notice.

p. Proposed Scope of Studies under Permit—A preliminary permit, if issued, does not authorize construction. The term of the proposed preliminary permit would be 36 months. The work proposed under the preliminary permit would include economic analysis, preparation of preliminary engineering plans, and a study of environmental impacts. Based on the results of these studies, the Applicant would decide whether to proceed with the preparation of a development application to construct and operate the project.

q. Comments, Protests, or Motions to Intervene—Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

r. Filing and Service of Responsive Documents—Any filings must bear in all capital letters the title ''COMMENTS'', ''NOTICE OF INTENT TO FILE COMPETING APPLICATION'', ''COMPETING APPLICATION'', ''PROTEST'', ''MOTION TO INTERVENE'', as applicable, and the Project Number of the particular application to which the filing refers. Any of the above-named documents must be filed by providing the original and the number of copies provided by the Commission's regulations to: The Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. An additional copy must be sent to Director, Division of Hydropower Administration and Compliance, Federal Energy Regulatory Commission, at the above-mentioned address. A copy of any notice of intent, competing application or motion to intervene must also be served upon each representative of the Applicant specified in the particular application.

s. Agency Comments—Federal, state, and local agencies are invited to file comments on the described application. A copy of the application may be obtained by agencies directly from the Applicant. If an agency does not file comments within the time specified for filing comments, it will be presumed to have no comments. One copy of an agency's comments must also be sent to the Applicant's representatives.

**Linwood A. Watson, Jr.,**

*Deputy Secretary.*

[FR Doc. 02–20529 Filed 8–13–02; 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, Protests, and Comments

August 8, 2002.

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Type of Application:* Preliminary Permit.

b. *Project No.:* 12246–000.

c. *Date filed:* June 18, 2002.

d. *Applicant:* Bear Creek Hydro, LLC.

e. *Name of Project:* Bear Creek Dam Project.

f. *Location:* On Bear Creek, in Franklin County, Alabama utilizing the Bear Creek Dam administered by the Tennessee Valley Authority.

g. *Filed Pursuant to:* Federal Power Act, 16 USC §§ 791(a)–825(r).

h. *Applicant Contact:* Mr. Brent L. Smith, President, Northwest Power Services, Inc., P.O. Box 535, Rigby, ID 83442, (208)745–0834, E-mail *npsi@nwpwrservices.com*.

i. *FERC Contact:* Robert Bell, (202) 219–2806.

j. *Deadline for filing motions to intervene, protests and comments:* 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 electronically filed via the Internet in lieu of paper. *See* 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site at *http://www.ferc.fed.us/efi/doorbell.htm*. Please include the project number (P–12246–000) on any comments or motions filed.

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 in 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.

k. *Description of Project:* The proposed project would consist of: (1) An existing 1,385-foot-long, 68-foot-high concrete dam, (2) an existing reservoir having a surface area of 320 acres with storage capacity of 2,550 acre-feet and normal water surface elevation of 610 feet msl, (3) a proposed 200-foot-long, 90-inch-diameter steel penstock, (4) a proposed powerhouse containing one generating unit having an installed capacity of 2 MW, (5) a proposed 1-mile-long, 25 kV transmission line, and (6) appurtenant facilities.

Applicant estimates that the average annual generation would be 5.8 GWh and would be sold to a local utility.

l. A copy of the application is available for inspection and reproduction at the Commission's Public Reference Room, located at 888 First Street, NE, Room 2A, Washington, DC 20426, or by calling (202) 208–1371. The application may be viewed on *http://www.ferc.gov* using the ''FERRIS'' link. Enter the docket number excluding the last three digits in the docket number to access the document. For assistance call (202) 502–8222 or for TTY, (202) 208–1659. A copy is also available for inspection and reproduction at the address in item h above.

Comments, protests and interventions may be filed electronically via the Internet in lieu of paper; *see* 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the ''e-Filing'' link.

m. Preliminary Permit—Anyone desiring to file a competing application for preliminary permit for a proposed project must submit the competing application itself, or a notice of intent to file such an application, to the Commission on or before the specified comment date for the particular application (*see* 18 CFR 4.36). Submission of a timely notice of intent allows an interested person to file the competing preliminary permit application no later than 30 days after the specified comment date for the particular application. A competing preliminary permit application must conform with 18 CFR 4.30(b) and 4.36.

n. Preliminary Permit—Any qualified development applicant desiring to file a competing development application must submit to the Commission, on or before a specified comment date for the particular application, either a competing development application or a notice of intent to file such an application. Submission of a timely notice of intent to file a development application allows an interested person to file the competing application no later than 120 days after the specified comment date for the particular application. A competing license application must conform with 18 CFR 4.30(b) and 4.36.

o. Notice of Intent—A notice of intent must specify the exact name, business address, and telephone number of the prospective applicant, and must include an unequivocal statement of intent to submit, if such an application may be filed, either a preliminary permit application or a development application (specify which type of application). A notice of intent must be served on the applicant(s) named in this public notice.

p. Proposed Scope of Studies under Permit—A preliminary permit, if issued, does not authorize construction. The term of the proposed preliminary permit would be 36 months. The work proposed under the preliminary permit would include economic analysis, preparation of preliminary engineering plans, and a study of environmental impacts. Based on the results of these studies, the Applicant would decide whether to proceed with the preparation of a development application to construct and operate the project.

q. Comments, Protests, or Motions to Intervene—Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

r. Filing and Service of Responsive Documents—Any filings must bear in all capital letters the title ''COMMENTS'', ''NOTICE OF INTENT TO FILE COMPETING APPLICATION'', ''COMPETING APPLICATION'', ''PROTEST'', ''MOTION TO INTERVENE'', as applicable, and the Project Number of the particular application to which the filing refers. Any of the above-named documents must be filed by providing the original and the number of copies provided by the Commission's regulations to: The Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. An additional copy must be sent to Director, Division of Hydropower Administration and Compliance, Federal Energy Regulatory Commission, at the above-mentioned address. A copy of any notice of intent, competing application or motion to intervene must also be served upon each representative of the Applicant specified in the particular application.

s. Agency Comments—Federal, state, and local agencies are invited to file comments on the described application. A copy of the application may be obtained by agencies directly from the Applicant. If an agency does not file comments within the time specified for filing comments, it will be presumed to have no comments. One copy of an agency's comments must also be sent to the Applicant's representatives.

**Linwood A. Watson, Jr.,**

*Deputy Secretary.*

[FR Doc. 02–20530 Filed 8–13–02; 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, Protests, and Comments

August 8, 2002.

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Type of Application:* Preliminary Permit.

b. *Project No.:* 12263–000.

c. *Date filed:* June 24, 2002.

d. *Applicant:* Great Salt Plains Hydro, LLC.

e. *Name of Project:* Great Salt Plains Dam Project.

f. *Location:* On the Salt Fork of the Arkansas River, in Alfalfa County, Oklahoma utilizing the Great Salt Plains Dam administered by the Corps of Engineers.

g. *Filed Pursuant to:* Federal Power Act, 16 USC §§ 791(a)–825(r).

h. *Applicant Contact:* Mr. Brent L. Smith, President, Northwest Power Services, Inc., P.O. Box 535, Rigby, ID 83442, (208) 745–0834, E-mail *npsi@nwpwrservices.com*.

i. *FERC Contact:* Robert Bell, (202) 219–2806.

j. *Deadline for filing motions to intervene, protests and comments:* 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 electronically filed via the Internet in lieu of paper. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site at *http://www.ferc.fed.us/efi/doorbell.htm*. Please include the project number (P–12263–000) on any comments or motions filed.

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 in 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.

k. *Description of Project:* The proposed project would utilize the existing U.S. Army Corps of Engineers' Great Salt Plains Dam and would consist of: (1) A proposed intake structure, (2) a proposed 500-foot-long, 96-inch-diameter steel penstock, (3) a proposed powerhouse containing one generating unit having an installed capacity of 1.6 MW, (4) a proposed 1-mile-long, 15 kV transmission line, and (5) appurtenant facilities.

Applicant estimates that the average annual generation would be 11 GWh and would be sold to a local utility.

l. A copy of the application is available for inspection and reproduction at the Commission's Public Reference Room, located at 888 First Street, NE., Room 2A, Washington, DC 20426, or by calling (202) 208–1371. The application may be viewed on *http://www.ferc.gov* using the ''FERRIS'' link. Enter the docket number excluding the last three digits in the docket number to access the document. For assistance call (202) 502–8222 or for TTY, (202) 208–1659. A copy is also available for inspection and reproduction at the address in item h above.

Comments, protests and interventions may be filed electronically via the Internet in lieu of paper; see 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site under the ''e-Filing'' link.

m. Preliminary Permit—Anyone desiring to file a competing application for preliminary permit for a proposed project must submit the competing application itself, or a notice of intent to file such an application, to the Commission on or before the specified comment date for the particular application (see 18 CFR 4.36). Submission of a timely notice of intent allows an interested person to file the competing preliminary permit application no later than 30 days after the specified comment date for the particular application. A competing preliminary permit application must conform with 18 CFR 4.30(b) and 4.36.

n. Preliminary Permit—Any qualified development applicant desiring to file a competing development application must submit to the Commission, on or before a specified comment date for the particular application, either a competing development application or a notice of intent to file such an application. Submission of a timely notice of intent to file a development application allows an interested person to file the competing application no later than 120 days after the specified comment date for the particular application. A competing license application must conform with 18 CFR 4.30(b) and 4.36.

o. Notice of Intent—A notice of intent must specify the exact name, business address, and telephone number of the prospective applicant, and must include an unequivocal statement of intent to submit, if such an application may be filed, either a preliminary permit application or a development application (specify which type of application). A notice of intent must be served on the applicant(s) named in this public notice.

p. Proposed Scope of Studies under Permit—A preliminary permit, if issued, does not authorize construction. The term of the proposed preliminary permit would be 36 months. The work proposed under the preliminary permit would include economic analysis, preparation of preliminary engineering plans, and a study of environmental impacts. Based on the results of these studies, the Applicant would decide whether to proceed with the preparation of a development application to construct and operate the project.

q. Comments, Protests, or Motions to Intervene—Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

r. Filing and Service of Responsive Documents—Any filings must bear in all capital letters the title ''COMMENTS'', ''NOTICE OF INTENT TO FILE COMPETING APPLICATION'', ''COMPETING APPLICATION'', ''PROTEST'', ''MOTION TO INTERVENE'', as applicable, and the Project Number of the particular application to which the filing refers. Any of the above-named documents must be filed by providing the original and the number of copies provided by the Commission's regulations to: The Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. An additional copy must be sent to Director, Division of Hydropower Administration and Compliance, Federal Energy Regulatory Commission, at the above-mentioned address. A copy of any notice of intent, competing application or motion to intervene must also be served upon each representative of the Applicant specified in the particular application.

s. Agency Comments—Federal, state, and local agencies are invited to file comments on the described application. A copy of the application may be obtained by agencies directly from the Applicant. If an agency does not file comments within the time specified for filing comments, it will be presumed to have no comments. One copy of an agency's comments must also be sent to the Applicant's representatives.

**Linwood A. Watson, Jr.,**

*Deputy Secretary.*

[FR Doc. 02–20531 Filed 8–13–02; 8:45 am]

**BILLING CODE 6717–01–P**

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

### Notice of Amendment of Licenses and Solicitation of Comments, Motions To Intervene, and Protests

August 8, 2002.

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Application Type:* Conveyance of Project Lands and Change in Land Rights.

b. *Project Nos.:* 2300–030, 2311–039, 2326–026, 2327–027, 2422–030, and 2423–016.

c. *Date Filed:* June 27, 2002.

d. *Applicants:* American Tissue—New Hampshire Electric, Inc. (Current licensee) and GNE, LLC (Transferee).

e. *Name of Projects:* Shelburne, Gorham, Cross Power, Cascade, Sawmill, and Riverside.

f. *Location:* All of the projects are located on the Androscoggin River in Coos County, New Hampshire. The projects do not utilize federal or tribal lands.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791(a)–825(r)).

h. *Applicants Contacts:* Amy S. Koch and Judith Andrade, Cameron McKenna LLP, 2175 K Street, NW., Fifth Floor, Washington, DC 20037, (202) 466–0060, and Jeff Martin, GNE, LLC, 1024 Central Street, Millinocket, ME 04462, (207) 723–4341 (for GNE).

i. *FERC Contact:* Any questions on this notice should be addressed to Mrs. Heather Campbell at (202) 219–3097, or e-mail address: *heather.campbell@ferc.gov*.

j. *Deadline for filing comments and or motions:* September 13, 2002.

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, protests, and interventions may be filed electronically via the internet in lieu of paper. *See*, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the ''e-Filing'' link.

Please include the Project Number (2300–030, *et al.*) on any comments or motions filed.

k. *Description of Filing:* The licensee and transferee of the above projects have filed a request for approval to transfer certain portions of the Androscoggin riverbed and banks to the State of New Hampshire. The transferee would retain all rights to operate and maintain the projects as licensed.

l. *Location of the Application:* 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, call (202) 502–8222 or for TTY, (202) 208–1659.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

n. Comments, Protests, or Motions to Intervene—Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, 214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

o. Filing and Service of Responsive Documents—Any filings must bear in all capital letters the title ''COMMENTS'', ''RECOMMENDATIONS FOR TERMS AND CONDITIONS'', ''PROTEST'', OR ''MOTION TO INTERVENE'', as applicable, and the Project Number of the particular application to which the filing refers. A copy of any motion to intervene must also be served upon each representative of the Applicant specified in the particular application.

p. Agency Comments—Federal, state, and local agencies are invited to file comments on the described application. A copy of the application may be obtained by agencies directly from the Applicant. If an agency does not file comments within the time specified for filing comments, it will be presumed to have no comments. One copy of an agency's comments must also be sent to the Applicant's representatives.

**Linwood A. Watson, Jr.,**

*Deputy Secretary.*

[FR Doc. 02–20532 Filed 8–13–02; 8:45 am]

**BILLING CODE 6717–01–P**

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

### Notice of Application Aceepted for Filing and Soliciting Motions To Intervene, Protests, and Comments

August 8, 2002.

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Type of Application:* Preliminary Permit.

b. *Project No.:* 12235–000.

c. *Date filed:* June 17, 2002.

d. *Applicant:* Moose Creek Hydro, LLC.

e. *Name of Project:* Moose Creek Dam Project.

f. *Location:* On the Chena River, in Fairbanks Northstar Borough, Alaska utilizing the Moose Creek Dam administered by the U.S. Army Corps of Engineers.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact:* Mr. Brent L. Smith, President, Northwest Power Services, Inc., P.O. Box 535, Rigby, ID 83442, (208)745–0834, e-mail *npsi@nwpwrservices.com*.

i. *FERC Contact:* Robert Bell, (202) 219–2806.

j. *Deadline for filing motions to intervene, protests and comments:* 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 electronically filed via the Internet in lieu of paper. *See* 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site at *http://www.ferc.fed.us/efi/doorbell.htm*. Please include the project number (P–12235–000) on any comments or motions filed.

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 in 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.

k. *Description of Project:* The proposed project would utilize the existing U.S. Army Corps of Engineers' Moose Creek Dam and would consist of: (1) A proposed intake structure, (2) a proposed 250-foot-long, 84-inch-diameter steel penstock, (3) a proposed powerhouse containing one generating unit having an installed capacity of 1.5 MW, (4) a proposed 5-mile-long, 25 kV transmission line, and (5) appurtenant facilities.

Applicant estimates that the average annual generation would be 7 GWh and would be sold to a local utility.

l. A copy of the application is available for inspection and reproduction at the Commission's Public Reference Room, located at 888 First Street, NE., Room 2A, Washington, DC 20426, or by calling (202) 208–1371. The application may be viewed on *http://www.ferc.gov* using the ''FERRIS'' link. Enter the docket number excluding the last three digits in the docket number to access the document. For assistance call (202) 502–8222 or for TTY, (202) 208–1659. A copy is also available for inspection and reproduction at the address in item h above.

Comments, protests and interventions may be filed electronically via the Internet in lieu of paper; *see* 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the ''e-Filing'' link.

m. Preliminary Permit—Anyone desiring to file a competing application for preliminary permit for a proposed project must submit the competing application itself, or a notice of intent to file such an application, to the Commission on or before the specified comment date for the particular application (*see* 18 CFR 4.36). Submission of a timely notice of intent allows an interested person to file the competing preliminary permit application no later than 30 days after the specified comment date for the particular application. A competing preliminary permit application must conform with 18 CFR 4.30(b) and 4.36.

n. Preliminary Permit—Any qualified development applicant desiring to file a competing development application must submit to the Commission, on or before a specified comment date for the particular application, either a competing development application or a notice of intent to file such an application. Submission of a timely notice of intent to file a development application allows an interested person to file the competing application no later than 120 days after the specified comment date for the particular application. A competing license application must conform with 18 CFR 4.30(b) and 4.36.

o. Notice of Intent—A notice of intent must specify the exact name, business address, and telephone number of the prospective applicant, and must include an unequivocal statement of intent to submit, if such an application may be filed, either a preliminary permit application or a development application (specify which type of application). A notice of intent must be served on the applicant(s) named in this public notice.

p. Proposed Scope of Studies under Permit—A preliminary permit, if issued, does not authorize construction. The term of the proposed preliminary permit would be 36 months. The work proposed under the preliminary permit would include economic analysis, preparation of preliminary engineering plans, and a study of environmental impacts. Based on the results of these studies, the Applicant would decide whether to proceed with the preparation of a development application to construct and operate the project.

q. Comments, Protests, or Motions to Intervene—Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

r. Filing and Service of Responsive Documents—Any filings must bear in all capital letters the title ''COMMENTS'', ''NOTICE OF INTENT TO FILE COMPETING APPLICATION'', ''COMPETING APPLICATION'', ''PROTEST'', ''MOTION TO INTERVENE'', as applicable, and the Project Number of the particular application to which the filing refers. Any of the above-named documents must be filed by providing the original and the number of copies provided by the Commission's regulations to: The Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. An additional copy must be sent to Director, Division of Hydropower Administration and Compliance, Federal Energy Regulatory Commission, at the above-mentioned address. A copy of any notice of intent, competing application or motion to intervene must also be served upon each representative of the Applicant specified in the particular application.

s. Agency Comments—Federal, state, and local agencies are invited to file comments on the described application. A copy of the application may be obtained by agencies directly from the Applicant. If an agency does not file comments within the time specified for filing comments, it will be presumed to have no comments. One copy of an agency's comments must also be sent to the Applicant's representatives.

**Linwood A. Watson, Jr.,**

*Deputy Secretary.*

[FR Doc. 02–20534 Filed 8–13–02; 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, Protests, and Comments

August 8, 2002.

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Type of Application:* Preliminary Permit.

b. *Project No.:* 12242–000.

c. *Date filed:* June 17, 2002.

d. *Applicant:* San Jacinto Hydro, LLC.

e. *Name of Project:* San Jacinto Dam Project.

f. *Location:* On the San Jacinto River, in Harris County, Texas utilizing the San Jacinto Dam owned by the City of Houston.

g. *Filed Pursuant to:* Federal Power Act, 16 USC 791(a)–825(r).

h. *Applicant Contact:* Mr. Brent L. Smith, President, Northwest Power Services, Inc., P.O. Box 535, Rigby, ID 83442, (208)745–0834, e-mail *npsi@nwpwrservices.com*.

i. *FERC Contact:* Robert Bell, (202) 219–2806.

j. Deadline for filing motions to intervene, protests and comments: 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 electronically filed via the Internet in lieu of paper. *See* 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site at *http://www.ferc.fed.us/efi/doorbell.htm*. Please include the project number (P–12242–000) on any comments or motions filed.

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 in 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.

k. *Description of Project:* The proposed project would consist of: (1) An existing 8,656-foot-long, 66-foot-high concrete dam, (2) an existing reservoir having a surface area of 12,240 acres with storage capacity of 281,800 acre-feet and normal water surface elevation of 43 feet msl, (3) a proposed 500-foot-long, 144-inch-diameter steel penstock, (4) a proposed powerhouse containing two generating units having a total installed capacity of 5 MW, (5) a proposed 3-mile-long, 25 kV transmission line, and (6) appurtenant facilities.

Applicant estimates that the average annual generation would be 15.3 GWh and would be sold to a local utility.

l. A copy of the application is available for inspection and reproduction at the Commission's Public Reference Room, located at 888 First Street, NE, Room 2A, Washington, DC 20426, or by calling (202) 208–1371. The application may be viewed on *http://www.ferc.gov* using the ''FERRIS'' link. Enter the docket number excluding the last three digits in the docket number to access the document. For assistance call (202) 502–8222 or for TTY, (202) 208–1659. A copy is also available for inspection and reproduction at the address in item h above.

Comments, protests and interventions may be filed electronically via the Internet in lieu of paper; *see* 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the ''e-Filing'' link.

m. Preliminary Permit—Anyone desiring to file a competing application for preliminary permit for a proposed project must submit the competing application itself, or a notice of intent to file such an application, to the Commission on or before the specified comment date for the particular application (*see* 18 CFR 4.36). Submission of a timely notice of intent allows an interested person to file the competing preliminary permit application no later than 30 days after the specified comment date for the particular application. A competing preliminary permit application must conform with 18 CFR 4.30(b) and 4.36.

n. Preliminary Permit—Any qualified development applicant desiring to file a competing development application must submit to the Commission, on or before a specified comment date for the particular application, either a competing development application or a notice of intent to file such an application. Submission of a timely notice of intent to file a development application allows an interested person to file the competing application no later than 120 days after the specified comment date for the particular application. A competing license application must conform with 18 CFR 4.30(b) and 4.36.

o. Notice of Intent—A notice of intent must specify the exact name, business address, and telephone number of the prospective applicant, and must include an unequivocal statement of intent to submit, if such an application may be filed, either a preliminary permit application or a development application (specify which type of application). A notice of intent must be served on the applicant(s) named in this public notice.

p. Proposed Scope of Studies under Permit—A preliminary permit, if issued, does not authorize construction. The term of the proposed preliminary permit would be 36 months. The work proposed under the preliminary permit would include economic analysis, preparation of preliminary engineering plans, and a study of environmental impacts. Based on the results of these studies, the Applicant would decide whether to proceed with the preparation of a development application to construct and operate the project.

q. Comments, Protests, or Motions to Intervene—Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

r. Filing and Service of Responsive Documents—Any filings must bear in all capital letters the title ''COMMENTS'', ''NOTICE OF INTENT TO FILE COMPETING APPLICATION'', ''COMPETING APPLICATION'', ''PROTEST'', ''MOTION TO INTERVENE'', as applicable, and the Project Number of the particular application to which the filing refers. Any of the above-named documents must be filed by providing the original and the number of copies provided by the Commission's regulations to: The Secretary, Federal Energy Regulatory Commission, 888 First Street, NE, Washington, DC 20426. An additional copy must be sent to Director, Division of Hydropower Administration and Compliance, Federal Energy Regulatory Commission, at the above-mentioned address. A copy of any notice of intent, competing application or motion to intervene must also be served upon each representative of the Applicant specified in the particular application.

s. Agency Comments—Federal, state, and local agencies are invited to file comments on the described application. A copy of the application may be obtained by agencies directly from the Applicant. If an agency does not file comments within the time specified for filing comments, it will be presumed to have no comments. One copy of an agency's comments must also be sent to the Applicant's representatives.

**Linwood A. Watson, Jr.,**

*Deputy Secretary.*

[FR Doc. 02–20535 Filed 8–13–02; 8:45 am]

**BILLING CODE 6717–01–P**

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## DEPARTMENT OF ENERGY

## Federal Energy Regulatory Commission

## Notice of Application Accepted for Filing and Soliciting Motions To Intervene, Protests, and Comments

August 8, 2002.

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Type of Application:* Preliminary Permit.

b. *Project No.:* 12251–000.

c. *Date filed:* June 18, 2002.

d. *Applicant:* Ute Hydro, LLC.

e. *Name of Project:* Ute Dam Project.

f. *Location:* On the Canadian River, in Quay County, New Mexico utilizing the Ute Dam owned by the New Mexico Interstate Stream Commission.

g. *Filed Pursuant to:* Federal Power Act, 16 USC §§ 791(a)–825(r).

h. *Applicant Contact:* Mr. Brent L. Smith, President, Northwest Power Services, Inc., P.O. Box 535, Rigby, ID 83442, (208)745–0834, E-mail *npsi@nwpwrservices.com*.

i. *FERC Contact:* Robert Bell, (202) 219–2806.

j. *Deadline for filing motions to intervene, protests and comments:* 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 electronically filed via the Internet in lieu of paper. *See* 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site at *http://www.ferc.fed.us/efi/doorbell.htm*. Please include the project number (P–12251–000) on any comments or motions filed.

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 in 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.

k. *Description of Project:* The proposed project would consist of: (1) An existing 6,530-foot-long,132-foot-high concrete dam, (2) an existing reservoir having a surface area of 3,392 acres with storage capacity of 403,000 acre-feet and normal water surface elevation of 3,770 feet msl, (3) a proposed 200-foot-long, 78-inch-diameter steel penstock, (4) a proposed powerhouse containing one generating unit having an installed capacity of 2.6 MW, (5) a proposed 2-mile-long, 25 kV transmission line, and (6) appurtenant facilities.

Applicant estimates that the average annual generation would be 3.8 GWh and would be sold to a local utility

l. A copy of the application is available for inspection and reproduction at the Commission's Public Reference Room, located at 888 First Street, NE, Room 2A, Washington, DC 20426, or by calling (202) 208–1371. The application may be viewed on *http://www.ferc.gov* using the ''FERRIS'' link. Enter the docket number excluding the last three digits in the docket number to access the document. For assistance call (202) 502–8222 or for TTY, (202) 208–1659. A copy is also available for inspection and reproduction at the address in item h above.

Comments, protests and interventions may be filed electronically via the Internet in lieu of paper; *see* 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the ''e-Filing'' link.

m. Preliminary Permit—Anyone desiring to file a competing application for preliminary permit for a proposed project must submit the competing application itself, or a notice of intent to file such an application, to the Commission on or before the specified comment date for the particular application (*see* 18 CFR 4.36). Submission of a timely notice of intent allows an interested person to file the competing preliminary permit application no later than 30 days after the specified comment date for the particular application. A competing preliminary permit application must conform with 18 CFR 4.30(b) and 4.36.

n. Preliminary Permit—Any qualified development applicant desiring to file a competing development application must submit to the Commission, on or before a specified comment date for the particular application, either a competing development application or a notice of intent to file such an application. Submission of a timely notice of intent to file a development application allows an interested person to file the competing application no later than 120 days after the specified comment date for the particular application. A competing license application must conform with 18 CFR 4.30(b) and 4.36.

o. Notice of Intent—A notice of intent must specify the exact name, business address, and telephone number of the prospective applicant, and must include an unequivocal statement of intent to submit, if such an application may be filed, either a preliminary permit application or a development application (specify which type of application). A notice of intent must be served on the applicant(s) named in this public notice.

p. Proposed Scope of Studies under Permit—A preliminary permit, if issued, does not authorize construction. The term of the proposed preliminary permit would be 36 months. The work proposed under the preliminary permit would include economic analysis, preparation of preliminary engineering plans, and a study of environmental impacts. Based on the results of these studies, the Applicant would decide whether to proceed with the preparation of a development application to construct and operate the project.

q. Comments, Protests, or Motions to Intervene—Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of rules of practice and procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

r. Filing and Service of Responsive Documents—Any filings must bear in all capital letters the title ''COMMENTS'', ''NOTICE OF INTENT TO FILE COMPETING APPLICATION'', ''COMPETING APPLICATION'', ''PROTEST'', ''MOTION TO INTERVENE'', as applicable, and the Project Number of the particular application to which the filing refers. Any of the above-named documents must be filed by providing the original and the number of copies provided by the Commission's regulations to: The Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. An additional copy must be sent to Director, Division of Hydropower Administration and Compliance, Federal Energy Regulatory Commission, at the above-mentioned address. A copy of any notice of intent, competing application or motion to intervene must also be served upon each representative of the Applicant specified in the particular application.

s. Agency Comments—Federal, state, and local agencies are invited to file comments on the described application. A copy of the application may be obtained by agencies directly from the Applicant. If an agency does not file comments within the time specified for filing comments, it will be presumed to have no comments. One copy of an agency's comments must also be sent to the Applicant's representatives.

**Linwood A. Watson, Jr.,**

*Deputy Secretary.*

[FR Doc. 02–20536 Filed 8–13–02; 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, Protests, and Comments

August 8, 2002.

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Type of Application:* Preliminary Permit.

b. *Project No.:* 12274–000.

c. *Date filed:* June 25, 2002.

d. *Applicant:* Meyers Hydro, LLC.

e. *Name of Project:* John T. Meyers Lock and Dam Project.

f. *Location:* On the Ohio River, in Posey County, Indiana utilizing the John T. Meyers Lock and Dam administered by the U.S. Army Corps of Engineers.

g. *Filed Pursuant to:* Federal Power Act, 16 USC §§ 791(a)–825(r).

h. *Applicant Contact:* Mr. Brent L. Smith, President, Northwest Power Services, Inc., PO Box 535, Rigby, ID 83442, (208)745–0834, e-mail *npsi@nwpwrservices.com*.

i. *FERC Contact:* Robert Bell, (202) 219–2806.

j. *Deadline for filing motions to intervene, protests and comments:* 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 electronically filed via the Internet in lieu of paper. *See* 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site at *http://www.ferc.fed.us/efi/doorbell.htm*. Please include the project number (P–12274–000) on any comments or motions filed.

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 in 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.

k. *Description of Project:* The proposed project would utilize the existing U.S. Army Corps of Engineers' John T. Meyers Lock and Dam and would consist of: (1) A proposed intake structure, (2) three proposed 50-foot-long, 240-inch-diameter steel penstock, (3) a proposed powerhouse containing three generating units having a total installed capacity of 45 MW, (4) a proposed 1-mile-long, 50 kV transmission line, and (5) appurtenant facilities.

Applicant estimates that the average annual generation would be 325 GWh and would be sold to a local utility

l. A copy of the application is available for inspection and reproduction at the Commission's Public Reference Room, located at 888 First Street, NE., Room 2A, Washington, DC 20426, or by calling (202) 208–1371. The application may be viewed on *http://www.ferc.gov* using the ''FERRIS'' link. Enter the docket number excluding the last three digits in the docket number to access the document. For assistance call (202) 502–8222 or for TTY, (202) 208–1659. A copy is also available for inspection and reproduction at the address in item h above.

Comments, protests and interventions may be filed electronically via the Internet in lieu of paper; *see* 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the ''e-Filing'' link.

m. Preliminary Permit—Anyone desiring to file a competing application for preliminary permit for a proposed project must submit the competing application itself, or a notice of intent to file such an application, to the Commission on or before the specified comment date for the particular application (*see* 18 CFR 4.36). Submission of a timely notice of intent allows an interested person to file the competing preliminary permit application no later than 30 days after the specified comment date for the particular application. A competing preliminary permit application must conform with 18 CFR 4.30(b) and 4.36.

n. Preliminary Permit—Any qualified development applicant desiring to file a competing development application must submit to the Commission, on or before a specified comment date for the particular application, either a competing development application or a notice of intent to file such an application. Submission of a timely notice of intent to file a development application allows an interested person to file the competing application no later than 120 days after the specified comment date for the particular application. A competing license application must conform with 18 CFR 4.30(b) and 4.36.

o. Notice of Intent—A notice of intent must specify the exact name, business address, and telephone number of the prospective applicant, and must include an unequivocal statement of intent to submit, if such an application may be filed, either a preliminary permit application or a development application (specify which type of application). A notice of intent must be served on the applicant(s) named in this public notice.

p. Proposed Scope of Studies under Permit—A preliminary permit, if issued, does not authorize construction. The term of the proposed preliminary permit would be 36 months. The work proposed under the preliminary permit would include economic analysis, preparation of preliminary engineering plans, and a study of environmental impacts. Based on the results of these studies, the Applicant would decide whether to proceed with the preparation of a development application to construct and operate the project.

q. Comments, Protests, or Motions to Intervene—Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of rules of practice and procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

r. Filing and Service of Responsive Documents—Any filings must bear in all capital letters the title ''COMMENTS'', ''NOTICE OF INTENT TO FILE COMPETING APPLICATION'', ''COMPETING APPLICATION'', ''PROTEST'', ''MOTION TO INTERVENE'', as applicable, and the Project Number of the particular application to which the filing refers. Any of the above-named documents must be filed by providing the original and the number of copies provided by the Commission's regulations to: The Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. An additional copy must be sent to Director, Division of Hydropower Administration and Compliance, Federal Energy Regulatory Commission, at the above-mentioned address. A copy of any notice of intent, competing application or motion to intervene must also be served upon each representative of the Applicant specified in the particular application.

s. Agency Comments—Federal, state, and local agencies are invited to file

comments on the described application. A copy of the application may be obtained by agencies directly from the Applicant. If an agency does not file comments within the time specified for filing comments, it will be presumed to have no comments. One copy of an agency's comments must also be sent to the Applicant's representatives.

**Linwood A. Watson, Jr.,**

*Deputy Secretary.*

[FR Doc. 02–20537 Filed 8–13–02; 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, Protests, and Comments

August 8, 2002.

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Type of Application:* Preliminary Permit.

b. *Project No.:* 12183–000.

c. *Date filed:* June 4, 2002.

d. *Applicant:* Medina Hydro, LLC.

e. *Name of Project:* Medina Dam Project.

f. *Location:* On the Medina River, Medina County, Texas utilizing the Medina Dam owned by Bexar-Medina-Atacosa Counties Water Improvement.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact:* Mr. Brent L. Smith, President, Northwest Power Services, Inc., PO Box 535, Rigby, ID 83442, (208)745–0834, e-mail *npsi@nwpwrservices.com*.

i. *FERC Contact:* Robert Bell, (202) 219–2806.

j. *Deadline for filing motions to intervene, protests and comments:* 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 electronically filed via the Internet in lieu of paper. *See* 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site at *http://www.ferc.fed.us/efi/doorbell.htm*. Please include the project number (P–12183–000) on any comments or motions filed.

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 in 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.

k. *Description of Project:* The proposed project would consist of: (1) An existing 1,580-foot-long, 164-foot-high concrete dam, (2) an existing reservoir having a surface area of 5,575 acres with storage capacity of 25,400 acre-feet and normal water surface elevation of 1,064 feet msl, (3) a proposed 200-foot-long, 60-inch-diameter steel penstock, (4) a proposed powerhouse containing one generating unit having an installed capacity of 1.5 MW, (4) a proposed 5-mile-long, 15 kV transmission line, and (5) appurtenant facilities.

Applicant estimates that the average annual generation would be 5.2 GWh and would be sold to a local utility

l. A copy of the application is available for inspection and reproduction at the Commission's Public Reference Room, located at 888 First Street, NE., Room 2A, Washington, DC 20426, or by calling (202) 208–1371. The application may be viewed on *http://www.ferc.gov* using the ''FERRIS'' link. Enter the docket number excluding the last three digits in the docket number to access the document. For assistance call (202) 502–8222 or for TTY, (202) 208–1659. A copy is also available for inspection and reproduction at the address in item h above.

Comments, protests and interventions may be filed electronically via the Internet in lieu of paper; *see* 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the ''e-Filing'' link.

m. Preliminary Permit—Anyone desiring to file a competing application for preliminary permit for a proposed project must submit the competing application itself, or a notice of intent to file such an application, to the Commission on or before the specified comment date for the particular application (*see* 18 CFR 4.36). Submission of a timely notice of intent allows an interested person to file the competing preliminary permit application no later than 30 days after the specified comment date for the particular application. A competing preliminary permit application must conform with 18 CFR 4.30(b) and 4.36.

n. Preliminary Permit—Any qualified development applicant desiring to file a competing development application must submit to the Commission, on or before a specified comment date for the particular application, either a competing development application or a notice of intent to file such an application. Submission of a timely notice of intent to file a development application allows an interested person to file the competing application no later than 120 days after the specified comment date for the particular application. A competing license application must conform with 18 CFR 4.30(b) and 4.36.

o. Notice of Intent—A notice of intent must specify the exact name, business address, and telephone number of the prospective applicant, and must include an unequivocal statement of intent to submit, if such an application may be filed, either a preliminary permit application or a development application (specify which type of application). A notice of intent must be served on the applicant(s) named in this public notice.

p. Proposed Scope of Studies under Permit—A preliminary permit, if issued, does not authorize construction. The term of the proposed preliminary permit would be 36 months. The work proposed under the preliminary permit would include economic analysis, preparation of preliminary engineering plans, and a study of environmental impacts. Based on the results of these studies, the Applicant would decide whether to proceed with the preparation of a development application to construct and operate the project.

q. Comments, Protests, or Motions to Intervene—Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

r. Filing and Service of Responsive Documents—Any filings must bear in all capital letters the title ''COMMENTS'', ''NOTICE OF INTENT TO FILE COMPETING APPLICATION'', ''COMPETING APPLICATION'', ''PROTEST'', ''MOTION TO INTERVENE'', as applicable, and the Project Number of the particular application to which the filing refers. Any of the above-named documents

must be filed by providing the original and the number of copies provided by the Commission's regulations to: The Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. An additional copy must be sent to Director, Division of Hydropower Administration and Compliance, Federal Energy Regulatory Commission, at the above-mentioned address. A copy of any notice of intent, competing application or motion to intervene must also be served upon each representative of the Applicant specified in the particular application.

s. Agency Comments—Federal, state, and local agencies are invited to file comments on the described application. A copy of the application may be obtained by agencies directly from the Applicant. If an agency does not file comments within the time specified for filing comments, it will be presumed to have no comments. One copy of an agency's comments must also be sent to the Applicant's representatives.

**Linwood A. Watson, Jr.,**

*Deputy Secretary.*

[FR Doc. 02–20538 Filed 8–13–02; 8:45 am]

**BILLING CODE 6717–01–P**

## DEPARTMENT OF ENERGY

## Federal Energy Regulatory Commission

**[Project No. 11887–000]**

## Notice of Application Accepted for Filing and Soliciting Comments, Motions To Intervene, and Protests

August 8, 2002.

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Type of Application:* Preliminary Permit.

b. *Project No:* 12237–000.

c. *Date Filed:* June 17, 2002.

d. *Applicant:* Nimrod Hydro, LLC.

e. *Name of Project:* Nimrod Dam Hydroelectric Project.

f. *Location:* The proposed project would be located on an existing dam owned by the U.S. Army Corps of Engineers, on the Fourche La Fave River in Perry County, Arkansas.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. §§ 791(a)–825(r).

h. *Applicant Contact:* Mr. Brent L. Smith, Northwest Power Services, Inc., PO Box 535, Rigby, ID 83442, (208) 745–8630.

i. *FERC Contact:* Any questions on this notice should be addressed to Mr. Lynn R. Miles, Sr. at (202) 219–2671.

j. *Deadline for filing motions to intervene, protests and comments:* 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, protests and interventions may be filed electronically via the Internet in lieu of paper; *see* 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the ''e-Filing'' link. Please include the project number(P–12237–000) on any comments or motions filed.

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 in 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.

k. *Description of Project:* The proposed run-of-river project using the existing Corps of Engineers' Nimrod Dam would consist of: (1) A 96-inch-diameter, 200-foot-long steel penstock, (2) a powerhouse containing one generating unit with an installed capacity of 2.5 MW, (3) a 25-kv transmission line approximately 1 mile long, and (4) appurtenant facilities. The project would have an annual generation of 8.3 GWh.

l. This filing is available for review at the Commission or may be viewed on the Commission's Web site at *http://www.ferc.gov* using the ''RIMS'' link, select ''Docket #'' and follow the instructions (call 202–208–2222 for assistance). A copy is also available for inspection and reproduction at the address in item h above.

m. Preliminary Permit—Anyone desiring to file a competing application for preliminary permit for a proposed project must submit the competing application itself, or a notice of intent to file such an application, to the Commission on or before the specified comment date for the particular application (see 18 CFR 4.36). Submission of a timely notice of intent allows an interested person to file the competing preliminary permit application no later than 30 days after the specified comment date for the particular application. A competing preliminary permit application must conform with 18 CFR 4.30(b) and 4.36.

n. Preliminary Permit—Any qualified development applicant desiring to file a competing development application must submit to the Commission, on or before a specified comment date for the particular application, either a competing development application or a notice of intent to file such an application. Submission of a timely notice of intent to file a development application allows an interested person to file the competing application no later than 120 days after the specified comment date for the particular application. A competing license application must conform with 18 CFR 4.30(b) and 4.36.

o. Notice of Intent—A notice of intent must specify the exact name, business address, and telephone number of the prospective applicant, and must include an unequivocal statement of intent to submit, if such an application may be filed, either a preliminary permit application or a development application (specify which type of application). A notice of intent must be served on the applicant(s) named in this public notice.

p. Proposed Scope of Studies under Permit—A preliminary permit, if issued, does not authorize construction. The term of the proposed preliminary permit would be 36 months. The work proposed under the preliminary permit would include economic analysis, preparation of preliminary engineering plans, and a study of environmental impacts. Based on the results of these studies, the Applicant would decide whether to proceed with the preparation of a development application to construct and operate the project.

q. Comments, Protests, or Motions to Intervene—Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of rules of practice and procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

r. Filing and Service of Responsive Documents—Any filings must bear in all capital letters the title ''COMMENTS'', ''NOTICE OF INTENT TO FILE COMPETING APPLICATION'', ''COMPETING APPLICATION'', ''PROTEST'', ''MOTION TO INTERVENE'', as applicable, and the Project Number of the particular application to which the filing refers. Any of the above-named documents

must be filed by providing the original and the number of copies provided by the Commission's regulations to: The Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. An additional copy must be sent to Director, Division of Hydropower Administration and Compliance, Federal Energy Regulatory Commission, at the above-mentioned address. A copy of any notice of intent, competing application or motion to intervene must also be served upon each representative of the Applicant specified in the particular application.

s. Agency Comments—Federal, state, and local agencies are invited to file comments on the described application. A copy of the application may be obtained by agencies directly from the Applicant. If an agency does not file comments within the time specified for filing comments, it will be presumed to have no comments. One copy of an agency's comments must also be sent to the Applicant's representatives.

**Linwood A. Watson, Jr.,**

*Deputy Secretary.*

[FR Doc. 02–20539 Filed 8–13–02; 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, Protests, and Comments

August 8, 2002.

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Type of Application:* Preliminary Permit.

b. *Project No.:* 12243–000.

c. *Date filed:* June 17, 2002.

d. *Applicant:* Spavinaw Hydro, LLC.

e. *Name of Project:* Spavinaw Dam Project.

f. *Location:* On Spavinaw Creek, Mayes County, Oklahoma utilizing the Spavinaw Dam owned by the City of Tulsa.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. §§ 791(a)–825(r).

h. *Applicant Contact:* Mr. Brent L. Smith, President, Northwest Power Services, Inc., PO Box 535, Rigby, ID 83442, (208)745–0834, e-mail *npsi@nwpwrservices.com.*

i. *FERC Contact:* Robert Bell, (202) 219–2806.

j. *Deadline for filing motions to intervene, protests and comments:* 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 electronically filed via the Internet in lieu of paper. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site at *http://www.ferc.fed.us/efi/doorbell.htm.* Please include the project number (P–12243–000) on any comments or motions filed.

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 in 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.

k. *Description of Project:* The proposed project would consist of: (1) An existing 3,680-foot-long, 75-foot-high concrete dam, (2) an existing reservoir having a surface area of 1,584 acres with storage capacity of 38,000 acre-feet and normal water surface elevation of 680 feet msl, (3) a proposed 200-foot-long, 84-inch-diameter steel penstock, (4) a proposed powerhouse containing one generating unit having an installed capacity of 2.3 MW, (5) a proposed 1-mile-long, 15 kV transmission line, and (6) appurtenant facilities.

Applicant estimates that the average annual generation would be 6.6 GWh and would be sold to a local utility.

l. A copy of the application is available for inspection and reproduction at the Commission's Public Reference Room, located at 888 First Street, NE., Room 2A, Washington, DC 20426, or by calling (202) 208–1371. The application may be viewed on *http://www.ferc.gov* using the ''FERRIS'' link. Enter the docket number excluding the last three digits in the docket number to access the document. For assistance call (202) 502–8222 or for TTY, (202) 208–1659. A copy is also available for inspection and reproduction at the address in item h above.

Comments, protests and interventions may be filed electronically via the Internet in lieu of paper; *see* 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the ''e-Filing'' link.

m. Preliminary Permit—Anyone desiring to file a competing application for preliminary permit for a proposed project must submit the competing application itself, or a notice of intent to file such an application, to the Commission on or before the specified comment date for the particular application (see 18 CFR 4.36). Submission of a timely notice of intent allows an interested person to file the competing preliminary permit application no later than 30 days after the specified comment date for the particular application. A competing preliminary permit application must conform with 18 CFR 4.30(b) and 4.36.

n. Preliminary Permit—Any qualified development applicant desiring to file a competing development application must submit to the Commission, on or before a specified comment date for the particular application, either a competing development application or a notice of intent to file such an application. Submission of a timely notice of intent to file a development application allows an interested person to file the competing application no later than 120 days after the specified comment date for the particular application. A competing license application must conform with 18 CFR 4.30(b) and 4.36.

o. Notice of Intent—A notice of intent must specify the exact name, business address, and telephone number of the prospective applicant, and must include an unequivocal statement of intent to submit, if such an application may be filed, either a preliminary permit application or a development application (specify which type of application). A notice of intent must be served on the applicant(s) named in this public notice.

p. Proposed Scope of Studies under Permit—A preliminary permit, if issued, does not authorize construction. The term of the proposed preliminary permit would be 36 months. The work proposed under the preliminary permit would include economic analysis, preparation of preliminary engineering plans, and a study of environmental impacts. Based on the results of these studies, the Applicant would decide whether to proceed with the preparation of a development application to construct and operate the project.

q. Comments, Protests, or Motions to Intervene—Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of rules of practice and procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the

Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

r. Filing and Service of Responsive Documents—Any filings must bear in all capital letters the title ''COMMENTS'', ''NOTICE OF INTENT TO FILE COMPETING APPLICATION'', ''COMPETING APPLICATION'', ''PROTEST'', ''MOTION TO INTERVENE'', as applicable, and the Project Number of the particular application to which the filing refers. Any of the above-named documents must be filed by providing the original and the number of copies provided by the Commission's regulations to: The Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. An additional copy must be sent to Director, Division of Hydropower Administration and Compliance, Federal Energy Regulatory Commission, at the above-mentioned address. A copy of any notice of intent, competing application or motion to intervene must also be served upon each representative of the Applicant specified in the particular application.

s. Agency Comments—Federal, state, and local agencies are invited to file comments on the described application. A copy of the application may be obtained by agencies directly from the Applicant. If an agency does not file comments within the time specified for filing comments, it will be presumed to have no comments. One copy of an agency's comments must also be sent to the Applicant's representatives.

**Linwood A. Watson, Jr.,**

*Deputy Secretary.*

[FR Doc. 02–20540 Filed 8–13–02; 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, Protests, and Comments

August 8, 2002.

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Type of Application:* Preliminary Permit.

b. *Project No.:* 12262–000.

c. *Date filed:* June 21, 2002.

d. *Applicant:* Universal Electric Power Corp.

e. *Name of Project:* Shenango Dam Project.

f. *Location:* On the Shenango River in Mercer County, Pennsylvania. The existing Shenango Dam is administered by the U.S. Army Corps of Engineers.

g. *Filed Pursuant to:* Federal Power Act, 16 USC 791(a)–825(r).

h. *Applicant Contact:* Mr. Raymond Helter, Universal Electric Power Corp., 1145 Highbrook Street, Akron, OH 44301, (330) 535–7115, e-mail *uep@neo.rr.com*.

i. *FERC Contact:* Robert Bell, (202) 219–2806.

j. *Deadline for filing motions to intervene, protests and comments:* 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 electronically filed via the Internet in lieu of paper. *See* 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site at *http://www.ferc.fed.us/efi/doorbell.htm*. Please include the project number (P–12262–000) on any comments or motions filed.

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 in 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.

k. *Description of Project:* The proposed project utilizing the existing U.S. Army Corps of Engineer's Shenango Dam and reservoir would consist of: (1) A penstock and discharge works; (2) a powerhouse on the tailrace side of the dam with a total installed capacity of 1,510 kW; (3) a transmission line; and (4) other appurtenances.

Applicant estimates that the average annual generation would be 5,800 MWh and would be sold to a local utility.

l. A copy of the application is available for inspection and reproduction at the Commission's Public Reference Room, located at 888 First Street, NE., Room 2A, Washington, DC 20426, or by calling (202) 208–1371. The application may be viewed on *http://www.ferc.gov* using the ''FERRIS'' link. Enter the docket number excluding the last three digits in the docket number to access the document. For assistance call (202) 502–8222 or for TTY, (202) 208–1659. A copy is also available for inspection and reproduction at the address in item h above.

Comments, protests and interventions may be filed electronically via the Internet in lieu of paper; *see* 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the ''e-Filing'' link.

m. Preliminary Permit—Anyone desiring to file a competing application for preliminary permit for a proposed project must submit the competing application itself, or a notice of intent to file such an application, to the Commission on or before the specified comment date for the particular application (*see* 18 CFR 4.36). Submission of a timely notice of intent allows an interested person to file the competing preliminary permit application no later than 30 days after the specified comment date for the particular application. A competing preliminary permit application must conform with 18 CFR 4.30(b) and 4.36.

n. Preliminary Permit—Any qualified development applicant desiring to file a competing development application must submit to the Commission, on or before a specified comment date for the particular application, either a competing development application or a notice of intent to file such an application. Submission of a timely notice of intent to file a development application allows an interested person to file the competing application no later than 120 days after the specified comment date for the particular application. A competing license application must conform with 18 CFR 4.30(b) and 4.36.

o. Notice of Intent—A notice of intent must specify the exact name, business address, and telephone number of the prospective applicant, and must include an unequivocal statement of intent to submit, if such an application may be filed, either a preliminary permit application or a development application (specify which type of application). A notice of intent must be served on the applicant(s) named in this public notice.

p. Proposed Scope of Studies under Permit—A preliminary permit, if issued, does not authorize construction. The term of the proposed preliminary permit would be 36 months. The work proposed under the preliminary permit would include economic analysis, preparation of preliminary engineering plans, and a study of environmental impacts. Based on the results of these studies, the Applicant would decide whether to proceed with the preparation

of a development application to construct and operate the project.

q. Comments, Protests, or Motions to Intervene—Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

r. Filing and Service of Responsive Documents—Any filings must bear in all capital letters the title ''COMMENTS'', ''NOTICE OF INTENT TO FILE COMPETING APPLICATION'', ''COMPETING APPLICATION'', ''PROTEST'', ''MOTION TO INTERVENE'', as applicable, and the Project Number of the particular application to which the filing refers. Any of the above-named documents must be filed by providing the original and the number of copies provided by the Commission's regulations to: The Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. An additional copy must be sent to Director, Division of Hydropower Administration and Compliance, Federal Energy Regulatory Commission, at the above-mentioned address. A copy of any notice of intent, competing application or motion to intervene must also be served upon each representative of the Applicant specified in the particular application.

s. Agency Comments—Federal, state, and local agencies are invited to file comments on the described application. A copy of the application may be obtained by agencies directly from the Applicant. If an agency does not file comments within the time specified for filing comments, it will be presumed to have no comments. One copy of an agency's comments must also be sent to the Applicant's representatives.

**Linwood A. Watson, Jr.,**

*Deputy Secretary.*

[FR Doc. 02–20541 Filed 8–13–02; 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, Protests, and Comments

August 8, 2002.

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Type of Application:* Preliminary Permit.

b. *Project No.:* 12277–000.

c. *Date filed:* June 26, 2002.

d. *Applicant:* G.V. Montgomery Hydro LLC.

e. *Name of Project:* G.V. Montgomery L & D Project.

f. *Location:* On the Tombigbee River in Itawamba County, Mississippi. The existing G. V. Montgomery L & D is administered by the U.S. Army Corps of Engineers.

g. *Filed Pursuant to:* Federal Power Act, 16 USC 791(a)–825(r).

h. *Applicant Contact:* Mr. Brent L. Smith, President, Northwest Power Services, Inc., P.O. Box 535, Rigby, ID 83442, (208)745–0834, e-mail *npsi@nwpwrservices.com*.

i. *FERC Contact:* Robert Bell, (202) 219–2806.

j. *Deadline for filing motions to intervene, protests and comments:* 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, protests and Iterrventions 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. Please include the project number (P–12277–000) on any comments or motions filed.

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 in 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.

k. *Description of Project:* The proposed project utilizing the existing U.S. Army Corps of Engineer's G. V. Montgomery Lock and Dam and reservoir would consist of: (1) A proposed intake structure, (2) a proposed 100-foot-long, 108-inch-diameter steel penstock, (3) a proposed powerhouse containing one generating unit having an installed capacity of 1.8 MW, (4) a proposed 2-mile-long, 15 kV transmission line, and (5) appurtenant facilities.

Applicant estimates that the average annual generation would be 13.2 GWh and would be sold to a local utility.

l. A copy of the application is available for inspection and reproduction at the Commission's Public Reference Room, located at 888 First Street, NE., Room 2A, Washington, DC 20426, or by calling (202) 208–1371. The application may be viewed on *http://www.ferc.gov* using the ''FERRIS'' link. Enter the docket number excluding the last three digits in the docket number to access the document. For assistance call (202) 502–8222 or for TTY, (202) 208–1659. A copy is also available for inspection and reproduction at the address in item h above.

Comments, protests and interventions may be filed electronically via the Internet in lieu of paper; *see* 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the ''e-Filing'' link.

m. Preliminary Permit—Anyone desiring to file a competing application for preliminary permit for a proposed project must submit the competing application itself, or a notice of intent to file such an application, to the Commission on or before the specified comment date for the particular application (*see* 18 CFR 4.36). Submission of a timely notice of intent allows an interested person to file the competing preliminary permit application no later than 30 days after the specified comment date for the particular application. A competing preliminary permit application must conform with 18 CFR 4.30(b) and 4.36.

n. Preliminary Permit—Any qualified development applicant desiring to file a competing development application must submit to the Commission, on or before a specified comment date for the particular application, either a competing development application or a notice of intent to file such an application. Submission of a timely notice of intent to file a development application allows an interested person to file the competing application no later than 120 days after the specified comment date for the particular application. A competing license application must conform with 18 CFR 4.30(b) and 4.36.

o. Notice of Intent—A notice of intent must specify the exact name, business

address, and telephone number of the prospective applicant, and must include an unequivocal statement of intent to submit, if such an application may be filed, either a preliminary permit application or a development application (specify which type of application). A notice of intent must be served on the applicant(s) named in this public notice.

p. Proposed Scope of Studies under Permit—A preliminary permit, if issued, does not authorize construction. The term of the proposed preliminary permit would be 36 months. The work proposed under the preliminary permit would include economic analysis, preparation of preliminary engineering plans, and a study of environmental impacts. Based on the results of these studies, the Applicant would decide whether to proceed with the preparation of a development application to construct and operate the project.

q. Comments, Protests, or Motions to Intervene—Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

r. Filing and Service of Responsive Documents—Any filings must bear in all capital letters the title ''COMMENTS'', ''NOTICE OF INTENT TO FILE COMPETING APPLICATION'', ''COMPETING APPLICATION'', ''PROTEST'', ''MOTION TO INTERVENE'', as applicable, and the Project Number of the particular application to which the filing refers. Any of the above-named documents must be filed by providing the original and the number of copies provided by the Commission's regulations to: The Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. An additional copy must be sent to Director, Division of Hydropower Administration and Compliance, Federal Energy Regulatory Commission, at the above-mentioned address. A copy of any notice of intent, competing application or motion to intervene must also be served upon each representative of the Applicant specified in the particular application.

s. Agency Comments—Federal, state, and local agencies are invited to file comments on the described application. A copy of the application may be obtained by agencies directly from the Applicant. If an agency does not file comments within the time specified for filing comments, it will be presumed to have no comments. One copy of an agency's comments must also be sent to the Applicant's representatives.

**Linwood A. Watson, Jr.,**

*Deputy Secretary.*

[FR Doc. 02–20542 Filed 8–13–02; 8:45 am]

**BILLING CODE 6717–01–P**

## DEPARTMENT OF ENERGY

## Federal Energy Regulatory Commission

## Notice of Application Tendered for Filing With the Commission, Soliciting Additional Study Requests, and Establishing Procedural Schedule for Relicensing and a Deadline for Submission of Final Amendments

August 7, 2002.

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection.

a. *Type of Application:* New Major License.

b. *Project No.:* 2726–012.

c. *Date Filed:* July 29, 2002.

d. *Applicant:* Idaho Power Company.

e. *Name of Project:* Upper and Lower Malad Hydroelectric Project.

f. *Location:* On the Malad River in Gooding County, Idaho, approximately 3 miles north of Hagerman, Idaho.

g. *Filed Pursuant to:* Federal Power Act 16 U.S.C. 791 (a)–825'').

h. *Applicant Contact:* Robert W. Stahman, Idaho Power Company, P.O. Box 70, Boise, Idaho 83707, (208) 388–2676.

I. *FERC Contact:* John Blair (202) 502–6092 or john.blair@FERC.gov.

j. *Cooperating agencies:* We are asking Federal, state, local, and tribal agencies with jurisdiction and/or special expertise with respect to environmental issues to cooperate with us in the preparation of the environmental document. Agencies who would like to request cooperating status should follow the instructions for filing comments described in item k below.

k. Pursuant to Section 4.32(b)(7) of 18 CFR of the Commission's regulations, if any resource agency, Indian Tribe, or person believes that an additional scientific study should be conducted in order to form an adequate factual basis for a complete analysis of the application on its merit, the resource agency, Indian Tribe, or person must file a request for a study with the Commission not later than 60 days from the date of filing of the application, and serve a copy of the request on the applicant.

l. Deadline for filing additional study requests and requests for cooperating agency status: September 26, 2002.

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 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.

Additional study requests and requests for cooperating agency status 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.

m. This application is not ready for environmental analysis at this time.

n. The existing project consists of: (1) An upper diversion dam consisting of a gated spillway section 100 feet long and a flume section 123 feet long; (2) A concrete flume 4,635 feet long between the upper diversion dam and the upper intake structure; (3) The upper concrete intake structure 80.5 feet long and approximately 21 feet wide; (4) A steel penstock 10 feet in diameter and approximately 238 feet long connected to the upper powerhouse; (5) The upper reinforced concrete powerhouse containing one generating unit having an installed nameplate capacity of 8.27 megawatts; (6) A lower diversion dam consisting of a gated spillway section 163 feet long and a flume section 136 feet long; (7) A concrete flume 5,318 feet long between the lower diversion dam and the lower intake structure; (8) The lower concrete intake structure 85 feet long and approximately 23 feet wide; (9) A steel penstock 12 feet in diameter and approximately 301 feet long connected to the lower powerhouse; (10) The lower reinforced concrete powerhouse containing one generating unit having an installed nameplate capacity of 13.5 megawatts; and (11) Other appurtenances.

o. A copy of the application is on file with the Commission and is available

for public inspection. This filing is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's website 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, call (202) 502–8222 or for Text Telephone (TTY) call (202) 208–1659. A copy is also available for inspection and reproduction at the address in item h above.

p. With this notice, we are initiating consultation with the *Idaho State Historic Preservation Officer (SHPO)*, as required by § 106, National Historic Preservation Act, and the regulations of the Advisory Council on Historic Preservation, 36 CFR 800.4.

q. Procedural schedule and final amendments: The application will be processed according to the following Hydro Licensing Schedule. Revisions to the schedule will be made as appropriate.

Issue Acceptance Letter—October 2002;
Request Additional Information—October 2002;
Issue Scoping Document 1 for comments—January 2003;
Request Additional Information—March 2003;
Issue Scoping Document 2—April 2003;
Notice of application is ready for environmental analysis—May 2003;
Notice of the availability of the draft EA—October 2003;
Notice of the availability of the final EA—January 2004;
Ready for Commission's decision on the application—February 2004;

Final amendments to the application must be filed with the Commission no later than 30 days from the issuance date of the notice of ready for environmental analysis.

**Linwood A. Watson, Jr.,**

*Deputy Secretary.*

[FR Doc. 02–20545 Filed 8–13–02; 8:45 am]

**BILLING CODE 6717–01–P**

## ENVIRONMENTAL PROTECTION AGENCY

**[FRL –7259–1]**

### Notice of Outer Continental Shelf Final Determination for McCovey Prospect

**AGENCY:** Environmental Protection Agency (''EPA'').

**ACTION:** Notice of Final Action.

**SUMMARY:** EPA Region 10 is hereby providing notice that it issued an Outer Continental Shelf (OCS) permit to EnCana Oil & Gas (USA) Inc. The permit (Authority to Construct) was issued on May 29, 2002, and became effective July 4, 2002.

EnCana proposes to conduct exploratory oil and gas drilling in the OCS near-shore waters of the Beaufort Sea at the McCovey Prospect exploration site, north-northeast of the Midway Islands, in the vicinity of Prudhoe Bay, Alaska. EnCana proposes to utilize a mobile offshore drilling unit consisting of a converted crude tanker with topside drilling facilities that sits on top of an all steel submersible barge. Exploratory drilling will be conducted from November 2002 through March 2003, and / or, from November 2003 through March 2004.

The proposed facility is subject to the State of Alaska requirements applicable to OCS sources. See 40 CFR part 55, Appendix A. The facility has proposed and accepted operating restrictions to avoid PSD review. No New Source Performance Standards (40 CFR part 60) or National Emissions Standards for Hazardous Air Pollutants (40 CFR parts 61 and 63) apply to emission units at the facility.

40 CFR 55.6(a)(3) requires EPA to follow the procedures in 40 CFR part 124 used to issue PSD permits. In accordance with those procedures, comments were received during the public comment period. EPA Region 10 responded to comments, and certain proposed permit conditions were changed in the final permit. EnCana received the final permit on June 3, 2002. A copy of the final permit was concurrently provided to commentors. Review of the final permit by the Environmental Appeals Board was not requested within 30 days of EnCana's receipt of the final permit, pursuant to 40 CFR 124.19, and thus the final permit became effective July 4, 2002.

40 CFR 124.19(f)(2) requires notice of any final agency action regarding a PSD (OCS) permit to be published in the **Federal Register** Review. This notice satisfies that requirement.

**FOR FURTHER INFORMATION CONTACT:** If you have any questions or would like a copy of the permit, please contact Dan Meyer at (206) 553–4150. You may also contact Mr. Meyer by mail at: Office of Air Quality (OAQ–107), U.S. Environmental Protection Agency, Region 10, 1200 Sixth Avenue, Seattle, WA 98101.

Dated: August 6, 2002.

**L. John Iani,**

*Regional Administrator, Region 10.*

[FR Doc. 02–20582 Filed 8–13–02; 8:45 am]

**BILLING CODE 6560–50–P**

## ENVIRONMENTAL PROTECTION AGENCY

**[OPPT–2002–0032; FRL–7191–2]**

### Access to Confidential Business Information by Midwest Research Institute (MRI)

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** EPA has authorized Midwest Research Institute (MRI) of Kansas City, MO access to information which has been submitted to EPA under sections 4 and 5 of the Toxic Substances Control Act (TSCA). Some of the information may be claimed or determined to be confidential business information (CBI).

**DATES:** Access to the confidential data submitted to EPA under sections 4 and 5 of TSCA occurred as a result of an approved waiver dated June 24, 2002.

**FOR FURTHER INFORMATION CONTACT:** By mail: Barbara A. Cunningham, Acting Director, Environmental Assistance Division (7408M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (202) 554–1404; e-mail address: TSCA-Hotline@epamail.epa.gov.

**SUPPLEMENTARY INFORMATION:**

#### I. Does this Notice Apply to Me?

This action is directed to the public in general. This action may, however, be of interest to those persons who are or may be required to conduct testing of chemical substances under the Toxic Substances Control Act (TSCA). Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

#### II. How Can I Get Additional Information, Including Copies of this Document or Other Related Documents?

You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations,'' ''Regulations and Proposed Rules,'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/.

## III. What Action is the Agency Taking?

Under contract number GS–10F–0127J, MRI of 425 Volker Boulevard, Kansas City, MO, will assist the Office of Pollution Prevention and Toxics (OPPT) in providing technical support for chemical management activities authorized under TSCA on halogenated dibenzodioxins and dibenzofurans (HDDs/HDFs) in commercial products. They will also provide support in the review of analytical protocols; sampling; and quality assurance projects plans, submitted by industries involved in the production, processing, distribution, use, and disposal of chemicals listed in 40 CFR 766.27.

In accordance with 40 CFR 2.306(j), EPA has determined that under EPA contract number GS–10F–0127J, MRI will require access to CBI submitted to EPA under sections 4 and 5 of TSCA, to perform successfully the duties specified under the contract.

MRI personnel was given access to information submitted to EPA under sections 4 and 5 of TSCA. Some of the information may be claimed or determined to be CBI. Access to the confidential data submitted to EPA under sections 4 and 5 of TSCA occurred as a result of an approved waiver dated June 24, 2002. This waiver was necessary to allow MRI to assist OPPT in providing technical support for chemical management activities authorized under TSCA on HDDs/HDFs in commercial products.

EPA is issuing this notice to inform all submitters of information under sections 4 and 5 of TSCA, that the Agency may provide MRI access to these CBI materials on a need-to-know basis only. All access to TSCA CBI under this contract will take place at EPA's Region VII site in Kansas City, MO and MRI's site located at 425 Volker Boulevard, Kansas City, MO. However, access will not occur at MRI's Kansas City, MO facility until after it has been inspected and approved for the storage of TSCA CBI.

MRI will be required to adhere to all provisions of EPA's *TSCA Confidential Business Information Security Manual.*

Clearance for access to TSCA CBI under this contract may continue until January 14, 2003.

MRI personnel will be required to sign nondisclosure agreements and will be briefed on appropriate security procedures before they are permitted access to TSCA CBI.

## List of Subjects

Environmental protection, Confidential business information.

Dated: July 25, 2002.

**Allan S. Abramson,**

*Director, Information Management Division, Office of Pollution Prevention and Toxics.*

[FR Doc. 02–20583 Filed 8–13–02; 8:45 am]

**BILLING CODE 6560–50–S**

## ENVIRONMENTAL PROTECTION AGENCY

**[OPP–2002–1531; FRL–7192–4]**

## Organophosphate Pesticides; Reassessment of Meat Commodity Tolerances for Tetrachlorvinphos

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** As part of its ongoing review of existing organophosphate (OP) tolerances under the Food Quality Protection Act (FQPA), EPA has determined that 11 meat commodity tolerances for tetrachlorvinphos can be reassessed at this time. These ''non-contributor'' tolerances meet the FQPA safety standard in section 408(b)(2) of the Federal Food, Drug and Cosmetic Act (FFDCA) and can be reassessed for the purposes of FFDCA section 408 (q). EPA has concluded that these tolerances make, at most, a negligible contribution to the cumulative risk from OP pesticides. This notice closely relates to a previous **Federal Register** notice of May 22, 2002 (67 FR 35991, FRL–7178–9) in which EPA announced the reassessment of non-contributing tolerances for certain meats, animal feeds, and refined sugars. EPA expects that additional tolerances will be appropriate for reassessment based on the kind of approach described in this notice.

**DATES:** The reassessment of these tolerances is effective as of July 23, 2002.

**FOR FURTHER INFORMATION CONTACT:** Karen Angulo, Special Review and Reregistration Division (7805C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308–8004; e-mail address: angulo.karen@epa.gov.

**SUPPLEMENTARY INFORMATION:**

## I. General Information

### *A. Does this Action Apply to Me?*

This action is directed to the public in general who are interested in the use of pesticides on food. As such, the Agency has not attempted to specifically describe all the entities potentially affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT.**

### *B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?*

1. *Electronically.*You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. On the Home Page select ''Laws and Regulations,'' ''Regulations and Proposed Rules,'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/. In addition, copies of this notice may also be accessed at http: www.epa.gov/oppsrrd1/op.

2. *In person.* The Agency has established an official record for this action under docket ID number OPP–2002–1531. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

## II. Background

The Food Quality Protection Act of 1996 significantly amended the FFDCA, creating a new safety standard for judging the acceptability of tolerances for pesticide residues in food. The new statutory standard allows EPA to approve a new tolerance or leave an existing tolerance in place only if the tolerance is ''safe.'' The statute defines ''safe'' to mean ''that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable data'' [FFDCA section

408(b)(2)(A)(ii)]. In making the safety determination, EPA ''shall consider, among other relevant factors . . . available information concerning the cumulative effects of such residues and other substances that have a common mechanism of toxicity'' [FFDCA section 408(b)(2)(D)(v)]. The FQPA amendments not only made the new safety standard applicable to new tolerances, but also to tolerances in existence when FQPA became law. FQPA set a ten year schedule for EPA to reassess all existing tolerances, with interim deadlines for completion of 33 percent and 66 percent of tolerance reassessments three and six years, respectively, after the date of enactment. Pesticide tolerances subject to reassessment under the FQPA section 408(q) may only remain in effect without modification if they meet the section 408(b)(2) safety standard. Finally, FQPA instructed EPA to give priority to the review of tolerances which appear to pose the greatest risk to public health.

Consistent with the FQPA mandate, EPA identified organophosphate pesticides as high priority for tolerance reassessment. EPA has determined that the OPs share a ''common mechanism of toxicity,'' and therefore that the Agency will consider the cumulative risks of OPs in making the safety determination for any tolerance for a pesticide in this group. The Agency has reviewed individual OP pesticides to determine whether they meet the current health and safety standards of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the FFDCA safety standard, and has presented its determinations in documents called ''Interim Reregistration Eligibility Decisions'' (IREDs). When the pesticide covered by an IRED shares a common mechanism of toxicity with other pesticides, the IRED addresses the aggregate risk of the chemical but does not take a position on the FFDCA standard until the Agency has also considered the potential cumulative risks of the group of pesticides.

In addition to its consideration of individual OP pesticides, EPA has also conducted a preliminary CRA for all of the OPs and sought public comment on the assessment. The Agency recently released the revised OP CRA for public comment. The preliminary and revised OP cumulative risk assessment documents are available at www.epa.gov/pesticides/cumulative. In addition, EPA presented the assessments to its FIFRA Scientific Advisory Panel (SAP) for expert, independent scientific peer review. The SAP provided a generally favorable review of the preliminary assessment. See www.epa.gov/scipoly/sap/index.htm. EPA has raised with stakeholders during a number of public meetings the concept of reassessing selected OP tolerances because, based on available data and assessments, EPA could determine that they make, at most, no more than a negligible contribution to risk. Most recently, the concept of reassessing such ''non-contributors'' was an agenda topic for the February, 2002, meeting of the Committee to Advise on Reassessment And Transition (CARAT). In a **Federal Register** notice of May 22, 2002 (67 FR 35991, FRL–7178–9), EPA announced the reassessment of non-contributing tolerances for certain meats, animal feeds, and refined sugars, and requested suggestions on other approaches for identifying tolerances that do not contribute risk to the OP cumulative risk assessment.

## III. What Action is the Agency Taking?

### *A. Reassessment of Non-Contributor Tolerances*

In this notice, EPA identifies non-contributor meat commodity tolerances for the OP pesticide tetrachlorvinphos and considers these tolerances reassessed for the purposes of FQPA section 408 (q) as of July 23, 2002. A pesticide tolerance subject to reassessment under the FQPA section 408(q) may only remain in effect without modification if it meets the section 408(b) safety standard. This standard is met if EPA finds that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue.'' In evaluating tolerances under the standard, the FQPA also instructs the Agency to consider the cumulative effects of the pesticide and other substances that have a common mechanism of toxicity. The Agency has now completed the Interim Reregistration Eligibility Decision (IRED) for tetrachlorvinphos, which found that, apart from consideration of the potential cumulative risks from all of the OPs, each of the tolerances would meet the FFDCA safety standard. EPA has now considered the impact of these cumulative risks in the reassessment of these tolerance and has determined that these tolerances make, at most, only a negligible contribution to the overall risks from OPs. Therefore, these tolerances can be maintained regardless of the outcome of the OP cumulative assessment and any potential regulatory action taken as a result of that assessment. Accordingly, EPA believes it is appropriate to consider these tolerances reassessed for the purposes of FQPA section 408(q) as of July 23, 2002.

In making the determination that these tolerances contribute negligible (if any) residues and/or risk, EPA considered, among other things, the nature of the use of the pesticide, the data used in conducting aggregate risk assessments for each individual OP, the potential for drinking water contamination, and other data and analyses available to the Agency (such as food residue monitoring and other information that the Agency is using for the CRA). The Agency concludes that these pesticide uses result in minimal or no detectable residues in food, and have no or negligible effects through drinking water. Because a tolerance may apply to more than one raw agricultural commodity, no tolerance is herein reassessed as a non-contributor unless all of the raw agricultural commodities (food forms) that are part of that tolerance are also considered to be non-contributors. EPA also considered the potential impacts of future OP risk management decisions and determined that such decisions would be very unlikely to increase the use of the pesticide on these use sites in a manner or to a degree that the potential exposure under the tolerance would no longer be negligible. As part of its preliminary cumulative risk assessment, the Agency developed an estimate of the potential contribution that OP pesticides used in different parts of the country could make to overall risk as a result of the presence of residues of such pesticides in drinking water. Because of the nature of the available data, EPA's estimate employs assumptions that are designed not to understate potential drinking water exposure. The OP preliminary and revised CRA concluded that drinking water was not a significant source of potential exposure. In reaching the determination to reassess these tolerances, EPA has considered this analysis, the public comment and the SAP's advice, as well as the information developed to assess the aggregate exposure from drinking water for each of the individual pesticides being reassessed.

The Agency's assessment of these tolerances is effectively complete and the tolerances are considered reassessed. Nothing in this notice is intended to modify in any way any determination or requirement set forth in individual pesticide IREDs, or affect existing or future regulatory agreements or use cancellation actions required for some other purpose (e.g., due to worker or ecological risk concerns). For any of the uses that may be cancelled pursuant

to any such decision, EPA expects that the associated tolerance would be revoked at the appropriate time unless it is properly supported for an import tolerance. In addition, all of these pesticide/use pattern combinations are included in the preliminary CRA and will remain in the CRA even though they involve exposures that pose negligible/minimal risk.

No conclusions about reassessment should be drawn about tolerances that are not identified as non-contributors in this notice. EPA expects that additional tolerances will be appropriate for reassessment based on the kind of approach described here and in a previous the **Federal Register** notice of May 22, 2002 (67 FR 35991, FRL–7178–9) in which EPA announced the reassessment of non-contributing tolerances for certain meats, animal feeds, and refined sugars. Additional tolerances may be reassessed without the need for regulation upon completion of the CRA. In other words, the failure of a tolerance to be identified as a non-contributor in this or any other announcement does not imply that the pesticide/use combination will ultimately be subject to regulatory action. For tolerances reassessed as announced in this notice or using the approach described herein, EPA has concluded that the decision to reassess these tolerances will have no impact on any subsequent determination or decisions that may be necessary if the CRA were to conclude that cumulative exposure to the OPs poses risks of concern.

*B. Meat Commodity Tolerances for Tetrachlorvinphos*

EPA has determined that 11 meat commodity tolerances for tetrachlorvinphos, listed later in the notice, are reassessed at this time. EPA reassessed other OP non-contributing meat tolerances in an earlier **Federal Register** notice (May 22, 2002, 67 FR 35991, FRL–7178–9). The assessment approach applied to those meat tolerances is now being applied to the tetrachlorvinphos non-contributor meat commodity tolerances listed in this notice, and is decsribed below.

Currently, there are OP tolerances for many animal commodities: Milk, eggs, poultry, and other meats (cattle, goats, hogs, horses, and sheep). Human exposure to pesticide residues can occur as a consequence of the use of a pesticide on animals or their feed if the residues transfer to the animal commodities that humans consume. EPA examined the potential for the transfer to such human foods of OP residues from animal feeds, and from the direct application of the OP to an animal (e.g., to control nuisance pests such as biting flies), and concludes that residue transfer generally does not occur, or if it does, the transfer is minimal. The following summarizes the factors that the Agency considered in making the decision to reassess these tolerances.

The Agency examined the available study data for the OPs, which includes extensive livestock feeding/metabolism studies. These study results are confirmed by extensive monitoring data on animal commodities reflecting all registered uses. There are very few detectable residues in the OP monitoring data for animal commodities. The extensive monitoring data are from the U.S. Department of Agriculture's (USDA) Pesticide Data Program (PDP) and U.S. Food and Drug Administration's (FDA) Total Diet Study (TDS) covering residues of multiple OPs in meats and poultry. The residue monitoring data showed infrequent detections, and those residues were detected at low levels. Out of approximately 400 meat samples analyzed by the TDS for multiple OPs from 1991–1999, only 9 samples detected any OP residues (the residues ranged between 0.002 ppm and 0.009 ppm). Out of the approximately 500 poultry samples analyzed by PDP for multiple OPs for 1997–2000, only 1 sample detected an OP residue (0.01 ppm) for a pesticide that currently has a tolerance.

For milk and eggs, extensive monitoring data are available from USDA's PDP and FDA's Surveillance Program. The residue monitoring data show no detectable OP residues in milk (there was only one trace sample detected out of approximately 1,800 samples analyzed by PDP for multiple OPs from 1996–1998). The residue monitoring for eggs also showed no detectable OP residues (only one trace sample was detected out of approximately 1,300 samples analyzed by the FDA's Surveillance Program for multiple OPs from 1992–1998).

In addition to an examination of the meat, poultry, milk, and egg monitoring data, as described above, the potential risk associated with the detected residues was addressed in the Agency's preliminary CRA of the OP pesticides. Although EPA concluded that OP residues would not be expected to occur in significant amounts in meat or milk, EPA nonetheless made the conservative assumption that all meat food forms contained OP residues equal to a level that was the highest found in the FDA monitoring program (TDS). Despite the fact that this assumption would overestimate potential exposure, the analysis in the OP CRA indicated that animal commodities do not significantly contribute to OP dietary exposure and total OP dietary risk.

EPA expects to announce other meat/poultry/egg/milk and animal feed tolerances as reassessed in future notices as appropriate in light of their individual OP assessments. In addition, some of these tolerances may be revoked in future notices in the **Federal Register** if EPA determines that the tolerances are no longer needed. The Agency plans to issue a notice announcing the Agency's intention to revoke several animal meat tolerances because they are no longer necessary.

The following 11 tetrachlorvinphos meat commodity tolerances (40 CFR 180.252) are considered reassessed:

Cattle, beef
Cattle, dairy
Cattle, fat
Egg
Goat, fat
Hog
Hog, fat
Horse
Horse, fat
Milk, fat
Poultry, fat

**List of Subjects**

Environmental protection, Chemicals, Pesticides and pests.

Dated: July 31, 2002.

**Lois A. Rossi,**

*Director, Special Review and Reregistration Division, Office of Pesticide Programs.*

[FR Doc. 02–20455 Filed 8–13–02; 8:45 am]

BILLING CODE 6560–50–S

## ENVIRONMENTAL PROTECTION AGENCY

**[OPP–2002–0152; FRL–7192–6]**

## Organophosphate Pesticides; Reassessment of Additional Non-Contributing Commodity Tolerances

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** As part of its ongoing review of existing organophosphate (OP) tolerances under the Food Quality Protection Act (FQPA), EPA has determined that 37 OP tolerances can be reassessed at this time. EPA has concluded that these tolerances make, at most, a negligible contribution to the cumulative risk from OP pesticides. These tolerances are considered to be ''non-contributors'' based on the especially small number (less than 1 percent) of reported pesticide residue

detections in the monitoring data being used in the OP cumulative risk assessment (U.S. Department of Agriculture's [USDA] Pesticide Data Program [PDP]). These non-contributor tolerances meet the FQPA safety standard in section 408(b)(2) of the Federal Food, Drug and Cosmetic Act (FFDCA) and can be reassessed for the purposes of FFDCA sec. 408 (q). This notice discusses the concept and basis for this approach to reassessing selected OP tolerances based on available information relating to the revised OP cumulative risk assessment (CRA). Nothing in this notice is intended to modify in any way any determination or requirement set forth in individual pesticide IREDs, or affect regulatory agreements or use cancellation actions required for some other purpose (e.g., due to worker or ecological risk concerns). This notice closely relates to two previous **Federal Register** notices: The notice of July 17, 2002 (67 FR 46972, FRL–7186–8) in which EPA announced the reassessment of non-contributing tolerances for certain commodities with no pesticide residue detections in PDP, and the notice of May 22, 2002 (67 FR 35991, FRL–7178–9) in which EPA announced the reassessment of non-contributing tolerances for certain meats, animal feeds, and refined sugars, and requested suggestions on other approaches for identifying tolerances that do not contribute risk to the OP cumulative risk assessment.

**DATES:** The reassessment of these tolerances is effective as of July 23, 2002.

**FOR FURTHER INFORMATION CONTACT:** Karen Angulo, Special Review and Reregistration Division (7805C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308–8004; e-mail address: angulo.karen@epa.gov.

**SUPPLEMENTARY INFORMATION:**

## I. General Information

### *A. Does this Action Apply to Me?*

This action is directed to the public in general who are interested in the use of pesticides on food. As such, the Agency has not attempted to specifically describe all the entities potentially affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

### *B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?*

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. On the Home Page select ''Laws and Regulations,'' ''Regulations and Proposed Rules,'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/. In addition, copies of this notice may also be accessed at http: www.epa.gov/oppsrrd1/op.

2. *In person.* The Agency has established an official record for this action under docket ID number OPP–2002–0152. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

## II. Background

The Food Quality Protection Act of 1996 significantly amended the FFDCA, creating a new safety standard for judging the acceptability of tolerances for pesticide residues in food. The new statutory standard allows EPA to approve a new tolerance or leave an existing tolerance in place only if the tolerance is ''safe.'' The statute defines ''safe '' to mean ''that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable data'' [FFDCA section 408(b)(2)(A)(ii)]. In making the safety determination, EPA ''shall consider, among other relevant factors . . . available information concerning the cumulative effects of such residues and other substances that have a common mechanism of toxicity'' [FFDCA section 408(b)(2)(D)(v)]. The FQPA amendments not only made the new safety standard applicable to new tolerances, but also to tolerances in existence when FQPA became law. FQPA set a ten year schedule for EPA to reassess all existing tolerances, with interim deadlines for completion of 33 percent and 66 percent of tolerance reassessments three and six years, respectively, after the date of enactment. Pesticide tolerances subject to reassessment under the FQPA section 408(q) may only remain in effect without modification if they meet the section 408(b)(2) safety standard. Finally, FQPA instructed EPA to give priority to the review of tolerances which appear to pose the greatest risk to public health.

Consistent with the FQPA mandate, EPA identified organophosphate pesticides as high priority for tolerance reassessment. EPA has determined that the OPs share a ''common mechanism of toxicity,'' and therefore that the Agency will consider the cumulative risks of OPs in making the safety determination for any tolerance for a pesticide in this group. The Agency has reviewed individual OP pesticides to determine whether they meet the current health and safety standards of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the FFDCA safety standard, and has presented its determinations in documents called ''Interim Reregistration Eligibility Decisions'' (IREDs). When the pesticide covered by an IRED shares a common mechanism of toxicity with other pesticides, the IRED addresses the aggregate risk of the chemical but does not take a position on the FFDCA standard until the Agency has also considered the potential cumulative risks of the group of pesticides.

In addition to its consideration of individual OP pesticides, EPA has also conducted a preliminary CRA for all of the OPs and sought public comment on the assessment. The Agency recently released the revised OP CRA for public comment. The preliminary and revised OP cumulative risk assessment documents are available at www.epa.gov/pesticides/cumulative. In addition, EPA presented the assessments to its FIFRA Scientific Advisory Panel (SAP) for expert, independent scientific peer review. The SAP provided a generally favorable review of the preliminary assessment. See www.epa.gov/scipoly/sap/index.htm.

EPA has raised with stakeholders during a number of public meetings the concept of reassessing selected OP tolerances because, based on available data and assessments, EPA could determine that they make, at most, no more than a negligible contribution to risk. Most recently, the concept of reassessing such ''non-contributors'' was an agenda topic for the February, 2002, meeting of the Committee to Advise on Reassessment And Transition (CARAT). In a **Federal Register** notice of May 22, 2002 (67 FR 35991, FRL–7178–9), EPA announced the reassessment of non-contributing tolerances for certain meats, animal feeds, and refined sugars, and requested suggestions on other approaches for identifying tolerances that do not contribute risk to the OP cumulative risk assessment. EPA announced in a **Federal Register** notice of July 17, 2002 (67 FR 46972, FRL–7186–8) the reassessment of non-contributing tolerances for certain commodities with no pesticide residue detections in PDP.

## III. What Action is the Agency Taking?

### *A. Reassessment of Non-Contributor Tolerances*

In this notice, EPA identifies non-contributor tolerances and considers these tolerances reassessed for the purposes of FQPA section 408 (q) as of July 23, 2002. A pesticide tolerance subject to reassessment under the FQPA section 408(q) may only remain in effect without modification if it meets the section 408(b) safety standard. This standard is met if EPA finds that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue.'' In evaluating tolerances under the standard, the FQPA also instructs the Agency to consider the cumulative effects of the pesticide and other substances that have a common mechanism of toxicity. For each of the tolerances being reassessed, the Agency has issued an Interim Reregistration Eligibility Decision (IRED), which found that, apart from consideration of the potential cumulative risks from all of the OPs, each of the tolerances would meet the FFDCA safety standard. EPA has now considered the impact of these cumulative risks in the reassessment of these tolerance and has determined that these tolerances make, at most, only a negligible contribution to the overall risks from OPs. Therefore, these tolerances can be maintained regardless of the outcome of the OP cumulative assessment and any potential regulatory action taken as a result of that assessment. Accordingly, EPA believes it is appropriate to consider these tolerances reassessed for the purposes of FQPA section 408(q) as of July 23, 2002.

In making the determination that these tolerances contribute negligible (if any) residues and/or risk, EPA considered, among other things, the nature of the use of the pesticide, the data used in conducting aggregate risk assessments for each individual OP, the potential for drinking water contamination, and other data and analyses available to the Agency (such as food residue monitoring and other information that the Agency is using for the CRA). The Agency concludes that these pesticide uses result in minimal detectable residues in food, and have no or negligible effects through drinking water. Because a tolerance may apply to more than one raw agricultural commodity, no tolerance is herein reassessed as a non-contributor unless all of the raw agricultural commodities (food forms) that are part of that tolerance are also considered to be non-contributors. EPA also considered the potential impacts of future OP risk management decisions and determined that such decisions would be very unlikely to increase the use of the pesticide on these use sites in a manner or to a degree that the potential exposure under the tolerance would no longer be minimal. As part of its preliminary and revised cumulative risk assessments, the Agency developed an estimate of the potential contribution that OP pesticides used in different parts of the country could make to overall risk as a result of the presence of residues of such pesticides in drinking water. Because of the nature of the available data, EPA's estimate employs assumptions that are designed not to understate potential drinking water exposure. The OP preliminary and revised CRA concluded that drinking water was not a significant source of potential exposure. In reaching the determination to reassess these tolerances, EPA has considered this analysis, the public comment and the SAP's advice, as well as the information developed to assess the aggregate exposure from drinking water for each of the individual pesticides being reassessed.

The Agency's assessment of these tolerances is effectively complete and the tolerances are considered reassessed. Nothing in this notice is intended to modify in any way any determination or requirement set forth in individual pesticide IREDs, or affect regulatory agreements or use cancellation actions required for some other purpose (e.g., due to worker or ecological risk concerns). For any of the uses that may be canceled pursuant to any such decision, EPA expects that the associated tolerance would be revoked at the appropriate time unless it is properly supported for an import tolerance. In addition, all of these pesticide/use pattern combinations are included in the preliminary and revised CRA and will remain in the CRA even though they involve exposures that pose negligible/minimal risk.

No conclusions about reassessment should be drawn about tolerances that are not identified as non-contributors in this notice. EPA expects that additional tolerances will be appropriate for reassessment based on the kind of approach described here and in previous **Federal Register** notices of May 22, 2002 (67 FR 35991, FRL–7178–9) in which EPA announced the reassessment of non-contributing tolerances for certain meats, animal feeds, and refined sugars, and July 17, 2002 (67 FR 46972, FRL–7186–8) in which EPA announced the reassessment of non-contributing tolerances for certain commodities with no pesticide residue detections in PDP. Additional tolerances may be reassessed without the need for regulation upon completion of the CRA. In other words, the failure of a tolerance to be identified as a non-contributor in this or any other announcement does not imply that the pesticide/use combination will ultimately be subject to regulatory action. For tolerances reassessed as announced in this notice or using the approach described herein, EPA has concluded that the decision to reassess these tolerances will have no impact on any subsequent determination or decisions that may be necessary if the CRA were to conclude that cumulative exposure to the OPs poses risks of concern.

### *B. Tolerances With Less Than One Percent Residue Detections in PDP*

EPA has determined that certain OP tolerances, listed later in the notice, are reassessed at this time because they make, at most, a minimal contribution to OP risk. The Agency examined the monitoring data being used in the OP cumulative risk assessment and found that pesticide residue was detected only in an insignificant number of the samples (less than one percent) that were analyzed for these food commodity/OP combinations, including the parent chemical and the degradates that were tested. In addition, the revised OP cumulative risk assessment indicates that relatively few pesticide/crop combinations account for the vast majority of exposure. These tolerances are not among those pesticide/crop

combinations that are major contributors to risk.

The monitoring data being used in the OP cumulative assessment, USDA's PDP data, are the Agency's preferred data for risk assessment. The number of samples analyzed in the PDP for these food commodity/OP combinations ranged from 275 to 2,600 samples. USDA's PDP program has been collecting data on pesticide residues found on foods since 1991, primarily for purposes of estimating dietary exposure to pesticides. For several years, EPA has routinely used the PDP database in developing assessments of dietary risk. The PDP's sampling procedures were designed to capture actual residues of the pesticide and selected metabolites in the food supply as close as possible to the time of consumption. Data collected close to actual consumption, such as PDP data, depicts a more realistic estimate of exposure, i.e., residues that could be encountered by consumers. The real-world nature of PDP data makes it preferable for the purposes of this assessment than pesticide field trials, which are another data source available to the Agency. Field trial data are designed to test for residues under exaggerated application scenarios, and are primarily used in establishing tolerances.

The PDP is designed to focus on foods highly consumed by children and to reflect foods typically available throughout the year. PDP's commodity testing profile includes not only fresh fruits and vegetables, but also canned and frozen fruits/vegetables, fruit juices, whole milk, wheat, soybeans, oats, corn syrup, peanut butter, rice, poultry, beef, and drinking water. The PDP generally collects foods at wholesale distribution centers and stores them frozen until analysis. Foods are washed and inedible portions are removed before analysis but these foods are not further cooked or processed. A complete description of the PDP and all data through 1999 are available on the internet at www.ams.usda.gov/science/pdp.

PDP data are not available for all food commodities with current OP registrations, including a limited number of food commodity tolerances that are listed in this notice. When PDP data are not available for a commodity, EPA uses data when it is appropriate to do so from commodities that are measured by PDP to serve as surrogate data sources. This well established practice of using surrogate, or ''translated,'' data is based upon the concept that families of commodities with similar cultural practices and insect pests are likely to have similar pesticide use patterns. For example, data on peaches can be used as surrogate data for apricots. The practice of translating data from tested sources to similar situations that have not been directly tested has been used for some time by EPA in the development of pesticide-specific dietary exposure assessments when monitoring data are unavailable. The methods of translation, specifically, what commodities may be used to represent other commodities, have been made public. EPA is using translated data where appropriate for the purposes of the OP cumulative risk assessment and tolerance reassessment as discussed in this notice.

EPA has examined the PDP data that is being used for the OP cumulative risk assessment and found that residues of the parent pesticide or any tested metabolite were reported in less than one percent of the samples analyzed for the 37 OP tolerances listed below. As a result, EPA has concluded that these tolerances make, at most, a minimal contribution to the cumulative risk from OP pesticides, and, therefore, these tolerances are considered reassessed. EPA expects to announce as reassessed other tolerances that have fewer than one percent detections in PDP in future notices as appropriate in light of their individual OP assessments.

The following 37 tolerances are considered reassessed at this time:

Azinphos methyl (40 CFR 180.154)
Fruit, citrus, group
Eggplant
Grape
Parsley, leaves
Parsley, root
Pepper
Spinach
Strawberry
Tomato, postharvest

Chlorpyrifos (40 CFR 180.342)
Bean, lima
Bean, snap
Brussels sprouts
Cabbage
Cabbage, chinese
Legume vegetables, succulent or dried (except soybean)
Pumpkin
Radish
Rutabaga
Strawberry
Turnip

Disulfoton (40 CFR 180.183)
Cabbage
Lettuce
Pepper
Potato
Soybean
Wheat, grain

Mevinphos (40 CFR 180.157)
Broccoli
Cucumber
Pepper
Strawberry
Tomato

Oxydemeton methyl (40 CFR 180.330)
Cucumber
Pepper
Squash, summer

Phorate (40 CFR 180.206)
Wheat, grain

Phosalone (40 CFR 180.263)
Apple

Phosmet (40 CFR 180.261)
Cherry

### List of Subjects

Environmental protection, Chemicals, Pesticides and pests.

Dated: July 31, 2002.

**Lois A. Rossi,**

*Director, Special Review and Reregistration Division, Office of Pesticide Programs.*

[FR Doc. 02–20456 Filed 8–13–02; 8:45 am]

BILLING CODE 6560–50–S

## ENVIRONMENTAL PROTECTION AGENCY

**[OPP–2002–0175; FRL–7191–7]**

## Notice of Filing Pesticide Petitions to Establish Tolerances for a Certain Pesticide Chemical in or on Food

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** This notice announces the initial filing of pesticide petitions proposing the establishment of regulations for residues of a certain pesticide chemical in or on various food commodities.

**DATES:** Comments, identified by docket ID number OPP–2002–0175, must be received on or before September 13, 2002.

**ADDRESSES:** Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I.C. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, it is imperative that you identify docket ID number OPP–2002–0175 in the subject line on the first page of your response.

**FOR FURTHER INFORMATION CONTACT:** By mail: Hoyt Jamerson, Registration Support Branch, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308–9368; e-mail address: *jamerson.hoyt@epa.gov*.

**SUPPLEMENTARY INFORMATION:**

## I. General Information

*A. Does this Action Apply to Me?*

You may be affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

| Categories | NAICS codes | Examples of potentially affected entities |
|---|---|---|
| Industry | 111<br>112<br>311<br><br>32532 | Crop production<br>Animal production<br>Food manufacturing<br>Pesticide manufacturing |

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

*B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?*

1. *Electronically*. You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet home page at *http://www.epa.gov/*. To access this document, on the home page select ''Laws and Regulations'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listings at *http://www.epa.gov/fedrgstr/*.

2. *In person*. The Agency has established an official record for this action under docket ID number OPP–2002–0175. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as confidential business information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

*C. How and to Whom Do I Submit Comments?*

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is imperative that you identify docket ID number OPP–2002–0175 in the subject line on the first page of your response.

1. *By mail*. Submit your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

2. *In person or by courier*. Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. The PIRIB is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

3. *Electronically*. You may submit your comments electronically by e-mail to: *opp-docket@epa.gov*, or you can submit a computer disk as described above. Do not submit any information electronically that you consider to be CBI. Avoid the use of special characters and any form of encryption. Electronic submissions will be accepted in Wordperfect 6.1/8.0 or ASCII file format. All comments in electronic form must be identified by docket ID number OPP–2002–0175. Electronic comments may also be filed online at many Federal Depository Libraries.

*D. How Should I Handle CBI That I Want to Submit to the Agency?*

Do not submit any information electronically that you consider to be CBI. You may claim information that you submit to EPA in response to this document as CBI by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public version of the official record. Information not marked confidential will be included in the public version of the official record without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person identified under **FOR FURTHER INFORMATION CONTACT**.

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

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.

2. Describe any assumptions that you used.

3. Provide copies of any technical information and/or data you used that support your views.

4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.

5. Provide specific examples to illustrate your concerns.

6. Make sure to submit your comments by the deadline in this notice.

7. To ensure proper receipt by EPA, be sure to identify the docket ID number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

## II. What Action is the Agency Taking?

EPA has received pesticide petitions as follows proposing the establishment and/or amendment of regulations for residues of a certain pesticide chemical in or on various food commodities under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that the petitions contain data or information regarding the elements set forth in section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petitions. Additional data may be needed before EPA rules on the petitions.

**List of Subjects**

Environmental protection, Agricultural commodities, Feed additives, Food additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: July 31, 2002.

**Peter Caulkins,**

*Acting Director, Registration Division, Office of Pesticide Programs.*

**Summary of Petitions**

The petitioner summaries of the pesticide petitions are printed below as required by section 408(d)(3) of the FFDCA. The summaries of the petitions were prepared by the petitioners and represent the views of the petitioners. EPA is publishing the summaries verbatim without editing them in any way. The summaries announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed.

**Interregional Research Project Number 4 (IR-4)**

**Dow Agro Sciences LLC**

*PP 1E6227, 1E6241, 1E6283, 1E6291, 1E6320, 1E6329, 1E6333, 1E6334, 1E6335, 1E6399, and 1E6340*

EPA has received pesticide petitions (PP) (1E6227, 1E6241, 1E6283, 1E6291, 1E6320, 1E6329, 1E6333, 1E6334, 1E6335, 1E6399 and 1E6340) from the Interregional Research Project Number 4 (IR-4), P.O. Box 231, Rutgers University, New Brunswick, NJ 08903 and PP 4F4379 from Dow Agro Sciences LLC, Indianapolis, IN 46268, proposing, pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), to amend 40 CFR part 180 to establish tolerances for clopyralid in or on the raw agricultural commodities as follows:

1. PP 1E6227 proposes a tolerance for flax seed at 3.0 part per million (ppm).

2. PP 1E6241 proposes a tolerance for strawberry at 1.0 ppm.

3. PP 1E6283 proposes a tolerance for hop, dried cones at 5.0 ppm.

4. PP 1E6291 proposes tolerances for rapeseed seed, rapeseed forage, canola seed, mustard seed, and crambe seed at 3 ppm, and canola meat at 6.0 ppm.

5. PP 1E6320 proposes a tolerance for spinach at 5.0 ppm.

6. PP 1E6329 proposes a tolerance for the stone fruit group at 0.5 ppm.

7. PP 1E6333 proposes tolerances for garden beet tops at 3.0 ppm and garden beet roots at 4.0 ppm.

8. PP 1E6334 proposes a tolerance for mustard greens at 5.0 ppm.

9. PP 1E6335 proposes tolerances for turnip roots at 1.0 ppm and turnip greens at 4.0 ppm.

10. PP 1E6340 proposes a tolerance for cranberry at 4 ppm.

11. PP 4F4379 proposes tolerances for sweet corn, kernel plus cob with husks removed at 1.0 ppm, sweet corn forage at 7.0 ppm, sweet corn stover at 10.0 ppm, pop corn grain at 1.0 ppm, pop corn stover at 10.0 ppm, liver of cattle, goat, horse, and sheep at 3.0 ppm, meat byproducts, except liver, of cattle, goat, horse and sheep at 36.0 ppm, and milk at 0.2 ppm.

12. PP 1E3999 proposes a tolerance for the Brassica, head and stem, subgroup at 2.0 ppm.

EPA has determined that the petitions contain data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petitions. Additional data may be needed before EPA rules on the petitions. This notice includes a summary of the petition prepared by Dow Agro Sciences LLC, Indianapolis, IN 46268.

*A. Residue Chemistry*

1. *Plant metabolism*. The metabolism in plants is adequately understood. No metabolites of significance were detected in plant metabolism studies.

2. *Analytical method*. There is a practical analytical method for detecting and measuring levels of clopyralid in or on food with a limit of quantitation (LOQ) of 0.05 ppm that allows monitoring of food with residues at or above the levels set in these tolerances. EPA has provided information on this method to FDA. The method is available to anyone who is interested in pesticide residue enforcement.

3. *Magnitude of residues*. For flax, magnitude of residue data on flax in Canada were used. The maximum residue limits for clopyralid in Canada are 0.2 ppm for flax. Trial sites conducted in Canada include Manitoba and Alberta which borders North Dakota and Minnesota. Clopyralid was applied at 150 to 300 g ai/ha (0.13 to 0.27 lb ai/acre). The maximum combined residue was 0.22 ppm.

For mustard greens, magnitude of residue data were collected from field trials conducted in New Jersey, California, South Carolina, Texas, Florida, Michigan, and Tennessee. Each of eight field trial sites consisted of one untreated control plot and one treated plot. The treated plots received one application of the test substance at a rate of approximately 0.187 lb ai/acre. Marketable greens (mustard plants) were collected approximately 30 days following the application. In treated greens (mustard) samples, clopyralid residues ranged from 0.48 to 4.4 ppm.

For turnip roots and tops, magnitude of residue data were collected from field trials conducted in Tennessee, North Carolina, Texas, Georgia, Wisconsin, and California. Each of the six field trial sites consisted of one untreated control plot and one treated plot. The treated plots received one application of the test substance at a rate of approximately 0.187 lb ai/acre. At the North Carolina trial, a banded application was made to simulate regional practices; broadcast applications were made at the five remaining trials. Marketable turnip tops and roots were collected approximately 15 days and 30 days following the application, respectively. In treated tops samples, clopyralid residues ranged from 0.64 to 3.2 ppm. Clopyralid residues in treated roots samples ranged from 0.059 to 0.56 ppm.

For garden beet, magnitude of residue data were collected from field trials conducted in Florida, Michigan, New York, Texas, Wisconsin, and Washington. Each of the seven field trial sites consisted of one untreated control plot and one treated plot. The treated plots received one application of the test substance at a rate of approximately 0.187 lb ai/acre. Marketable beet (garden) roots and tops were collected approximately 30 days following the application, respectively. In treated tops samples, clopyralid residues ranged from 0.36 to 2.8 ppm. Clopyralid residues in treated roots samples ranged from 0.71 to 3.0 ppm.

For stone fruit, cherry field trials were conducted in Michigan, Washington, and New Jersey. Cherry plots were treated once by a broadcast application directed to the orchard floor with clopyralid at approximately 0.5 lb ai/acre. Samples were taken 21 to 31 days after the last treatment. All cherries were pitted prior to freezing. Peach trials were conducted in New Jersey, Michigan, North Carolina, and California. One application of clopyralid at approximately 0.5 lb ai/acre was made to a band on each side of the trees in the treated plots. The fruit in the New Jersey trials matured quickly and were harvested after 20 to 21 days. In North Carolina, the peaches were harvested after 20 days because insect and disease pressure threatened to ruin the crop. All peaches were pitted prior to freezing. Plum trials were conducted in New Jersey, Washington, and California. One application of clopyralid at approximately 0.5 lb ai/acre was made to a bank on each side of the trees in the treated plots. The fruit in one California trial matured quickly and was harvested after 21 days. The other California trial included collection of both fresh and dried plums. All plums were pitted prior to freezing or drying.

No detectable residues of clopyralid were found in any of the untreated peach samples. The treated samples from California and one of the treated samples from North Carolina also had no detectable residues. The residues in the other samples were no higher than 0.35 ppm. No detectable residues of clopyralid were found in any of the untreated or treated cherries in this study. No detectable residues of clopyralid were found in any of the untreated plums or dried plums. No detectable residues of clopyralid were found in the treated plum samples from California. The treated plum samples from New Jersey and Washington had residues in the range 0.05 to 0.41 ppm. The dried plum samples had residues in the range 0.16 to 0.19 ppm.

For hops, magnitude of residue data were collected from field trials conducted in Oregon and Washington. Each field trial site consisted of one untreated control plot and one treated plot. The treated plots received two applications of the test substance at a rate of 0.38 lb ai/acre + 5%. All applications were made post-emergence, directed, 21 to 22 days apart. Dried hop cone samples were collected 27 to 32 days following the final application. Residue concentrations from treated samples ranged from a high 4.14 ppm to a low 0.3 ppm. All residues found in treated samples fell between the highest and lowest concentrations tested in method validation, 0.1 ppm and 0.5 ppm. None of the untreated samples were found to contain clopyralid above the instrumental detection limit of 0.08 ppm.

For cranberry, field trials were conducted in Maine, New Jersey, Oregon, Washington, and Wisconsin. Clopyralid was broadcast onto fruiting cranberry vines at approximately 0.25 lb ai/acre to the treated plots, twice, at an interval of 13 to 16 days. Treated and untreated cranberries were harvested 44 to 51 days after the second application and stored frozen. No detectable residues of clopyralid were found on untreated cranberries from any of the field trials. Residues on treated samples were in the range 0.88 to 3.1 ppm.

For spinach, field trials were conducted in Texas, New York, California, Tennessee, South Carolina, and Georgia. Clopyralid was applied once at a rate of 0.092 to 0.290 lb ai/acre 20 to 22 days before harvest. Spinach was harvested and stored frozen. Residues on treated samples were in the range 0.056 to 3.8 ppm.

For strawberry, field trials were conducted in Oregon, California, North Carolina, New Jersey, and Michigan. Clopyralid applied foliar post-emergence in the late summer or early fall at a use rate of approximately 0.25 lb ai/acre, followed by a second application of approximately 0.125 lb ai/acre at 28 to 31 days before harvest resulted in residues of clopyralid ranging from 0.10 to 0.505 ppm. When applied at 0.50 lb ai/acre followed by a second application of approximately 0.25 lb ai/acre at 28 to 31 days before harvest resulted in residues of clopyralid ranging from 0.295 to 1.61 ppm.

For sweet corn, field trials were conducted in California, Georgia, Illinois, Michigan, Minnesota, North Carolina, New York, Ohio and Pennsylvania. Clopyralid was applied once as a post-emergent broadcast spray with water as a carrier at the rate of 0.66 to 0.70 percent treated (pt)/acre (0.25 to 0.26 lb ai/acre). The application was made when the corn was 12 to 18 inches in height and prior to tasseling. The ears were removed before the remaining plant (forage) was chopped. Residues were detected at the following ppm ranges: Grain, 0.087–0.12; forage, 0.34–2.0; ears (K + CWHR) 0.029–0.23; cannery waste, no residues were detected above the limit of quantitation (LOQ) of the method.

For popcorn, field trials were conducted in Indiana, Iowa, Nebraska and Ohio. Clopyralid was applied once as a post-emergent broadcast spray with water as the carrier at the rate of 0.67 pt/acre (0.25 lb ai/acre). The application was made when the popcorn was 22 to 24 inches in height. Green forage was collected when kernels were in the milk stage (i.e., at a pre-harvest interval of 45 to 55 days). Kernels and fodder were collected at normal harvest (i.e., at pre-harvest intervals of 78 to 129 days). Residues were detected at the following ppm ranges: Grain, 0.03–0.91; fodder, no detectable residues above the LOQ of the method - 0.60; forage, 0.14–1.2.

In the magnitude of residue field studies for canola, crambe, and mustard seed, the first study had three field trials, one each in Georgia, South Dakota, and Washington. Each field trial site consisted of one untreated control plot and one treated plot. The treated plots received one broadcast application of the test substance 70 to 74 days before harvest. The test substance was applied to the treated plot at a rate of 0.211 lb ai/acre to 0.256 lb ai/acre. Residues of clopyralid detected in the field treated samples ranged from 0.42 to 1.32 ppm. The second field study had three field trials, one each in Georgia, South Dakota, and Washington. Again, each field trial site consisted of one untreated control plot and one treated plot. The treated plots received one broadcast application of the test substance 48 to 49 days before harvest. The test substance was applied to the treated plot at a rate of 0.231 lb ai/acre to 0.255 lb ai/acre. Two additional samples from the Washington trial (one treated and one untreated) were sent for processing into oil and meal. Residues of clopyralid detected in the field treated samples of canola seed ranged from >0.05 to 1.86 ppm. There were no detectable residues of clopyralid in either the canola oil or canola meal samples.

*B. Toxicological Profile*

1. *Acute toxicity*. Clopyralid has low acute toxicity. The rat oral $LD_{50}$ is 5,000 milligrams/kilogram (mg/kg) or greater for males and females. The rabbit dermal $LD_{50}$ is greater than 2,000 mg/kg and the rat inhalation $LC_{50}$ is greater than 1.0 mg/L air (the highest attainable concentration). In addition, clopyralid is not a skin sensitizer in guinea pigs and is not a dermal irritant. Technical clopyralid is an ocular irritant, but ocular exposure to the technical material would not normally be expected to occur to infants or children or the general public. End use formulations of clopyralid have similar low acute toxicity profiles and most have low ocular toxicity as well.

2. *Genotoxicty*. Clopyralid is not genotoxic. The following studies have been conducted and all were negative for genotoxic responses: Ames bacterial mutagenicity assay (with and without exogenous metabolic activation); host-mediated assay *in vivo* cytogenetic test, rat; *in vivo* cytogenetic test, mouse; *in vivo* dominant lethal test, rat; *in vitro* unscheduled DNA synthesis assay in primary rat hepatocyte cultures; *in vitro* mammalian cell gene mutations assay in Chinese hamster ovary cell cultures (with and without exogenous metabolic activation).

3. *Reproductive and developmental toxicity*. Developmental toxicity was studied using rats and rabbits. The developmental study in rats resulted in a developmental no observed adverse effect level (NOAEL) of >250 mg/kg/day (a maternally toxic dose) and a maternal toxicity NOAEL of 75 mg/kg/day. A 1974 study in rabbits revealed no evidence of developmental or maternal toxicity at 250 mg/kg/day; thus, the developmental and maternal NOEL was >250 mg/kg/day. A more recent study in rabbits (1990) resulted in developmental and maternal NOAELs of 110 mg/kg/day based on maternal toxicity at 250 mg/kg/day. Based on all of the data for clopyralid, there is no evidence of developmental toxicity at dose levels that do not result in maternal toxicity.

In a 2-generation reproduction study in rats, pups from the high dose group which were fed diets containing clopyralid had a slight reduction in body weight during lactation and an increase in liver weights in F1a and F1b weanlings. The NOAEL for parental systemic toxicity was 500 mg/kg/day. There was no effect on reproductive parameters at >1,500 mg/kg/day nor was there an adverse effect on the morphology, growth or viability of the offspring; thus, the reproductive NOAEL is >1,500 mg/kg/day.

4. *Subchronic toxicity*. The following studies have been conducted using clopyralid. In a rat 90–day feeding study, Fischer 344 rats were fed diets containing clopyralid at doses of 5, 15, 50, or 150 mg/kg/day with no adverse effects attributed to treatment. In a second study, Fischer 344 rats were fed diets containing clopyralid at doses of 300, 1,500, and 2,500 mg/kg/day. Effects at the highest doses were decreased food consumption accompanied by decreased body weights and weight gains in both males and females. Slightly increased mean relative liver and kidney weights were noted in males of all doses and in females at the top two doses. Because there were no other effects, the kidney and liver weight effects were judged as being adaptive rather than directly toxic. The NOAEL was 1,500 mg/kg/day for males and females. The NOAEL was 300 mg/kg/day for females. In a mouse 90–day feeding study, B6C3F1 mice were fed diets containing clopyralid at doses of 200, 750, 2,000, or 5,000 mg/kg/day. A slight decrease in body weight occurred at the top dose in both sexes. The liver was identified as the target organ based on slight increases in liver weights and minimal microscopic alterations at the higher dose levels. The liver changes were considered to be reversible and adaptive. The NOAEL for males was 2,000 mg/kg/day and for females was 750 mg/kg/day. In a 180–day feeding study, beagle dogs were fed diets containing clopyralid at doses of 15, 50, or 150 mg/kg/day; there were no adverse effects. In a second dietary study, dogs also were fed diets containing clopyralid at doses of 15, 50, or 150 mg/kg/day; the only effect was an increase in the mean relative liver weight in females at the 150 mg/kg/day. In a 21–day dermal study, clopyralid was applied by repeated dermal application to New Zealand White rabbits at dose levels up to 1,000 mg/kg/day. Treatment produced no systemic effects.

5. *Chronic toxicity*. In a chronic toxicity and oncogenicity study, Sprague-Dawley rats were fed diets containing clopyralid at doses of 5, 15, 50 or 150 mg/kg/day. The only effect was a trend toward a decreased body weight of female rats receiving the 150 mg/kg/day dose and the NOAEL was 50 mg/kg/day. In a second study, clopyralid was fed to Fischer 344 rats in the diet at doses of 15, 150, or 1,500 mg/kg/day. The effects were confined almost entirely to the 1,500 mg/kg/day dose groups and included slightly decreased food consumption and body weights, slightly increased liver and kidney weights and macroscopic and microscopic changes in the stomach. No tumorigenic response was present. The NOAEL for this study was 150 mg/kg/day. B6C3F1 mice were maintained for 2 years on diets formulated to provide targeted dose levels of 10, 500, or 2,000 mg/kg/day. The only evidence of toxicity was body weight depression in males dosed at 2,000 mg/kg/day. There was no evidence of tumorigenic response at any dose level. Based on the chronic toxicity data, EPA has established the reference dose (RfD) for clopyralid at 0.5 mg/kg/day. The RfD for clopyralid based on a 2–year chronic oncogenicity study in rats with a NOAEL of 50 mg/kg/day and an uncertainty (or safety) factor of 100.

6. *Carcinogenicity*. Using Guidelines for Carcinogen Risk Assessment published September 24, 1986 (51 FR 33992), clopyralid would be classified as Group E for carcinogenicity (no evidence of carcinogenicity) based on the results of the carcinogenicity studies. There was no evidence of carcinogenicity in 2–year feeding studies in mice and rats at the dosage levels tested. The doses tested are adequate for identifying a cancer risk. Thus, a cancer risk assessment would not be appropriate.

7. *Animal metabolism*. Disposition and metabolism of clopyralid were tested in male and female rats at a dose of 5 mg/kg (oral). The majority of a radioactive dose was excreted in 24 hours of all dose groups. Fecal elimination was minor. Detectable levels of residual radioactivity were observed in the carcass and stomach at 72 hours post-dose. High performance liquid chromotography (HPLC) and thin layer chromotography (TLC) analysis of urine and fecal extracts showed no apparent metabolism of clopyralid.

8. *Metabolite toxicology*. There are no clopyralid metabolites of toxicological significance.

9. *Endocrine disruption*. There is no evidence to suggest that clopyralid has an effect on the endocrine system.

*C. Aggregate Exposure*

1. *Dietary exposure*. Acute dietary risk assessment is performed for a food-use pesticide if a toxicological study has indicated the possibility of an acute effect of concern occurring as a result of a 1–day or single exposure. EPA has previously used a NOAEL of 75 mg/kg/day from a rat developmental toxicity study to assess risk from acute dietary exposure, which is also the value used for assessment of acute dietary risk in this analysis. An acute RfD of 0.75 mg/kg/day was calculated, based on a NOAEL of 75 mg/kg/day and an uncertainty factor of 100 (10 for interspecies extrapolation and 10 for intraspecies variation). The maternal NOAEL was 75 mg/kg/day based on decreased weight gain during gestation days 6–9. The developmental NOEL was >250 mg/kg/day, indicating no additional sensitivity for developing young relative to adults. The acute RfD of 0.75 mg/kg/day was used to assess acute dietary risk for the general population, including infants and children.

Chronic dietary exposure to clopyralid is possible due to the potential presence of clopyralid residue in certain foods and drinking water. Chronic dietary risk was evaluated using a chronic RfD of 0.5 mg/kg/day, which is based on a NOAEL of 50 mg/kg/day from a chronic rat study along with an uncertainty factor of 100.

Since there was no evidence of carcinogenicity in the toxicology studies, a cancer risk assessment is not applicable.

i. *Food*. The dietary exposure assessment was based on all commodities with tolerances for clopyralid established at 40 CFR 180.431 together with the following proposed tolerances: Sweet corn: 3.0 ppm; popcorn: 3.0 ppm; canola: 3.0 ppm; flax seed: 0.3 ppm; hops: 5.0 ppm; strawberries: 1.0 ppm; mustard seed: 3 ppm; mustard greens: 5 ppm; stone fruits (crop group 12): 0.5 ppm; spinach: 5 ppm; garden-beet tops: 3 ppm; garden-beet roots: 4 ppm; turnip tops: 4 ppm; turnip roots: 1 ppm; and cranberry: 4 ppm. Crambe seed tolerance at 3 ppm is also requested, although it was not included within the residue file, since it is not considered by the Dietary Exposure Evaluation Model (DEEM) version 7.76 due to low cultivated area and low consumption patterns. The DEEM 7.76, which is produced by Novigen Sciences, Inc. and licensed to Dow AgroSciences, was used to estimate dietary exposure. This software used the food consumption data for the 1994–96 USDA Continuing Surveys of Food Intake by Individuals (CSFII 1994–96).

a. *Acute*. A Tier 1 acute dietary risk assessment was conducted with the conservative assumptions of 100% crop

treated and tolerance level residues for 108 crop commodities. Acute dietary risk was assessed using an acute RfD of 0.75 mg/kg/day. Even with conservative assumptions used in this analysis, acute dietary exposure was estimated to occupy only 3.97% of the acute RfD for the overall U.S. population, at the 95th percentile. Acute dietary exposure for children 1–6 years old, the population subgroup estimated to have the highest exposure, occupies only 6.91% of the acute RfD, at the 95th percentile. Adverse effects are not expected for exposures occupying 100% or less of the RfD. Therefore, acute exposure and risk from food is well within acceptable levels.

b. *Chronic*. A Tier 1 chronic dietary exposure and risk was estimated with the conservative assumptions of 100% crop treated and tolerance level residues for all crops. The estimate of potential chronic exposure and risk is very conservative and estimated risk would be substantially reduced with further refinement to the exposure estimate. Even with the conservative assumptions used in this analysis, chronic exposure is estimated to occupy only 2.3% of the RfD for the general U.S. population. Chronic dietary exposure for children 1–6 years old, the population subgroup estimated to have the highest exposure, occupies only 5.4% the chronic RfD. Therefore, chronic exposure and risk from food is well within acceptable levels.

ii. *Drinking water*. There is no established Maximum Contaminant Level (MCL) or Health Advisory Level (HAL) for residues of clopyralid in drinking water. High-end potential drinking water concentrations of clopyralid were estimated for ground water and surface water using the Screening Concentration in Ground Water (SCI-GROW) and Generic Expected Environmental Concentration (GENEEC) models respectively. Both GENEEC and SCI-GROW are Tier I screening level models that provide very conservative Estimated Environmental Concentrations (EECs) of pesticide residue in surface water and ground water, respectively. The EECs of a pesticide in surface water and ground water can be compared to a Drinking Water Level of Comparison (DWLOC) as a surrogate estimate of exposure and risk. The DWLOC is the concentration of a pesticide in drinking water that would be acceptable as an upper limit in light of total aggregate exposure to that pesticide in food and from residential uses.

The EEC of clopyralid in ground water according to SCI-GROW is 2 mg/L. Based on GENEEC, the estimated peak and 56–day concentration of clopyralid in surface water is 27 mg/L. EPA has previously indicated that the 56–day value from GENEEC should be divided by 3 for comparison to short-term and chronic DWLOC values. Therefore, a surface water concentration of 9 mg/L was used for comparison to short-term and chronic DWLOCs.

a. *Acute*. EPA has indicated that peak concentrations of a pesticide in surface water should be used in an acute assessment for comparison with DWLOC values. The peak surface water concentration of clopyralid was estimated to be 27 parts per billion (ppb) while the potential concentration in ground water was estimated to be 2 ppb. The DWLOC for acute exposure was based on an acute RfD of 0.75 mg/kg/day and was calculated to be 13,664 ppb and 8,853 ppb for the overall U.S. population and children 1–6 years old, respectively. Therefore, the acute DWLOC is substantially greater than estimated high-end concentrations of clopyralid in surface water or ground water, indicating that potential acute exposure and risk from drinking water is well within acceptable levels.

b. *Chronic*. As indicated previously, EECs in ground water and surface water for chronic exposures were estimated at 2 ppb and 9 ppb, respectively. The chronic DWLOC was calculated based on a chronic RfD of 0.5 mg/kg/day and accounted for potential chronic exposure to clopyralid through residues in food. The chronic DWLOC for the general U.S. population and children 1–6 years old was calculated to be 17,100 ppb and 4,740 ppb, respectively. Therefore, the chronic DWLOCs are substantially greater than estimated residue concentrations in surface water or ground water, indicating that chronic exposure and risk from drinking water is well with acceptable levels.

2. *Non-dietary exposure*. Clopyralid is registered for residential use on turf. Therefore, there is potential for both residential applicator exposure and post-application reentry exposure. EPA previously determined that there was no dermal toxicity endpoint since no systemic toxicity was observed at the highest dose tested (HDT) in a rabbit dermal toxicity study. Therefore, a dermal risk assessment is not required for residential exposure. EPA previously selected a maternal NOAEL of 75 mg/kg/day from a rat developmental toxicity study for assessing risk from short-term residential exposure through oral and inhalation routes, which is also the value used in this assessment. Inhalation exposure for residential applicators as well as post-application reentry exposure for children through incidental non-dietary ingestion of clopyralid residues were estimated using default values given in EPA's SOPs for Residential Exposure Assessments. Clopyralid residues have been found to dissipate rapidly from turfgrass, having a half-life of approximately 1–day. Considering the rapid dissipation of residues from turf along with the labeled use pattern, residential exposure may occur over a short-term interval, but would not be expected over an intermediate-term interval. Therefore, a short-term residential risk assessment was conducted, but an intermediate-term assessment was not required.

EPA has previously indicated that it is appropriate to aggregate chronic food and water exposure with short-term residential exposures for clopyralid. In addition to its use in assessment of risk from short-term residential exposure, the short-term NOAEL of 75 mg/kg/day was also used for assessing risk from dietary and drinking water exposure during a short-term interval. A Tier 1 estimate of aggregated exposure for adults from food and from inhalation for residential applicators resulted in a Margin of Exposure (MOE) of 6,800. Additionally, a short-term DWLOC for adults was calculated to be 25,800 ppb. Aggregated exposure for children 1–6 years old from food and from incidental non-dietary ingestion of clopyralid residues from treated turf resulted in an MOE of 2,300. Additionally, a short-term DWLOC for children 1–6 years old was calculated to be 7,100 ppb. EPA has indicated that the EECs for chronic exposure through ground water and surface water may also be used for assessing short-term exposure and risk. Therefore, the short-term ground water and surface water EECs are 2 ppb and 9 ppb, respectively. The minimum acceptable MOE was based on an uncertainty factor of 100. Since the short-term MOE for adults and children is well above 100 and DWLOCs are well above EECs for drinking water, aggregated short-term exposures are not expected to exceed a level of concern.

*D. Cumulative Effects*

The potential for cumulative effects of clopyralid and other substances that have a common mechanism of toxicity was considered. The mammalian toxicity of clopyralid is well defined. However, no reliable information exists to indicate that toxic effects produced by clopyralid would be cumulative with those of any other chemical compound. Additionally, clopyralid does not appear to produce a toxic metabolite produced by other substances. Therefore, consideration of a common

mechanism of toxicity with other compounds is not appropriate at this time. Thus, potential exposures to clopyralid were considered only in an aggregate exposure assessment.

*E. Safety Determination*

1. *U.S. population*. Using the conservative exposure assumptions previously described, acute dietary exposure to residues of clopyralid from current and proposed uses was estimated to occupy only 3.97% of the RfD for the general U.S. population. EPA generally has no concern for exposures below 100% of the RfD since the RfD represents the level at or below which exposure will not pose appreciable risks to human health. Additionally, the acute DWLOC was calculated to be over 1,500 fold greater than potential clopyralid residue in drinking water as predicted by conservative screening-level models. A conservative Tier 1 assessment indicated that chronic dietary exposure would occupy only 2.3% of the chronic RfD for the general U.S. population. Additionally, the chronic DWLOC was calculated to be over 1,900 fold greater than surface water or ground water EECs developed by screening-level models. A Tier 1 estimate of short-term dietary and residential exposure resulted in an MOE of 6,800, which is well above the minimum acceptable MOE of 100. Further, the short-term DWLOC is over 2,800 fold greater than the short-term EEC for surface water and ground water. Thus, based on the completeness and reliability of the toxicity data and the conservative exposure assessment, Dow AgroSciences concludes that there is a reasonable certainty that no harm will result to the general U.S. population from aggregate acute, short-term or chronic exposure to clopyralid residues from current and proposed uses.

2. *Infants and children*. In assessing the potential for additional sensitivity of infants and children to residues of clopyralid, data are considered from developmental toxicity studies in the rat and rabbit, and from multiple generation reproduction studies in rats. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from maternal pesticide exposure during gestation. Reproductive studies provide information relating to prenatal and postnatal effects from exposure to the pesticide, on the reproductive capability of mating animals, and data on systemic toxicity.

Based on the results of developmental toxicity and multigenerational reproduction studies, there are no indications of prenatal or postnatal toxicity concerns for infants and children from exposure to clopyralid. FFDCA section 408 provides that EPA may apply an additional safety factor for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database. Based on the current toxicological data requirements, the database for clopyralid relative to prenatal and postnatal effects for children is complete. There were no indications of neurotoxicity and developmental toxicity was not observed in the absence of maternal toxicity. It is concluded that there is no indication of increased sensitivity of infants and children relative to adults and that an additional FQPA safety factor is not required.

Using conservative exposure assumptions previously described, acute dietary exposure to residues of clopyralid from current and proposed uses was estimated to occupy only 6.91% of the RfD for children 1–6 years old, the population subgroup estimated to be most highly exposed. EPA generally has no concern for exposures below 100% of the RfD since the RfD represents the level at or below which exposure will not pose appreciable risks to human health. Additionally, the acute DWLOC was calculated to be over 900 fold greater than potential clopyralid residue in drinking water as predicted by conservative screening-level models. A conservative Tier 1 assessment indicated that chronic dietary exposure for children 1–6 years old would occupy only 5.4% of the chronic RfD. Additionally, the chronic DWLOC was calculated to be over 500 fold greater than surface water or ground water EECs developed by screening-level models. A Tier 1 estimate of short-term dietary and residential exposure for children 1–6 years old resulted in an MOE of 2,300, which is well above the minimum acceptable MOE of 100. Further, the short-term DWLOC is over 700 fold greater than the short-term EEC for surface water and ground water. Thus, based on the completeness and reliability of the toxicity data and the conservative exposure assessment, Dow AgroSciences concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate acute, short-term or chronic exposure to clopyralid residues from current and proposed uses.

*F. International Tolerances*

There are no Codex or Mexican maximum residue limits. Canada has set a maximum residue limit of 2.0 ppm for barley, oats, and wheat, and 7.0 ppm for the milled fractions of barley, oats, and wheat (excluding flour).

[FR Doc. 02–20230 Filed 8–13–02; 8:45 am]

BILLING CODE 6560–50–S

## ENVIRONMENTAL PROTECTION AGENCY

**[OPP–2002–0174; FRL–7191–9]**

## Notice of Filing Pesticide Petitions to Establish Tolerances for a Certain Pesticide Chemical in or on Food

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** This notice announces the initial filing of pesticide petitions proposing the establishment of regulations for residues of a certain pesticide chemical in or on various food commodities.

**DATES:** Comments, identified by docket ID number OPP–2002–0174, must be received on or before September 13, 2002.

**ADDRESSES:** Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I.C. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, it is imperative that you identify docket ID number OPP–2002–0174 in the subject line on the first page of your response.

**FOR FURTHER INFORMATION CONTACT:** By mail: Sidney Jackson, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305–7610; e-mail address: *jackson.sidney@epa.gov*.

**SUPPLEMENTARY INFORMATION:**

### I. General Information

*A. Does this Action Apply to Me?*

You may be affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

| Categories | NAICS codes | Examples of potentially affected entities |
|---|---|---|
| Industry | 111<br>112<br>311<br><br>32532 | Crop production<br>Animal production<br>Food manufacturing<br>Pesticide manufacturing |

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

*B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?*

1. *Electronically*. You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet home page at *http://www.epa.gov/*. To access this document, on the home page select ''Laws and Regulations,'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listings at *http://www.epa.gov/fedrgstr/*.

2. *In person*. The Agency has established an official record for this action under docket ID number OPP–2002–0174. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as confidential business information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

*C. How and to Whom Do I Submit Comments?*

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is imperative that you identify docket ID number OPP–2002–0174 in the subject line on the first page of your response.

1. *By mail*. Submit your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

2. *In person or by courier*. Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. The PIRIB is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

3. *Electronically*. You may submit your comments electronically by e-mail to: *opp-docket@epa.gov*, or you can submit a computer disk as described above. Do not submit any information electronically that you consider to be CBI. Avoid the use of special characters and any form of encryption. Electronic submissions will be accepted in Wordperfect 6.1/8.0 or ASCII file format. All comments in electronic form must be identified by docket ID number OPP–2002–0174. Electronic comments may also be filed online at many Federal Depository Libraries.

*D. How Should I Handle CBI That I Want to Submit to the Agency?*

Do not submit any information electronically that you consider to be CBI. You may claim information that you submit to EPA in response to this document as CBI by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public version of the official record. Information not marked confidential will be included in the public version of the official record without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person identified under **FOR FURTHER INFORMATION CONTACT**.

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

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.

2. Describe any assumptions that you used.

3. Provide copies of any technical information and/or data you used that support your views.

4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.

5. Provide specific examples to illustrate your concerns.

6. Make sure to submit your comments by the deadline in this notice.

7. To ensure proper receipt by EPA, be sure to identify the docket ID number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

## II. What Action is the Agency Taking?

EPA has received pesticide petitions as follows proposing the establishment and/or amendment of regulations for residues of a certain pesticide chemical in or on various food commodities under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that the petitions contain data or information regarding the elements set forth in section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petitions.

**List of Subjects**

Environmental protection, Agricultural commodities, Feed additives, Food additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: July 31, 2002.

**Peter Caulkins,**

*Acting Director, Registration Division, Office of Pesticide Programs.*

**Summary of Petitions**

The petitioner summaries of the pesticide petitions are printed below as required by section 408(d)(3) of the FFDCA. The summaries of the petitions were prepared by the petitioner and represents the view of the petitioner. EPA is publishing the summaries verbatim without editing them in any way. The summaries announce the availability of a description of the analytical methods available to EPA for

the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed.

**Interrregional Research Project Number 4, (IR-4)**

*PP 2E6382, 2E6408, and 2E6441*

EPA has received pesticide petitions (2E6382, 2E6408, and 2E6441) from the Interregional Research Project Number 4 (IR-4), Technology Centre of New Jersey, the State University of New Jersey, 681 U.S. Highway #1 South, North Brunswick, NJ 08902–3390 proposing, pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), to amend 40 CFR part 180, by establishing tolerances for residues of methoxyfenozide in or on the raw agricultural commodities as follows:

1. PP 2E6382 proposes a tolerance for artichoke, globe at 3.0 parts per million (ppm).

2. PP 2E6408 proposes a tolerance for lychee, longan, spanish lime, rambutan and pulasan at 2.0 ppm.

3. PP 2E6441 proposes a tolerance for cranberry at 0.5 ppm.

EPA has determined that the petitions contain data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petitions. Additional data may be needed before EPA rules on the petitions.

This notice includes a summary of the petitions prepared by Dow Agro Sciences, LLC, Indianapolis, IN 46268–1054, the manufacturer of methoxyfenozide.

*A. Residue Chemistry*

1. *Plant metabolism*. The qualitative nature of methoxyfenozide residues in plants and animals is adequately understood and was previously published in the **Federal Register** of July 5, 2000 (65 FR 41355) (FRL–6497–5).

2. *Analytical method*. An high performance liquid chromatography using ultra-violet detection (HPLC/UV) method TR 34–00–109 for the enforcement of tolerances in stone fruits has been developed and is adequate to support the proposed tolerances. Confirmatory method validation data have been submitted for this method. The validated limit of quantitation (LOQ) of the analytical method was 0.02 ppm in all matrices for methoxyfenozide.

3. *Magnitude of residues*. Complete residue data for methoxyfenozide on artichoke, globe; longan; spanish lime; rambutan; pulasan; and cranberry have been submitted. The requested tolerances are adequately supported.

*B. Toxicological Profile*

1. *Acute toxicity*. The toxicological profile and endpoints for methoxyfenozide which support this petition to establish tolerances were previously published in the **Federal Register** of July 5, 2000 (65 FR 41355).

2. *Endocrine disruption*. The petitioner believes that, since the definition and regulatory significance of the term ''endocrine disruptor chemical'' have not yet been established by the Agency, it is not clear whether methoxyfenozide, on the basis of observed effects on the thyroid gland and adrenal gland, should be considered to be an ''endocrine disruptor chemical.'' Other than the morphological changes reported in the above referenced document (July 5, 2000, 65 FR 41355), there were no signs of thyroid or adrenal dysfunction in these or in any other studies on methoxyfenozide.

*C. Aggregate Exposure*

1. *Dietary exposure*—i. *Food*. Assessments were conducted to evaluate potential risks due to chronic and acute dietary exposure of the U. S. population subgroups to residues of methoxyfenozide. These analyses cover all registered crops, as well as, uses pending with the Agency, active and proposed section 18 uses, and proposed IR-4 minor uses. There are no registered residential nonfood uses of methoxyfenozide.

a. *Acute risk*. No appropriate toxicological endpoint attributable to a single exposure was identified in the available toxicology studies on methoxyfenozide including the acute neurotoxicity study in rats, the developmental toxicity study in rats and the developmental toxicity study in rabbits. Since no acute toxicological endpoints were established, Dow Agro Sciences considers acute aggregate risk to be negligible.

b. Chronic assessments were conducted to evaluate potential risks due to chronic dietary exposure of the U.S. population and selected population subgroups to residues of methoxyfenozide. These analyses cover all registered crops, uses pending with the EPA, active and proposed section 18 uses and new proposed IR-4 uses. Dow Agro Sciences used the Dietary Exposure Evaluation Model™ (DEEM), (Novigen Sciences, Washington, DC) software for conducting a chronic dietary (food) risk analysis. DEEM is a dietary exposure analysis system that is used to estimate exposure to a pesticide chemical in foods comprising the diets of the U.S. population, including population subgroups. DEEM contains food consumption data as reported by respondents in the U.S. Department of Agriculture Continuing Surveys of Food Intake by Individuals conducted in 1994–1996. Dow Agro Sciences assumed 100% of crops would be treated and contain methoxyfenozide residues at tolerance levels. The resulting chronic dietary exposure analysis is summarized in Table 1.

TABLE 1.—CHRONIC DIETARY EXPOSURE ANALYSIS BY DEEM (TIER 1)

| Population subgroup | Exposure milligrams/kilogram/day (mg/kg/day) | Percent of chronic population adjusted dose |
|---|---|---|
| U.S. population - 48 contiguous States | 0.0189 | 18.9 |
| All infants (<1 year old) | 0.0315 | 31.5 |
| Nursing infants (<1 year old) | 0.0134 | 13.4 |
| Non-nursing infants (<1 year old) | 0.0368 | 36.8 |
| Children 1 to 6 years old | 0.0376 | 37.6 |
| Children 7 to 12 years old | 0.0216 | 21.6 |

TABLE 1.—CHRONIC DIETARY EXPOSURE ANALYSIS BY DEEM (TIER 1)—Continued

| Population subgroup | Exposure milligrams/kilogram/day (mg/kg/day) | Percent of chronic population adjusted dose |
|---|---|---|
| Females 13+ (nursing) | 0.0156 | 19.1 |
| U.S. population (autumn season) | 0.0191 | 19.1 |
| U.S. population (spring season) | 0.0190 | 19.0 |
| Northeast region | 0.0206 | 20.6 |
| Western region | 0.0210 | 21.0 |
| Hispanics | 0.0191 | 19.1 |
| Non-Hispanic/non-white/non-black | 0.0249 | 24.8 |

Percent chronic PAD = (Exposure divided by chronic PAD) x 100%.
The subgroups listed are:
1. The U.S. population (total)
2. Those for infants and children
3. The other subgroup(s), if any, for which the percentage of the chronic PAD occupied is greater than that occupied by the subgroup U.S. population (total).

The resulting dietary food exposures occupy up to 37.6% of the chronic population adjusted dose (PAD) for the most highly exposed population subgroup, children 1 to 6 years old. These results should be viewed as conservative (health protective) risk estimates. Refinements such as use of percent crop-treated (PCT) information and/or anticipated residue values would yield even lower estimates of chronic dietary exposure.

ii. *Drinking water.* There are no water-related exposure data from monitoring to complete a quantitative drinking water exposure analysis and risk assessment for methoxyfenozide. Generic Expected Environmental Concentration (GENEEC) and/or EPA's Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) (both product estimates of pesticide concentration in a farm pond) are used to generate estimated environmental concentrations (EECs) for Surface Water and Screening Concentration in Ground Water (SCI-GROW) (an empirical model based upon actual monitoring data collected for a number of pesticides that serve as benchmarks) predicts EECs in ground water. These models take into account the use patterns and the environmental profile of a pesticide, but do not include consideration of the impact that processing raw water for distribution as drinking water would likely have on the removal of pesticides from the source water. The primary use of these models at this stage is to provide a coarse screen for assessing whether a pesticide is likely to be present in drinking water at concentrations which would exceed human health levels of concern

A drinking water level of comparison (DWLOC) is the concentration of a pesticide in drinking water that would be acceptable as a theoretical upper limit in light of total aggregate exposure to that pesticide from food, water, and residential uses. EPA uses DWLOCs internally in the risk assessment process as a surrogate measure of potential exposure associated with pesticide exposure through drinking water. In the absence of monitoring data for a pesticide, the DWLOC is used as a point of comparison against the conservative EECs provided by computer modeling SCI-GROW, GENEEC, and PRZM/EXAMS.

a. *Acute exposure and risk.* Because no acute dietary endpoint was determined, Dow Agro Sciences concludes that there is a reasonable certainty of no harm from acute exposure from drinking water.

b. *Chronic exposure and risk.* Tier II screening-level assessments can be conducted using the simulation models SCI-GROW and PRZM/EXAMS to generate EECs for ground water and surface water, respectively. The modeling was conducted based on the environmental profile and the maximum seasonal application rate proposed for methoxyfenozide (1.0 lb ai/acre/season). PRZM/EXAMS was used to generate the surface water EECs, because it can factor the persistent nature of the chemical into the estimates.

The EECs for assessing chronic aggregate dietary risk used by HED are 6 parts per billion (ppb) (in ground water, based on SCI-GROW) and 98.5 ppb (in surface water, based on the PRZM/EXAMS, long-term mean). The back-calculated DWLOCs for assessing chronic aggregate dietary risk range from 624 ppb for the most highly exposed population subgroup (children 1 to 6 years old) to 2,839 ppb for the U.S. population (48 contiguous States - all seasons).

The SCI-GROW and PRZM/EXAMS chronic EECs are less than the Agency's level of comparison (the DWLOC value for each population subgroup) for methoxyfenozide residues in drinking water as a contribution to chronic aggregate exposure. Dow Agro Sciences thus concludes with reasonable certainty that residues of methoxyfenozide in drinking water will not contribute significantly to the aggregate chronic human health risk and that the chronic aggregate exposure from methoxyfenozide residues in food and drinking water will not exceed the Agency's level of concern (100% of the chronic PAD) for chronic dietary aggregate exposure by any population subgroup. EPA generally has no concern for exposures below 100% of the chronic PAD, because it is a level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to the health and safety of any population subgroup. This risk assessment is considered high confidence, conservative, and very protective of human health.

TABLE 2.—DWLOC FOR CHRONIC EXPOSURE TO METHOXYFENOZIDE

| Population subgroup | Chronic PAD (mg/kg/day) | Food exposure (mg/kg/day) | Maximum water exposure (mg/kg/day | SCI-GROW (µg/L) | GENEEC 56–day average (µg/L) | DWLOC (µg/L) |
|---|---|---|---|---|---|---|
| U.S. population (48 contiguous States) | | 0.0189 | 0.0811 | | | 2,839 |
| Females 13+ (nursing) | | 0.0191 | 0.0809 | | | 2,427 |
| Non-nursing infants (<1 year old) | 0.10 | 0.0368 | 0.0632 | 6 | 98.5 | 632 |
| Children 1 to 6 years old | | 0.0376 | 0.0624 | | | 624 |
| Children 7 to 12 years old | | 0.0216 | 0.0784 | | | 784 |

Maximum water exposure (mg/kg/day) = chronic PAD (mg/kg/day) - chronic food exposure.
1. DWLOC (µg/L) = (Maximum water exposure mg/kg/day) x body weight (kg)) divided by (1/1,000 mg/µg x water consumed daily (L/day)).
2. Body weights (kg) for adults is 70, for females 13+ is 60 kg and for all children is 10 kg.
3. Drinking water consumption is 2 liters per day for adults and 1 liter per day for children.

2. *Non-dietary exposure*. Methoxyfenozide is not currently registered for use on any residential non-food sites. Therefore, there is no non-dietary acute, chronic, short- or intermediate-term exposure.

*D. Cumulative Effects*

Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency considers ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

EPA does not have, at this time, available data to determine whether methoxyfenozide has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, methoxyfenozide does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, it is assumed that methoxyfenozide does not have a common mechanism of toxicity with other substances.

*E. Safety Determination*

1. *U.S. population*. Using the DEEM exposure assumptions described in this unit, Dow Agro Sciences has concluded that aggregate exposure to methoxyfenozide from the proposed new tolerances will utilize 18.9% of the chronic PAD for the U.S. population. The major identifiable subgroup with the highest aggregate exposure is children 1 to 6 years old at 37.6% of the chronic PAD and is discussed below. EPA generally has no concern for exposures below 100% of the chronic PAD because the chronic PAD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Despite the potential for exposure to methoxyfenozide in drinking water, the aggregate exposure is not expected to exceed 100% of the chronic PAD. Dow Agro Sciences concludes that there is a reasonable certainty that no harm will result from aggregate exposure to methoxyfenozide residues.

2. *Infants and children*. In assessing the potential for additional sensitivity of infants and children to residues of methoxyfenozide, EPA considered data from developmental toxicity studies in the rat and rabbit and a 2-generation reproduction study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from maternal pesticide exposure during gestation. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

FFDCA section 408 provides that EPA shall apply an additional ten-fold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. EPA believes that reliable data support using the standard uncertainty factor (UF) (usually 100 for combine interspecies and intraspecies variability) and not the additional ten-fold MOE/UF when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard MOE/safety factor.

The toxicology data base for methoxyfenozide included acceptable developmental toxicity studies in both rats and rabbits as well as a 2-generation reproductive toxicity study in rats. The data provided no indication of increased sensitivity of rats or rabbits to *in utero* and/or postnatal exposure to methoxyfenozide. There is a complete toxicity data base for methoxyfenozide an exposure data are complete or are estimated based on data that reasonably account for potential exposures. Based on the completeness of the data base and the lack of prenatal and postnatal toxicity, EPA determined that an additional safety factor was not needed for the protection of infants and children.

Since no toxicological endpoints were established, acute aggregate risk is considered to be negligible. Using the exposure assumptions described in this unit, Dow AgroSciences has concluded that aggregate exposure to methoxyfenozide from the proposed new tolerances will utilize 37.6% of the cPAD for infants and children. EPA

generally has no concern for exposures below 100% of the cPAD because the cPAD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Despite the potential for exposure to methoxyfenozide in drinking water, Dow Agro Sciences does not expect the aggregate exposure to exceed 100% of the cPAD. Short-term and intermediate-term risks are judged to be negligible due to the lack of significant toxicological effects observed. Based on these risk assessments, Dow Agro Sciences concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to methoxyfenozide residues.

*F. International Tolerances*

There are no established or proposed Codex, Canadian or Mexican limits for residues of methoxyfenozide in/on plant or animal commodities. Therefore, no compatibility issues exist with regard to the proposed U.S. tolerances.

[FR Doc. 02–20356 Filed 8–13–02; 8:45 am]

BILLING CODE 6560–50–S

## ENVIRONMENTAL PROTECTION AGENCY

**[FRL–7259–2]**

### Real-Time Monitoring for Toxicity Caused by Harmful Algal Blooms and Other Water Quality Perturbations

**AGENCY:** Environmental Protection Agency.

**ACTION:** Notice of availability.

**SUMMARY:** This notice announces the availability of a final report titled, *Real-Time Monitoring for Toxicity Caused by Harmful Algal Blooms and Other Water Quality Perturbations* (EPA/600/R–01/103), which was prepared by the U.S. Environmental Protection Agency's (EPA) National Center for Environmental Assessment (NCEA) of the Office of Research and Development (ORD). This project, sponsored by EPA's Environmental Monitoring for Public Access and Community Tracking (EMPACT) program, evaluated the ability of an automated biological monitoring system that measures fish ventilatory responses (ventilatory rate, ventilatory depth, and cough rate) to detect developing toxic conditions in water.

**DATES:** This document will be available on August 14, 2002.

**ADDRESSES:** The document is available electronically through the NCEA Web site at (*www.epa.gov/ncea*) under the *What's New or Publications menus.* A limited number of paper copies will be available from EPA's National Service Center for Environmental Publications (NSCEP), PO Box 42419, Cincinnati, Ohio 45242; telephone: 1–800–490–8190 or 513–489–8190; facsimile: 5–13–489–8695. Please provide your name and mailing address and the title and EPA number of the requested publication.

**FOR FURTHER INFORMATION CONTACT:** 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.

**SUPPLEMENTARY INFORMATION:** This report describes the development and operation of a real-time automated biomonitoring system for detecting toxicity caused by harmful algal blooms and other water quality perturbations. The system was developed and evaluated over a 2-year period (March 1999 through November 2000) on the Chicamacomico and Transquaking Rivers, tributaries to the Chesapeake Bay on Maryland's Eastern Shore. Relevant literature has been reviewed through May 2001.

Dated: August 6, 2002.

**Michael Slimak,**

*Acting Director, National Center for Environmental Assessment.*

[FR Doc. 02–20581 Filed 8–13–02; 8:45 am]

BILLING CODE 6560–50–P

## ENVIRONMENTAL PROTECTION AGENCY

**[OPPT–2002–0046; FRL–7193–1]**

### TSCA Chemical Testing; Receipt of Test Data

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** This notice announces EPA's receipt of test data on 1,1,2-Trichloroethane (1,1,2-TCE) (CAS No. 79–00–5). These data were submitted pursuant to an enforceable testing consent agreement/order issued by EPA under section 4 of the Toxic Substances Control Act (TSCA).

**FOR FURTHER INFORMATION CONTACT:** Barbara Cunningham, Acting Director, Environmental Assistance Division (7408M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (202) 554–1404; e-mail address: *TSCA-Hotline@epa.gov*.

**SUPPLEMENTARY INFORMATION:**

#### I. Does this Action Apply to Me?

This action is directed to the public in general. This action may, however, be of interest to those persons who are concerned about data on health and/or environmental effects and other characteristics of this chemical. Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

#### II. How Can I Get Additional Information, Including Copies of this Document or Other Related Documents?

1. *Electronically*. You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet home page at *http://www.epa.gov/*. To access this document, on the Home Page select ''Laws and Regulations,'' ''Regulations and Proposed Rules,'' and then look up the entry for this document under ''**Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listings at *http://www.epa.gov/fedrgstr/*.

2. *In person*. The Agency has established an official record for this action under docket ID number OPPT–2002–0046. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the TSCA Nonconfidential Information Center, North East Mall Rm. B–607, Waterside Mall, 401 M St., SW., Washington, DC. The Center is open from noon to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Center is (202) 260–7099.

**III. Test Data Submissions**

Under 40 CFR 790.60, all TSCA section 4 enforceable consent agreements/orders must contain a statement that results of testing conducted pursuant to enforceable consent agreements/orders will be announced to the public in accordance with section 4(d) of TSCA.

Test data for 1,1,2-TCE, a hazardous air pollutant (HAP) listed under section 112 of the Clean Air Act Amendments of 1990, were submitted by the HAP Task Force. These data were submitted pursuant to a TSCA section 4 enforceable consent agreement/order and were received by EPA on June 14, 2002. The submission includes two final reports titled: (1) ''A 90–Day Inhalation Toxicity Study of 1,1,2-Trichloroethane (1,1,2-TCE) in Rats (With Satellite Groups for Pharmacokinetic Evaluations in Rats and Mice),'' and (2) ''Physiologically Based Pharmacokinetic Model Development, Simulations, and Sensitivity Analysis for Repeated Exposure to 1,1,2-Trichloroethane.'' 1,1,2-TCE is used as a feedstock intermediate in the production of vinylidene chloride and some tetrachloroethanes. It is used as a solvent where its high solvency for chlorinated rubbers and other substances is needed, and for pharmaceuticals and electronic components.

EPA has initiated its review and evaluation process for this submission. At this time, the Agency is unable to provide any determination as to the completeness of the submission.

**Authority:** 15 U.S.C. 2603.

**List of Subjects**

Environmental protection, Hazardous substances, Toxic substances.

Dated: August 6, 2002.

**Rebecca S. Cool,**

*Acting Director, Chemical Control Division, Office of Pollution Prevention and Toxics.*

[FR Doc. 02–20355 Filed 8–13–02; 8:45 am]

**BILLING CODE 6560–50–S**

## 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.:* 010099–036.

*Title:* International Council of Containership Operators.

*Parties:* A.P. Moller-Maersk Sealand; American President Lines, Ltd.; ANL Container Line Pty, Ltd.; APL Co. PTE Ltd.; Atlantic Container Line AB; Australia-New Zealand Direct Line; Canada Maritime; Cast Line; COSCO Container Lines Company, Ltd.; China Shipping Container Lines Co., Ltd.; CMA GCM, S.A.; Compania Sud Americana de Vapores S.A.; Companhia Libra de Navegacao; Contship Containerlines; Crowley Maritime Corp.; Evergreen Marine Corp. (Taiwan), Ltd.; Hamburg Sud; Hanjin Shipping Company, Ltd.; Hapag-Lloyd Container Linie GmbH; Hyundai Merchant Marine Co., Ltd.; Italia de Navigazione SpA; Kawasaki Kisen Kaisha, Ltd.; Lykes Lines Ltd.; Malaysia International Shipping Corp. Berhad; Mediterranean Shipping Company, S.A.; Montemar Maritime S.A.; Mitsui O.S.K. Lines, Ltd.; Nippon Yusen Kaisha; Norasia Container Line Ltd.; Orient Overseas Container Line Limited; P&O Nedlloyd Limited; P&O Nedlloyd B.V.; Pacific International Lines (Pte) Ltd.; TMM Lines Ltd.; United Arab Shipping Co. (S.A.G.); Wan Hai Lines, Ltd.; Wallenius Wilhelmsen Lines AS; Yang Ming Marine Transport Corp.; Zim Israel Navigation Co. Ltd.

*Synopsis:* The amendment adds Pacific International Lines (Pte) Ltd. as an agreement party.

*Agreement No.:* 011325–028.

*Title:* Westbound Transpacific Stabilization Agreement.

*Parties:* A.P. Moller-Maersk Sealand, American President Lines, Ltd., APL Co. PTE Ltd., COSCO Container Lines Company, Ltd., Evergreen Marine Corp. (Taiwan), Ltd., Hapag-Lloyd Container Linie GmbH, Hanjin Shipping Company, Ltd., Hyundai Merchant Marine Co., Ltd., Kawasaki Kisen Kaisha, Ltd., Mitsui O.S.K. Lines, Ltd., Nippon Yusen Kaisha, Orient Overseas Container Line Limited, P&O Nedlloyd Limited, P&O Nedlloyd B.V., Yang Ming Marine Transport.

*Synopsis:* The amendment deletes A.P. Moller-Maersk Sealand as an agreement party.

*Agreement No.:* 11737–007.

*Title:* The MCA Agreement.

*Parties:* Alianca Navegacao e Logistica Ltda., Antillean Marine Shipping Corporation, CMA CGM S.A., Companhia Libra de Navegacao, Compania Sud Americana de Vapores S.A., CP Ships (UK) Limited d/b/a ANZDL and d/b/a Contship Containerlines, Crowley Liner Services, Inc., Dole Ocean Cargo Express, Inc., Hamburg-Sud d/b/a Columbus Line and d/b/a Crowley American Transport, Hapag-Lloyd Container Linie, King Ocean Central America S.A., King Ocean Service de Colombia S.A., King Ocean Service de Venezuela S.A., Lykes Lines Limited, LLC, Montemar Maritima S.A., Nippon Yusen Kaisha, Norasia Container Line Limited, Wallenius Wilhelmsen Lines AS, TMM Lines Limited, LLC, Tecmarine Lines, Inc., Tropical Shipping & Construction Co., Ltd.

*Synopsis:* The proposed amendment adds Atlantic Container Line to the membership list and includes further indemnification language regarding confidentiality.

*Agreement No.:* 011813.

*Title:* Frontier/Tecmarine Space Charter Agreement.

*Parties:* Tecmarine Lines, Inc., Frontier Liner Services, Inc.

*Synopsis:* The proposed agreement authorizes the parties to charter space to each other in the trade between U.S. East Coast ports and ports in the Dominican Republic.

*Agreement No.:* 011814.

*Title:* CAT/King Ocean Space Charter Agreement.

*Parties:* Hamburg-Süd, King Ocean Services Limited, King Ocean Services de Venezuela.

*Synopsis:* The proposed agreement authorizes the parties to charter space to/from one another on their respective vessels in the trade between ports on the Atlantic Coast of Florida and ports in Aruba, Bonaire, Curaçao, Colombia, and Venezuela.

*Agreement No.:* 011815.

*Title:* Transpacific Space Charter Agreement.

*Parties:* COSCO Container Lines Company, Limited, Hapag-Lloyd Container Linie GmbH, Nippon Yusen Kaisha, Orient Overseas Container Line Limited/Orient Overseas Container Line Inc./Orient Overseas Container Line (UK) Limited, P&O Nedlloyd Limited/P&O Nedlloyd BV.

*Synopsis:* The proposed agreement would authorize COSCO to charter space to the other parties on its vessels operating between Asia and the West Coast of North America.

*Agreement No.:* 011816.

*Title:* Mediterranean Ancillary Agreement.

*Parties:* CP Ships Limited, D'Amico Societa di Navigazione SpA, Italia di Navigazione SpA, Medbulk Maritime Co.

*Synopsis:* Under the proposed agreement, D'Amico agrees not to

compete with CP Ships between the United States and ports on the Mediterranean Sea and in Mexico, Central America, and South America for five years.

*Agreement No.:* 200860–002.

*Title:* Lease and Operating Agreement.

*Parties:* Philadelphia Regional Port Authority, Dependable Distribution Services Inc.

*Synopsis:* The amendment allows for the construction of a temporary storage facility upon Pier 84 South, provides how much the lessor and the lessee will each contribute to the cost of the construction, includes provisions regarding the ownership and control of the temporary structure, and makes adjustments in tonnage fees paid by the lessee.

Dated: August 9, 2002.

By Order of the Federal Maritime Commission.

**Bryant L. VanBrakle,**

*Secretary.*

[FR Doc. 02–20667 Filed 8–13–02; 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**

FCC Logistics Inc. dba GOF Logistics Group, 10722 S. La Cienega Blvd., Inglewood, CA 90304. Officers: Tan-Ing Chou (aka Tammy), Secretary, (Qualifying Individual); Zeng Chun Guan, CEO.

Sinotrans Express Inc., 10338 Rush Street, S. El Monte, CA 91733. Officers: Daniel D.L. Au, Vice President, (Qualifying Individual); Kaiyang Lin, President.

Ocean Air Freight International, Inc., 3921 NW 144th Street, Bldg. 66, Opalooka, FL 33054. Officers: Paul Kupke, Vice President, (Qualifying Individual); Greg Cole, President.

Gift and Parcel, Inc. dba FP Express; Pesocard, 4700 Mission Street, San Francisco, CA 94112. Officers: Fernando M. Banaria, Jr., President, (Qualifying Individual); Steven Foo, CEO.

American Logistics Intermodal, Inc., 320 Pine Avenue, Suite 503, Long Beach, CA 90802. Officers: Romika K. Singh, Vice President, (Qualifying Individual); Mian S. Waheed, CEO.

**Non-Vessel Operating Common Carrier and Ocean Freight Forwarder Transportation Intermediary Applicants**

Re Transportation, Inc. dba Re Trans, 7305 Mont Blanc, Germantown, TN 38138. Officer: David Wedaman, President, (Qualifying Individual).

Power Link Logistic Inc., 1751 Deerwood Drive, Fullerton, CA 92833. Officers: Polly Yang, General Manager, (Qualifying Individual); Pamela Yang, CEO.

Pactrans Air & Sea Inc., 950 Thornedale Avenue, Elk Grove Village, IL 60007. Officers: Kitty Pon, Vice President, (Qualifying Individual); Alexander Pon, President.

Dated: August 9, 2002.

**Bryant L. VanBrakle,**

*Secretary.*

[FR Doc. 02–20666 Filed 8–13–02; 8:45 am]

**BILLING CODE 6730–01–P**

## GENERAL SERVICES ADMINISTRATION

### President's Homeland Security Advisory Council

**AGENCY:** Office of Governmentwide Policy, General Services Administration.

**ACTION:** Notice of Federal Advisory Committee meeting.

**SUMMARY:** The President's Homeland Security Advisory Council (PHSAC or Council) will meet in an open session on Thursday, August 29, 2002, from 8:30 a.m. to 12:35 p.m., in the Indian Treaty Room of the Eisenhower Executive Office Building, 725 Seventeenth NW., Washington, DC. The PHSAC will meet to receive briefings and to discuss best practices in the areas of mergers/acquisitions, information technology, personnel management and related issues that may concern the creation of the proposed Department of Homeland Security, and homeland security in general.

*Objectives:* The President's Homeland Security Advisory Council was established by Executive Order 13260 (67 FR 13241, March 21, 2002). The objectives of the PHSAC are to provide advice and recommendations to the President of the United States through the Assistant to the President for Homeland Security on matters relating to homeland security.

*Public Attendance:* Due to limited availability of seating, members of the public will be admitted on a first-come, first-served basis. In addition, due to the security requirements of the Eisenhower Executive Office Building, any members of the public who wish to attend the meeting must provide their name, social security number, and date of birth no later than 5 p.m. EDT, Monday, August 26, 2002, to Mr. Fred Butterfield, General Services Administration, by phone: (202) 273–3566, or e-mail: *fred.butterfield@gsa.gov*. Photo identification will be required for entry into the building. Persons with disabilities who require assistance should indicate this in their message.

*Public Comments:* Members of the public who wish to file a written statement with the PHSAC may do so by mail to Mr. Fred Butterfield at the following address: President's Homeland Security Advisory Council, U.S. General Services Administration (GSA/MC, Room G230), 1800 F St. NW., Washington, DC 20405. Comments may also be sent to Fred Butterfield by e-mail at *fred.butterfield@gsa.gov*, or by facsimile (FAX) to (202) 273–3559.

Dated: August 9, 2002.

**James L. Dean,**

*Director, Committee Management Secretariat, Office of Governmentwide Policy, General Services Administration.*

[FR Doc. 02–20705 Filed 8–13–02; 8:45 am]

**BILLING CODE 6820–34–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

### Disease, Disability, and Injury Prevention and Control Special Emphasis Panel: Cooperative Agreements for Centers of Excellence in Health Statistics, Program Announcement No. 02193

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following meeting:

*Name:* Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Cooperative Agreements for

Centers of Excellence in Health Statistics, PA# 02193.

*Times and Dates:* 1 p.m.–1:30 p.m., September 5, 2002 (Open), 1:30 p.m.–5:30 p.m., September 5, 2002 (Closed).

*Place:* Teleconference number (800) 713–1971.

*Status:* Portions of the meeting will be closed to the public in accordance with provisions set forth in section 552b(c) (4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92–463.

*Matters to be Discussed:* The meeting will include the review, discussion, and evaluation of applications received in response to PA# 02193.

**CONTACT PERSON FOR MORE INFORMATION:** Linda Blankenbaker, Program Specialist, National Center for Health Statistics, CDC, 6525 Belcrest Road, Room 1140, Hyattsville, Maryland 20782, (301) 458–4612.

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 the Agency for Toxic Substances and Disease Registry.

Dated: August 6, 2002.

**John Burckhardt,**

*Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).*

[FR Doc. 02–20559 Filed 8–13–02; 8:45 am]

**BILLING CODE 4160–18–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare and Medicaid Services

**[Document Identifier: CMS–9042]**

### Agency Information Collection Activities: Proposed Collection; Comment Request

**AGENCY:** Centers for Medicare and Medicaid Services.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare and Medicaid Services (CMS) (formerly known as the Health Care Financing Administration (HCFA)), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

*Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Request for Accelerated Payments and Supporting Regulations in 42 CFR Sections 412.116, 412.632, 413.64, 413.350, and 484.245; *Form No.:* CMS–9042; *Use:* These forms/instructions are used by fiscal intermediaries to access a provider's eligibility for accelerated payments. Such payment is granted if there is an unusual delay in processing bills. *Frequency:* On occasion; *Affected Public:* Business or other for-profit, and Not for-profit institutions; *Number of Respondents:* 750; *Total Annual Responses:* 750; *Total Annual Hours Requested:* 375.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS's Web Site address at *http://www.hcfa.gov/regs/prdact95.htm,* or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@hcfa.gov,* or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the CMS Paperwork Clearance Officer designated at the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development and Issuances, Attention: Dawn Willinghan, CMS–9042, Room: N2–14–26, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: August 6, 2002.

**John P. Burke, III,**

*Paperwork Reduction Act Team Leader, CMS Reports Clearance Officer, Office of Strategic Operations and Strategic Affairs, Division of Regulations Development and Issuances.*

[FR Doc. 02–20520 Filed 8–13–02; 8:45 am]

**BILLING CODE 4120–03–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare and Medicaid Services

**[Document Identifier: CMS–R–138]**

### Agency Information Collection Activities: Submission for OMB Review; Comment Request

**AGENCY:** Centers for Medicare and Medicaid Services.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare and Medicaid Services (CMS) (formerly known as the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

*Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Medicare Geographic Classification Review Board (MGCRG) Procedures and Criteria and Supporting Regulations in 42 CFR, Section 412.256 & 412.230; *Form No.:* CMS–R–138 (OMB# 0938–0573); *Use:* This collection sets up an application process for prospective payment system hospitals who choose to appeal their geographic status to the Medicare Geographic Classification Review Board (MGCRB). This also establishes procedural guidelines for the MGCRB.; *Frequency:* Annually; *Affected Public:* Business or other for-profit, and Not-for-profit institutions; *Number of Respondents:* 650; *Total Annual Responses:* 650; *Total Annual Hours:* 650.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS Web Site address at *http://www.hcfa.gov/regs/prdact95.htm,* or E-mail your request, including your address, phone number, OMB number, and CMS document

identifier, to *Paperwork@hcfa.gov,* or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the OMB desk officer: OMB Human Resources and Housing Branch, Attention: Brenda Aguilar, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: August 7, 2002.

**John P. Burke, III,**

*Paperwork Reduction Act Team Leader, CMS Reports Clearance Officer, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development and Issuances.*

[FR Doc. 02–20521 Filed 8–13–02; 8:45 am]

**BILLING CODE 4120–03–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 02D–0306]**

### Medical Devices; Class II Special Controls Guidance Document: Dental Sonography and Jaw Tracking Devices; Draft Guidance for Industry and FDA Reviewers; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Class II Special Controls Guidance Document: Dental Sonography and Jaw Tracking Devices; Draft Guidance for Industry and FDA Reviewers.'' This draft guidance document was developed as a special control guidance to support the classification of certain dental sonography and jaw tracking devices into class II. Elsewhere in this issue of the **Federal Register**, FDA is publishing a proposed rule to classify these device types. This guidance is neither final nor is it in effect at this time.

**DATES:** Submit written or electronic comments on the draft guidance by November 12, 2002.

**ADDRESSES:** Submit written requests for single copies on a 3.5″ diskette of the draft guidance document entitled ''Class II Special Controls Guidance Document: Dental Sonography and Jaw Tracking Devices; Draft Guidance for Industry and FDA Reviewers'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818.

Submit written comments concerning this draft guidance to the Dockets Management Branch (HFA–305), 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments. Comments should be identified with the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

**FOR FURTHER INFORMATION CONTACT:** Mary S. Runner, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–827–5283.

**SUPPLEMENTARY INFORMATION:**

#### I. Background

FDA developed this draft guidance document as a special control guidance to support the classification of certain dental sonography and jaw tracking devices into class II. FDA believes that special controls, when combined with the general controls, will be sufficient to provide reasonable assurance of the safety and effectiveness of dental sonography and jaw tracking devices. This draft guidance document identifies the class, product code, and classification definition for these devices. In addition, it identifies the risks to health generally associated with this generic type of device, describes the device evaluation and labeling measures that FDA believes will mitigate those risks, explains how manufacturers should address those risks in a premarket notification submission, and serves as a special control that, when combined with the general controls, will address the risks associated with this generic device type.

#### II. Significance of Guidance

This draft guidance document represents the agency's current thinking on certain dental sonography and jaw tracking devices. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

The agency has adopted good guidance practices (GGPs), and published the final rule, which set forth the agency's regulations for the development, issuance, and use of guidance documents (21 CFR 10.115). This guidance document is issued as a level 1 draft guidance in accordance with the GGP regulations.

#### III. Electronic Access

In order to receive the draft guidance entitled ''Class II Special Controls Guidance Document: Dental Sonography and Jaw Tracking Devices; Draft Guidance for Industry and FDA Reviewers'' via your fax machine, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt press 1 to order a document. Enter the document number (1393) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidance may also do so using the Internet. The Center for Devices and Radiological Health (CDRH) maintains an entry on the Internet for easy access to information including text, graphics, and files that you may download to a personal computer. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. You may access the CDRH home page at http://www.fda.gov/cdrh. You may search for all CDRH guidance documents at http://www.fda.gov/cdrh/guidance.html. Guidance documents are also available at http://www.fda.gov/ohrms/dockets.

#### IV. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The burden hours associated with 21 CFR part 807, subpart E were approved under OMB control number 0910–0120.

#### V. Comments

You may submit to the Dockets Management Branch (see **ADDRESSES**) written comments regarding this draft guidance by November 12, 2002. You should submit two copies of any comments. Individuals may submit one copy. You must identify comments with the docket number found in brackets in the heading of this document. You may see the guidance document and any

comments FDA receives in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 1, 2002.

**Linda S. Kahan,**

*Deputy Director, Center for Devices and Radiological Health.*

[FR Doc. 02–20500 Filed 8–13–02; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Center on Minority Health and Health Disparities; 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 Center on Minority and Health Disparities Special Emphasis Panel PROJECT EXPORT.

*Date:* August 7–9, 2002.

*Time:* 8:30 AM to 4:30 PM.

*Agenda:* To review and evaluate grant applications.

*Place:* Marriott Pooks Hill, 5151 Pooks Hill Road, Bethesda, MD 20814.

*Contact Person:* Teresa Chapa, PHD, Chief, Division of Extramural Activities, National Center on Minority Health and Health Disparities, National Institutes of Health, Bethesda, MD 20852, 301/402–1366, *chapat@od.nih.gov*

This notice is being published less than 15 days prior to the meeting due to the time limitations imposed by the review and funding cycle.

Dated: August 7, 2002.

**LaVerne Y. Stringfield,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 02–20548 Filed 8–13–02; 8:45 am]

**BILLING CODE 4140–01–M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Institute of Arthritis and Musculoskeletal and Skin 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 Arthritis and Musculoskeletal and Skin Diseases Special Emphasis Panel. Review of R01 Applications.

*Date:* August 20, 2002.

*Time:* 1 PM to 4 PM.

*Agenda:* To review and evaluate grant applications.

*Place:* 6707 Democracy Boulevard, Building II, Room 106, Bethesda, MD 20892, (Telephone Conference Call).

*Contact Person:* Tracy A. Shahan, PhD., Scientific Review Administrator, National Institute of Arthritis and Musculoskeletal and Skin Diseases, 6701 Democracy Plaza, Bethesda, MD 20892, (301) 594–4952.

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. 93.846, Arthritis, Musculoskeletal and Skin Diseases Research, National Institutes of Health, HHS)

Dated: August 7, 2002.

**LaVerne Y. Stringfield,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 02–20549 Filed 8–13–02; 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 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:* Center for Scientific Review Special Emphasis Panel.

*Date:* August 15, 2002.

*Time:* 4 PM to 5 PM.

*Agenda:* To review and evaluate grant applications.

*Place:* NIH, Rockledge 2, Bethesda, MD 20892, (Telephone Conference Call).

*Contact Person:* Mary Clare Walker, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5104, MSC 7852, Bethesda, MD 20892, (301) 435–1165.

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. 93.306, Comparative Medicine, 93.306; 93.333, Clinical Research, 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)

August 7, 2002.

**LaVerne Y. Stringfield,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 02–20550 Filed 8–13–02; 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 Center for Scientific Review Special Emphasis Panel, August 12, 2002, 12 PM to August 12, 2002, 1 PM, NIH, Rockledge 2, Bethesda, MD, 20892 which was published in the **Federal Register** on August 5, 2002, 67 FR 50682–50683.

The meeting will be held August 13, 2002, from 11:30 AM to 12:30 PM. The location remains the same. The meeting is closed to the public.

Dated: August 7, 2002.

**LaVerne Y. Stringfield,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 02–20551 Filed 8–13–02; 8:45 am]

**BILLING CODE 4140–01–M**

## DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

**[Docket No. FR–4665–N–03]**

### Manufactured Housing Program: Notice Announcing the Selection of Members for the Manufactured Housing Consensus Committee

**AGENCY:** Office of the Assistant Secretary for Housing—Federal Housing Commissioner, HUD.

**ACTION:** Notice of Selection of Manufactured Housing Consensus Committee Members.

**SUMMARY:** This notice announces the voting members who have been appointed to the Consensus Committee for manufactured housing under the Manufactured Housing Improvement Act of 2000. The twenty-one voting members are comprised of seven representatives from each of three interest categories: producers, users, and general interest and public officials.

**FOR FURTHER INFORMATION CONTACT:** William W. Matchneer III, Administrator, Manufactured Housing Program, Office of Consumer and Regulatory Affairs, Department of Housing and Urban Development, 451 7th Street SW., Washington, DC 20410, telephone (202) 708–6409 (this is not a toll-free number). Hearing- or speech-impaired individuals may access this number via TTY by calling the toll-free Federal Information Relay Service at (800) 877–8339.

**SUPPLEMENTARY INFORMATION:** In accordance with the National Manufactured Housing Construction and Safety Standards Act of 1974 (42 U.S.C. 5401 *et seq.*) (the Act), the Department initiated a program that, in part, provides for establishment of standards by which all manufactured homes are constructed. The Act provides that these construction and safety standards preempt all standards of a State or political subdivision applicable to the same aspect of performance of a manufactured home that are not identical to the Federal manufactured home construction and safety standards.

The Manufactured Housing Improvement Act of 2000 (Title VI of Public Law 106–569, approved December 27, 2000) (the 2000 Act) amended the Act in several areas. The 2000 Act specifically provides for the establishment of a Consensus Committee for manufactured housing. In accordance with the 2000 Act, the Department acquired the services of an Administering Organization (AO), in part to undertake the process of seeking qualified candidates and recommending to HUD the initial members for the Consensus Committee. The AO selected candidates to recommend as the initial members based on procedures for consensus committees promulgated by the American National Standards Institute (ANSI). As required by the 2000 Act, the selections were designed to ensure equal representation among the prescribed interest categories: producers, users, and general interest and public officials.

Twenty-one individuals have been selected by HUD to serve as voting members on the committee. Those persons selected are listed below, with the localities and States from which they come, in the major interest category they represent. In order to remain eligible for service, each member must continue to qualify as a representative of the category for which he or she has been selected.

*Producers*

C. Edgar Bryant, Auburn Hills, MI
William Farish, Riverside, CA
Danny Ghorbani, Washington, DC
Douglas Gorman, Tulsa, OK
Ronald LaMont, Grand Prairie, TX
Nader Tomasbi, Goshen, IN
Frank Walter, Arlington, VA

*Users*

Jack Berger, Camp Hill, PA
Karl Braun, Las Vegas, NV
Susan Brenton, Tempe AZ
Earl Gilson, Port Angeles, WA
Charles Leven, Millbrook, NY
Jerome McHale, Port Charlotte, FL
Alan Youse, Salem, OR

*General Interest and Public Officials*

William Lagano, Clearwater, FL
Bryan Portz, Cleveland, OH
Dana Roberts, Salem, OR
Randy Vogt, St. Paul, MN
Christine Walsh Rogers, Seattle, WA
Richard Weinert, Sacramento, CA
Michael Zieman, Long Beach, CA

**Authority:** 42 U.S.C. 5403(a)(3).

Dated: August 6, 2002.

**John C. Weicher,**

*Assistant Secretary for Housing—Federal Housing Commissioner.*

[FR Doc. 02–20546 Filed 8–13–02; 8:45 am]

**BILLING CODE 4210–27–P**

## INTERNATIONAL TRADE COMMISSION

**[Inv. No. 337–TA–476]**

### Certain Radios and Components Thereof; Notice of Investigation

**AGENCY:** International Trade Commission.

**ACTION:** Institution of investigation pursuant to 19 U.S.C. § 1337.

**SUMMARY:** Notice is hereby given that a complaint was filed with the U.S. International Trade Commission on July 12, 2002, under section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, on behalf of Bose Corporation of Framingham, Massachusetts. Letters supplementing the complaint were filed on July 30, 2002, and August 5, 2002. The complaint as supplemented alleges violations of section 337 in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain radios and components thereof by reason of infringement of U.S. Trademark Registration No. 2,299,158. The complaint further alleges that an industry in the United States exists as required by subsection (a)(2) of section 337.

The complainant requests that the Commission institute an investigation and, after the investigation, issue a permanent exclusion order and a permanent cease and desist order.

**ADDRESSES:** The complaint and supplements, except for any confidential information contained therein, are available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street, SW., Room 112, Washington, DC 20436, telephone 202–205–2000. Hearing impaired individuals are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its Internet server at *http://www.usitc.gov.* The public record for this investigation may be viewed on the Commission's electronic docket (EDIS-ON-LINE) at *http://dockets.usitc.gov/eol/public.*

**FOR FURTHER INFORMATION CONTACT:** David H. Hollander, Jr., Esq., Office of Unfair Import Investigations, U.S. International Trade Commission, telephone 202–205–2746.

**Authority:** The authority for institution of this investigation is contained in section 337 of the Tariff Act of 1930, as amended, and in section 210.10 of the Commission's rules of practice and procedure, 19 CFR § 210.10 (2002).

*Scope of Investigation:* Having considered the complaint, the U.S. International Trade Commission, on August 7, 2002, *ordered that*—

(1) Pursuant to subsection (b) of section 337 of the Tariff Act of 1930, as amended, an investigation be instituted to determine whether there is a violation of subsection (a)(1)(C) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation, of certain radios or components thereof by reason of infringement of U.S. Trademark Registration No. 2,299,158, and whether an industry in the United States exists as required by subsection (a)(2) of section 337.

(2) For the purpose of the investigation so instituted, the following are hereby named as parties upon which this notice of investigation shall be served:

(a) The complainant is—Bose Corporation, The Mountain, Framingham, Massachusetts 01701.

(b) The respondent is the following company alleged to be in violation of section 337, and is the party upon which the complaint is to be served: Sun Coast Merchandise Corporation, 6315 Bandini Blvd., Commerce, California 90040.

(c) David H. Hollander, Jr., Esq., Office of Unfair Import Investigations, U.S. International Trade Commission, 500 E Street, SW., Suite 401, Washington, DC 20436, who shall be the Commission investigative attorney, party to this investigation; and

(3) For the investigation so instituted, the Honorable Delbert R. Terrill, Jr., is designated as the presiding administrative law judge.

A response to the complaint and the notice of investigation must be submitted by the named respondent in accordance with section 210.13 of the Commission's rules of practice and procedure, 19 CFR § 210.13. Pursuant to 19 CFR §§ 201.16(d) and 210.13(a), such response will be considered by the Commission if received no later than 20 days after the date of service by the Commission of the complaint and the notice of investigation. An extension of time for submitting a response to the complaint will not be granted unless good cause therefor is shown.

Failure of the respondent to file a timely response to each allegation in the complaint and in this notice may be deemed to constitute a waiver of the right to appear and contest the allegations of the complaint and to authorize the administrative law judge and the Commission, without further notice to the respondent, to find the facts to be as alleged in the complaint and this notice and to enter both an initial determination and a final determination containing such findings, and may result in the issuance of a limited exclusion order or a cease and desist order or both directed against the respondent.

By order of the Commission.

Issued: August 9, 2002.

**Marilyn R. Abbott,**

*Secretary.*

[FR Doc. 02–20579 Filed 8–13–02; 8:45 am]

**BILLING CODE 7020–02–P**

## DEPARTMENT OF LABOR

### Office of the Secretary

### Submission for OMB Review, Comment Request

August 1, 2002.

The Department of Labor (DOL) has submitted the following public information collection requests (ICRs) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. Chapter 35). A copy of each individual ICR, with applicable supporting documentation, may be obtained by calling the Department of Labor. To obtain documentation contact Marlene Howze at (202) 693–4158 or E-mail *Howze-Marlene@dol.gov*.

Comments should be sent to Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for ESA, Office of Management and Budget, Room 10235, Washington, DC 20503 ((202) 395–7316), within 30 days from the date of this publication in the **Federal Register**.

The OMB 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 submission of responses.

*Type of Review:* Extension of a currently approved collection.

*Agency:* Employment Standards Administration (ESA).

*Title:* Housing Terms and Conditions.

*OMB Number:* 1215–0146.

*Affected Public:* Farms; individuals or households; and business or other for-profit.

*Frequency:* On occasion.

*Number of Respondents:* 1,300.

*Number of Annual Responses:* 1,300.

*Estimated Time Per Response:* 30 minutes.

*Total Burden Hours:* 650.

*Total Annualized Capital/Startup Costs:* $0.

*Total Annual Costs (operating/maintaining systems or purchasing services):* $0.

*Description:* Section 201(c) of the Migrant and Seasonal Agricultural Worker Protection Act (MSPA), 29 USC 1801 *et seq.,* requires that any farm labor contractor, agricultural employer or agricultural association that provides housing to any migrant agricultural worker post in a conspicuous place or present to such worker a statement of the terms and conditions, if any, of occupancy of such housing. In addition, Section 201(g) of MSPA requires that such information be provided in English, or as necessary and reasonable, in a language common to the workers and that the Department of Labor make forms available to provide such information. Section 500.75(f) and (g) of Regulations, 29 CFR part 500, of MSPA, sets forth the terms of occupancy of housing which are to be posted or given in a written statement to the worker. Section 500.1(i)(2) provides for optional Form WH–521, which may be used to satisfy sections 201(c) and 201(g) of MSPA. While use of the form is optional, disclosure of the information is required by MSPA. Less frequent disclosure would prevent the Department of Labor from determining compliance with this requirement of MSPA.

**Ira L. Mills,**

*Department Clearance Officer.*

[FR Doc. 02–20608 Filed 8–13–02; 8:45 am]

**BILLING CODE 4510–27–M**

## DEPARTMENT OF LABOR

### Office of the Secretary

### A Bangladesh Network of Women Workers' Education Centers

**AGENCY:** Bureau of International Labor Affairs, Department of Labor.

**ACTION:** Notice of Availability of Funds and Solicitation for Cooperative Agreement Applications (SGA 02–23).

*This notice contains all of the necessary information and forms needed to apply for cooperative agreement funding.*

**SUMMARY:** The U.S. Department of Labor (USDOL), Bureau of International Labor Affairs (ILAB), will award up to US $700,000 through one or more cooperative agreements to an organization or organizations (''the applicant'') to implement a program in the Bangladeshi garment industry to increase adherence to internationally-recognized worker rights; improve workplace safety and health; and to provide garment workers with access to basic health care and legal counseling. USDOL is seeking applications from qualified applicants for the expansion of a pilot project initiated in Dhaka, Bangladesh, in 2000 to design and establish a Working Women's Education Center (WWEC) for the delivery of information and services to women working in the garment industry—the country's largest export industry. The pilot project, funded by USAID and implemented by the American Center for International Labor Solidarity (ACILS), involved a partnership with a number of local non-governmental organizations (such as Ain o Shalish Kendra, the Bangladesh Legal Aid and Services Trust, the Bangladesh National Women's Lawyers Association, and the Welfare Association of Repatriated Bangaldeshi Employees) and the Bangladesh Independent Garment Workers Union Federation.

**DATES:** The closing date for receipt of applications is September 11th, 2002. As described in Section III.B. and C., applications must be received by 4:45 p.m. (Eastern Daylight Savings Time) at the address below. No exceptions to the mailing, delivery, 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 not be honored.

**ADDRESSES:** Application forms will not be mailed. They are published in this **Federal Register** Notice, and in the **Federal Register** which may be obtained from your nearest U.S. Government office, public library or on-line at *http://www.archives.gov/federal_register/index*. Applications must be delivered to: U.S. Department of Labor, Procurement Services Center, 200 Constitution Avenue, NW., Room N–5416, Attention: Lisa Harvey, Reference: SGA 02–23, Washington, DC 20210. Applications sent by e-mail, telegram, or facsimile (FAX) will not be accepted. Applications sent by other delivery services, such as Federal Express, UPS, etc., will be accepted; however, the applicant bears the responsibility for timely submission. Submission requirements are described in Section III.C. of this notice.

**FOR FURTHER INFORMATION CONTACT:** Lisa Harvey: e-mail address: *harvey-lisa@dol.gov*. All applicants are advised that U.S. mail delivery in the Washington, DC area has been slow and erratic due to the recent enhanced security measures. All applicants must take this into consideration when preparing to meet the application deadline. It is recommended that you confirm receipt of your application by contacting Lisa Harvey, U.S. Department of Labor, Procurement Services Center, telephone (202) 693–4570 (this it not a toll-free number), prior to the closing deadline. All inquiries should reference SGA 02–23. *See* Section III.B. for further information regarding submission of applications.

**SUPPLEMENTARY INFORMATION:** ILAB announces the availability of funds to be granted by cooperative agreement to a qualifying organization to achieve the following program objectives in the Bangladesh garment export industry: (1) Increase adherence to internationally-recognized worker rights as described in the 1998 ILO Declaration on Fundamental Principles and Rights at Work; (2) promote greater awareness of national and international labor law among workers; (3) provide workers with access to basic health care and legal counseling; and (4) improve the occupational safety and health of workers, particularly with regard to fire prevention and safety. The cooperative agreement will be carried out in collaboration with local NGOs and workers' representatives, and with the participation of employers and employer organizations. Proposals must include ways to support the existing WWEC in Dhaka, and must include recommendations for the location of additional centers. Of the additional centers, one must be located in Dhaka. In each location, the pilot project should address the above-mentioned objectives. In addition, the project should take into consideration the availability of local collaborating organizations, the specific needs of workers in that location, and the prospects for sustained improvements.

The cooperative agreement is to be actively managed by ILAB to assure the achievement of the stated objectives. Applicants are encouraged to be creative in proposing an innovative and cost-effective program that will have a demonstrable impact on achieving the overall objectives.

#### I. Background and Program Scope

*A. Background: Bangladesh Garment Export Industry*

The driving force of the Bangladeshi economy is the sustained growth of its garment industry, which now accounts for 75% of the country's export revenues and employs 1.5 million workers. The country is in the very early stages of implementing laws and regulations to protect workers. The workers in the garment industry are mostly young women who lack access to education regarding their rights in the workplace and have difficulty exercising these rights. Consequently, abusive labor practices, including the harassment of women workers, are alleged to occur frequently.

The Working Women's Education Center (WWEC) pilot project was established in 2000 to address these challenges. The WWEC sponsors education programs on labor issues, and it offers participants, mainly young women working in garment factories, basic medical care, and legal counseling. Issues covered at the center include workers' rights and responsibilities, factory laws, family laws, gender issues, trafficking in persons, and dispute resolution. In the first year of the pilot project, the center sponsored 200 activities benefiting approximately 2,500 female workers. The program has demonstrated strengths in several ways. First, program activities directly and effectively address the day-to-day concerns of the workers; timely assistance is provided to resolve issues that often directly affect the lives of workers and their families (such as gender-based discrimination in the workplace, dangerous, and even life-threatening, working conditions, and the payment of legal wages). Second, workshops and legal counseling sessions are conducted primarily by leading Bangladeshi legal and labor experts.

Support for this program has helped forge stronger links between key actors in the emerging civil society and garment workers and it operates with the endorsement of the Government of Bangladesh. ''Promoting democracy'' is

a key U.S. objective in Bangladesh, where the U.S. mission is currently focusing on efforts that ensure seamless introduction of effective and responsible modern industrial relations practices in the Export Processing Zones.

*B. Program Scope*

For any proposal to be considered responsive to this solicitation, it must contain proposed projects that cover all of the following four aspects: (i) Strengthening the rule of labor law; (ii) the development of one or more WWECs; (iii) the provision of workers' education and services; and (iv) the preparation, publication, translation, and distribution of research and educational materials for workers. Applicants are encouraged to develop innovative forms of cooperative relationships with employers, employers' and workers' representatives, the Government of Bangladesh, and national organizations, including non-governmental organizations in performing activities proposed.

(i) Strengthening the Rule of Law

Applicants should propose specifically how they will provide legal aid to garment workers. Applicants may consider offering counseling at the WWECs, providing services directly or through referrals to other local, national, or international organizations.

(ii) Development of WWEC(s)

Applicants should: (a) Define the number and location of WWECs; (b) offer a rationale for said number and location; (c) describe the way in which workers will be made aware of the WWECs and the services they offer; (d) specify the total number of workers to be served over the duration of the project and their characteristics; (e) detail the staffing and administration of the centers; (f) explain how workers will actually receive services; and (g) describe how the centers will be sustained after the grant period.

(iii) Provision of Workers' Education Programs and Services

Applicants should provide a description of the variety of education programs that will provide workers with important information on a broad range of subjects such as: sexual harassment and other gender-related issues; family law; labor law, grievance handling and court procedures; occupational safety and health, particularly fire safety; collective bargaining; leadership skills; and health and hygiene, including the prevention of HIV/AIDS.

(iv) Research, Publication, Translation, and Distribution of Research and Education Materials for Workers

Applicants should describe the education materials and pedagogical approach that will be used at the Centers and indicate if materials already exist or will be developed after the initiation of the project. Applicants should propose a program of formal and informal research as needed to build broad-based support for the issues to be addressed by the WWECs' education programs and they should include a component on publication, translation, and distribution to ensure the use and effectiveness of the research findings.

**II. Authority**

ILAB is authorized to award and administer this program by the Departments of Labor, Health and Human Services, and Education and Related Agencies Appropriations Act, 2002, Public Law 107–116, 115 Stat. 2177 (2002).

**III. Application Process**

*A. Eligible Applicants*

Any commercial, international, or non-profit organization, including faith-based organizations, capable of successfully implementing the scope of work and meeting the following requirements is eligible to submit an application. Joint applications, consisting of more than one organization, are also eligible and are encouraged. In such a case, a lead organization must be identified. The capability of an applicant and collaborating organizations to perform necessary aspects of this solicitation will be determined under Section V.B. Rating Criteria and Selection.

Please note that eligible cooperative agreement applicants must not be classified under the Internal Revenue Code as a Section 501(c)(4) Entity. *See* 26 U.S.C. 501(c)(4). According to the Lobbying Disclosure Act of 1995, as amended, 2 U.S.C. 1611, an organization, as 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.

*B. Submission of Applications*

One (1) ink-signed original, complete application plus two (2) copies must be submitted to the U.S. Department of Labor, Procurement Services Center, 200 Constitution Avenue, NW., Room N–5416, Washington, DC 20210, not later than 4:45 p.m. EDST, September 11th, 2002.

The application must consist of two (2) separate parts. Part I of the application must contain the Standard Form (SF) 424, ''Application for Federal Assistance'' (Appendix A) (The entry on SF 424 for the Catalog of Federal Domestic Assistance Number (CFDA) is 17.700) and sections A–F of the Budget Information Form SF 424A (Appendix B). Part II must contain a technical proposal that demonstrates capabilities in accordance with the Program Scope (Section I.B.), the Statement of Work (Section IV.A.) and the selection criteria (Section V.B.).

To be considered responsive to this solicitation, the application must consist of the above-mentioned separate sections not to exceed 40 single-sided (8½″ x 11″), double-spaced, 10 to 12 pitch typed pages. Any applications that do not conform to these standards may be deemed non-responsive to this solicitation and may not be evaluated. Standard forms and attachments are not included in the page limit. The application must include a table of contents and an abstract summarizing the application in not more than two (2) pages. These pages are also *not* included in the page limits.

Upon completion of negotiations, the individual signing the SF 424 on behalf of the applicant must be authorized to bind the applicant.

*C. Acceptable Methods of Submission*

The grant application package must be received at the designated place by the date and time specified or it will not be considered. Any application received at the Procurement Services Center after 4:45 p.m. EDST, September 11th, 2002, will not be considered unless it is received before the award is made and:

1. It was sent by registered or certified mail not later than the fifth calendar day before September 11th, 2002;

2. It is determined by the Government that the late receipt was due solely to mishandling by the Government after receipt at the U.S. Department of Labor at the address indicated; or

3. It was sent by U.S. Postal Service Express Mail Next Day Service-Post Office to Addressee, not later than 5 pm at the place of mailing two (2) working days, excluding weekends and Federal holidays, prior to September 11th, 2002.

The only acceptable evidence to establish the date of mailing of a late application sent by registered or certified mail is the U.S. Postal Service postmark on the envelope or wrapper and on the original receipt from the U.S. Postal Service. If the postmark is not legible, an application received after the above closing time and date shall be processed as if mailed late. ''Postmark''

means a printed, stamped or otherwise placed impression (not a postage meter machine impression) that is readily identifiable without further action as having been applied and affixed by an employee of the U.S. Postal Service on the date of mailing. Therefore applicants should request that the postal clerk place a legible hand cancellation ''bull's eye'' postmark on both the receipt and the envelope or wrapper.

The only acceptable evidence to establish the date of mailing of a late application sent by U.S. Postal Service Express Mail Next Day Service-Post Office to Addressee is the date entered by the Post Office receiving clerk on the ''Express Mail Next Day Service-Post Office to Addressee'' label and the postmark on the envelope or wrapper and on the original receipt from the U.S. Postal Service. ''Postmark'' has the same meaning as defined above. Therefore, applicants should request that the postal clerk place a legible hand cancellation ''bull's-eye'' postmark on both the receipt and the envelope or wrapper.

The only acceptable evidence to establish the time of receipt at the U.S. Department of Labor is the date/time stamp of the Procurement Services Center on the application wrapper or other documentary evidence or receipt maintained by that office.

Applications sent by e-mail, telegram, or facsimile (FAX) will not be accepted. Applications sent by other delivery services, such as Federal Express, UPS, *etc.*, will be accepted, however, the applicant bears the responsibility for timely submission. Because of delay in the receipt of mail in the Washington, DC area, it is recommended that you confirm receipt of your application by contacting Lisa Harvey, U.S. Department of Labor, Procurement Services Center, telephone (202) 693–4570, prior to the closing deadline. All inquires should reference SGA 02–23.

*D. Funding Levels*

Approximately US $700,000 is budgeted to fund this program. Although USDOL reserves the right to award more than one cooperative agreement, several collaborating organizations may apply jointly to implement the program. Joint applicants will submit one application for the implementation of all projects (including pilot projects in localities) and are encouraged to utilize local organizations to implement portions of the program in order to institutionalize and sustain project improvements and reduce costs. The award of any contract or sub-contract to a local organization will be subject to USDOL approval. *See* Section IV.D. Administrative Requirements.

*E. Program Duration*

The duration of the program is two (2) years. The start date of project activities will be negotiated upon the award of the cooperative agreements.

**IV. Requirements**

*A. Statement of Work*

In developing their proposals, applicants should develop a strategy for implementation of the project objectives as stated in the section **SUPPLEMENTARY INFORMATION.** The strategy should take into account the implementing environment in Bangladesh as well as that of the specific locations of the centers. The strategy should also demonstrate how the applicant proposes to build upon the success of existing or past projects supported by other international donors, and coordinate activities among them at the local and national level. Further, the applicant should draft a strategy demonstrating how it will meet the project objectives by the end of the grant period, and how sustainability will be an integral element of the overall program. The strategy should also demonstrate how it will include nongovernmental organizations, as appropriate, in the development and implementation of the project.

The applicants must present a strategy that demonstrates that at least

- 15,000 to 20,000 working women will receive services sponsored by the WWECs; and
- 800 to 1,600 events (for the purpose of this notice, events are classes, training activities, or consultation activities, *etc.*) will be held under the auspices of the WWECs.

These figures are supported by the results of the pilot project initiated in 2000. The strategy must also include the collection of baseline data from WWEC participants so that indicators of performance may be established as part of the project design document discussed below.

*B. Deliverables*

Following the award of the cooperative agreement(s), unless otherwise indicated, the grantee must submit copies of all required reports to USDOL by the specified due dates. Other documents, such as project designs, are to be submitted by mutually agreed-upon deadlines.

1. Project Designs

The grantee(s) will draft the design and submit a project document, in consultation with ILAB officials and in the format established by ILAB, to include a background/justification section, project strategy (objectives, outputs, activities, indicators), project implementation timetable, project management organizational chart, project budget, logical framework and performance monitoring plan to systematically monitor project results. The document shall also include sections, which cover coordination strategies, project management, and sustainability of project improvements involving government, employers' and workers' organizations as well as other nongovernmental organizations as appropriate. The project design will be drawn, in part, from the proposal written in response to this solicitation. USDOL may determine that it is necessary for the organization(s) awarded the cooperative agreement (grantee) to travel to Bangladesh with USDOL officials on a project design mission trip in order to prepare this document.

2. Technical Progress Reports

The grantee(s) must furnish a typed technical report to USDOL on a quarterly basis, no later than 15 days from the last date of each quarter, *i.e.*, 31 March, 30 June, 30 September and 31 December of each year. The 30 June (2nd quarter) and 31 December (4th quarter) reports are abbreviated and need only indicate whether the work plan was fully implemented and if not, explain why not and attach the amended work plan. The grantee(s) must also furnish a separate financial report (SF 272) to USDOL on the same quarterly basis. The format for the technical progress report will be the standard format developed by USDOL and must contain the following information:

a. For each project objective, an accurate account of activities carried out under that objective during the reporting period as it relates to the work plan;

b. Major trends in the project that note particular success with a particular activity or trends that indicate a need to readjust or expand the work plan;

c. An account of problems, proposed solutions, actions taken or required regarding implementation of the project;

d. New proposals for activities, staffing, funding, *etc.*;

e. Lessons learned in project implementation;

f. Future actions planned in support of each project objective;

g. An accounting of staff and any sub-contractor hours expended; and

h. Aggregate amount of costs incurred during the reporting period, including

estimated budget expenditures vs. actual expenditures.

3. Annual Work Plan

An annual work plan for the project will be submitted within 45 days after the approval of the project design by USDOL. The second annual work plan, when revised, will be delivered to reflect modifications in implementation, no later than one year following submission of the previous work plan, or when based on recommendations made during mid-term evaluations, no later than 30 days following the mid-term evaluation.

4. Monitoring and Evaluation

A performance monitoring plan will be developed in collaboration with USDOL, including beginning and ending dates for projects and dates for mid-term and final project evaluations, and will be included as part of the submission of the project document for USDOL approval. The plan will include performance indicators and instruments to collect and report on performance data on a semi-annual basis.

5. Evaluation Reports

The Grant Officer's Technical Representative (GOTR) will determine whether a mid-term evaluation will be conducted by an internal or external evaluation team. The final evaluation will be external in nature. In all cases, evaluations will be objective and carried out by independent evaluators. The grantee(s) must respond to any comments and recommendations resulting from the review of the mid-term report and will submit a work plan for implementing the recommendations of the mid-term report within 15 days following formal submission of the report to the grantee(s) by USDOL. Applicants need to allocate funds for these activities in the proposed budget.

*C. Production of Deliverables*

1. Materials Prepared and Purchased Under the Cooperative Agreement

The grantee(s) must obtain prior approval from the Grant Officer for all materials developed or purchased under this cooperative agreement. The grantee(s) must submit to USDOL all media-related and educational materials developed by it or its sub-contractor under this cooperative agreement(s), including relevant press releases, for use in this project(s) before they are reproduced, published, or used. The grantee(s) must consult with USDOL to ensure that such materials are compatible with USDOL materials relating to the program, *i.e.*, public relations material such as video and web site. USDOL considers brochures, pamphlets, videotapes, slide-tape shows, curricula, and any other training materials used in the program as media-related and educational materials. USDOL will review materials for technical accuracy. USDOL will also review training curricula and purchased training materials for accuracy before they are used. All materials produced by grantee(s) must be provided to USDOL in a digital format for possible publication on the Internet by USDOL.

2. Acknowledgment of USDOL Funding

In all circumstances, the following must be displayed on printed materials:

Preparation of this item was funded by the United States Department of Labor under Cooperative Agreement No. [insert the appropriate cooperative agreement number].

When issuing statements, press releases, requests for proposals, bid solicitations, and other documents describing projects or programs funded in whole or in part with Federal money, all grantees receiving Federal funds, including State and local governments and recipients of research grants, must clearly state:

a. The percentage of the total costs of the program or project that will be financed with Federal money;

b. The dollar amount of Federal funds for the project or program; and

c. The percentage and dollar amount of the total costs of the project or program that will be financed by non-governmental sources.

In consultation with USDOL, USDOL's role will be acknowledged in one of the following ways:

a. The USDOL logo may be applied to USDOL-funded material prepared for world-wide distribution, including posters, videos, pamphlets, research documents, national survey results, impact evaluations, best practice reports, and other publications of global interest. The grantee(s) will consult with USDOL on whether the logo should be used on any such items prior to final draft or final preparation for distribution. In no event shall the USDOL logo be placed on any item until USDOL has given the grantee written permission to use the logo, after obtaining appropriate internal USDOL approval for use of the logo on the item.

b. If the USDOL determines the logo is not appropriate and does not give written permission, the following notice must appear on the document:

''This document does not necessarily reflect the views or policies of the U.S. Department of Labor, nor does mention of trade names, commercial products, or organizations imply endorsement by the U.S. Government.''

*D. Administrative Requirements*

1. General

Grantee organizations will be subject to applicable Federal laws (including provisions of appropriations law) and the applicable Office of Management and Budget (OMB) Circulars. Determinations of allowable costs will be made in accordance with the applicable Federal cost principles, *e.g.*, Non-Profit Organizations—OMB Circular A–122. The cooperative agreement(s) awarded under this SGA will be subject to the following administrative standards and provisions, if applicable:

*29 CFR part 36*—Federal Standards for Nondiscrimination on the Basis of Sex in Education Programs or Activities Receiving Federal Financial Assistance.

*29 CFR part 93*—New Restrictions on Lobbying.

*29 CFR part 95*—Uniform Administrative Requirements for 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*—Federal Standards for Audit of Federally Funded Grants, Contracts and Agreements.

*29 CFR part 98*—Federal Standards for Government-wide Debarment and Suspension (Nonprocurement) and Government-wide Requirements for Drug-Free Workplace (Grants).

*29 CRF part 99*—Federal Standards for Audits of States, Local Governments, and Non-Profit Organizations.

2. Sub-contracts

Sub-contracts must be awarded in accordance with 29 CFR 95.40–48. In compliance with Executive Orders 12876 as amended, 13230, 12928, and 13021 as amended, the grantee(s) is strongly encouraged to provide subcontracting opportunities to Historically Black Colleges and Universities, Hispanic-Serving Institutions, and Tribal Colleges and Universities.

3. Key Personnel

The applicant must list the individual(s) who has been designated as having primary responsibility for the conduct and completion of all work in the project(s) it proposes. The grantee(s) agrees to inform the GOTR whenever it appears impossible for one or more of these individual(s) to continue work on

the project as planned. The grantee(s) may nominate substitute personnel for approval of the GOTR; however, the grantee(s) must obtain prior approval from the Grant Officer for all key personnel. If the Grant Officer determines not to approve the personnel change, he/she reserves the right to terminate the cooperative agreement.

4. Encumbrance of Cooperative Agreement Funds

Cooperative agreement funds may not be encumbered/obligated by the grantee(s) before or after the cooperative agreement period of performance. Encumbrances/obligations outstanding as of the end of the cooperative agreement period may be liquidated (paid out) after the end of the cooperative agreement period. Such encumbrances/obligations may involve only commitments for which a need existed during the cooperative agreement period and which are supported by approved contracts, purchase orders, requisitions, invoices, bills, or other evidence of liability consistent with the grantee(s)'s purchasing procedures and incurred within the cooperative agreement period. All encumbrances/obligations incurred during the cooperative agreement period must be liquidated within 90 days after the end of the cooperative agreement period, if practicable.

5. Site Visits

USDOL, through its authorized representatives, has the right, at all reasonable times, to make site visits to review project accomplishments and management control systems and to provide such technical assistance as may be required. If USDOL makes any site visit on the premises of the grantee(s) or a sub-contractor(s) under this cooperative agreement(s), the grantee(s) must provide and must require its sub-contractors to provide all reasonable facilities and assistance for the safety and convenience of the Government representatives in the performance of their duties. All site visits and evaluations must be performed in such a manner as will not unduly delay the work.

## V. Review and Selection of Applications for Cooperative Agreement Award

*A. The Review Process*

USDOL will screen all applications to determine whether all required elements are present and clearly identifiable. A technical panel will objectively rate each complete application against the criteria described in this announcement. The panel recommendations to the Grant Officer are advisory in nature. The Grant Officer may choose to select one or more grantees on the basis of the initial proposal submission; or, the Grant Officer may establish a competitive or technically acceptable range for the purpose of selecting qualified applicants. If deemed appropriate, following the Grant Officer's call for the preparation and receipt of final revisions of proposals, the evaluation process described above will be repeated to consider such revisions. The Grant Officer will make a final selection determination based on what is most advantageous to the Government, considering factors such as panel findings, geographic presence of the applicants, the best value to the Government, cost, and other factors. The Grant Officer's determination for award under this SGA 02–20 is final.

**Notice:** Selection of an organization as a cooperative agreement recipient does not constitute approval of the cooperative agreement application as submitted. Before the actual cooperative agreement is awarded, the Grant Officer may enter into negotiations concerning such items as program components, funding levels, and administrative systems. If the negotiations do not result in an acceptable submission, the Grant Officer reserves the right to terminate the negotiation and decline to fund the application.

*B. Rating Criteria and Selection*

The technical panel will review grant applicants against the criteria listed below on the basis of 100 points with up to five additional points available for applications identifying non-federal or leveraged resources.

The criteria are presented in the order of emphasis that they will receive.

1. Approach, Understanding of the Issue, and Program Plans (40 points)

a. *Overview.* This section of the proposal must explain the strategy employed by the applicant to achieve the objectives of the project within the specified timeframe. The applicant must describe in detail the proposed approach to comply with each requirement in Section IV.A. of this solicitation, including all tasks and methods to be utilized to implement the project. Also, the applicant must demonstrate how the proposed activities would address issues discussed in Sections I.A. and B.

b. *Logical Framework.* The strategy should include an outline of the objectives, activities, and indicators envisioned for implementation of the program.

c. *Implementation Plan.* The applicant must submit an implementation plan for the entire program, preferably with a visual aid such as a Gantt chart. The implementation plan should outline the approach that will be used to implement the program. The plan should list the activities envisioned for the duration of the program and should lay out an activity schedule by objective, starting with the execution of the cooperative agreement and ending with the final report. In describing the implementation plan, the applicant must address the following points:

(1) Describe the use of existing or potential infrastructure and use of qualified personnel, including qualified nationals, to implement the project in Dhaka as well as in other selected project sites. The applicant also must include a project organizational chart, demonstrating the management structure, key personnel positions, and indicating proposed links with the relevant government ministries, local government agencies/bureaus, NGOs, universities, and other significant local actors.

(2) Develop a list of activities and explain how each relates to the overall development objectives as stated in Section I.

(3) Explain how appropriate information and education materials and training curriculum will be developed.

(4) Explain the strategy for coordinating activities conducted at each center with lessons learned.

(5) Demonstrate how the program will strengthen the ability of working women to protect their rights as prescribed by national law.

(6) Demonstrate how the grantee will collect baseline data and systematically monitor and report on project performance to measure the achievement of the project objective(s).

(7) Demonstrate how the grantee will build national and local capacity to ensure that project efforts to enhance the implementation and enforcement of national labor laws would be sustained after completion of the project.

d. *Management and Staff Loading Plan.* The application must also include a management and staff loading plan. The management plan should include the following:

(1) If two organizations are applying for the award in collaboration, they must demonstrate an approach to ensure successful collaboration including clear delineation of respective roles and responsibilities. The applicants must also identify the lead organization and submit the collaboration agreement.

(2) A project organization chart and accompanying narrative which differentiates between elements of the applicant's staff and subcontractors or consultants who will be retained;

(3) A description of the functional relationship between elements of the project's organization; and

(4) The identity of the individual(s) responsible for project management and the lines of authority between this/these individual(s) and other elements of the project.

The staff loading plan must identify all key tasks and the person-days required to complete each task. Labor estimates for each task must be broken down by individuals assigned to the task, including sub-contractors and consultants. All key tasks must be charted to show time required to perform them by months or weeks.

2. Experience and Qualifications of the Applicant (25 points)

The evaluation criteria in this category are as follows:

a. The applicant organization and collaborating organizations must demonstrate experience of working on developmental projects in Bangladesh.

b. The applicant must demonstrate prior experience of working directly with government ministries, local government organizations, employers, workers, NGOs, and academic institutions, as well as with U.S. Missions, in the area of legal aid and worker education generally and more specifically in applying that experience to the following issues: sexual harassment and other gender-related issues; family law; labor law, grievance handling and court procedures; occupational safety and health, particularly fire safety; collective bargaining; leadership skills; and health and hygiene, including the prevention of HIV/AIDS.

c. The applicant must also demonstrate that it can negotiate and implement developmental projects in Bangladesh and that it has the appropriate international experience and expertise to carry out program responsibilities in Bangladesh.

d. The applicant must demonstrate that it has staff or is able to recruit staff that can communicate effectively with Bangladeshi employers, workers, migrant workers, and officials. Preference will be given to applicant organizations with staff that have local language skills.

e. The proposal must include information regarding previous grants, contracts, or cooperative agreements relevant to this solicitation. This information must include:

(1) The organization for whom the work was done;

(2) A contact person in that organization with his/her current phone number;

(3) The dollar value of the grant, contract or cooperative agreement for the project(s);

(4) The time frame and administrative and programmatic effort involved in the project(s);

(5) A brief summary of the work performed; and

(6) A brief summary of accomplishments.

This information on previous grants and contracts shall be provided in appendices and will not count toward the 40-page maximum page requirement.

3. Experience and Qualifications of Key Personnel (25 points)

This section of the application must include sufficient information for judging the quality and the competence of key staff proposed to be assigned to the project(s) proposed to assure that they meet the required qualifications. Successful performance of the proposed work depends heavily on the qualifications of the individuals committed to the project. Accordingly, in its evaluation of each application, USDOL will place emphasis on the applicant's commitment of key personnel qualified for the work involved in accomplishing the assigned tasks. Information provided on the experience and educational background of personnel must indicate the following:

(a) The identity of key personnel assigned to the project. ''Key personnel'' are staff who are essential to the successful operation of the project and completion of the proposed work and, therefore, may not be replaced or have his or her hours reduced without the approval of the Grant Officer.

(b) The educational background, relevant language skills, and experience of proposed staff.

(c) The special capabilities of key personnel that demonstrate prior experience in organizing, managing and performing similar efforts.

(d) The current employment status of key personnel and availability for this project. The applicant must also indicate whether the proposed work will be performed by persons currently employed or is dependent upon planned recruitment or sub-contracting.

Note that management and professional technical staff members comprising the applicant's proposed team should be individuals who have prior experience with organizations working in similar efforts, and are fully qualified to perform work specified in the Statement of Work. Where sub-contractors or outside assistance is proposed, organizational control should be clearly delineated to ensure responsiveness to the needs of USDOL. Key personnel must sign letters of agreement to serve on the project, and indicate availability to commence work within three weeks of grant award.

The following information must be furnished:

(a) The applicant must designate a Program Director and other key personnel to oversee the program. The Program Director must have a minimum of three years of professional experience in a leadership role in implementation of complex labor programs in developing countries. He or she must demonstrate sufficient knowledge of and understanding of Bangladesh's political and economic development, its government, and the complexity of employer and worker relations.

(b) The applicant should specify other key personnel proposed to carry out the requirements of this solicitation.

(c) An organization chart showing the applicant's proposed organizational structure for performing task requirements for the project(s) proposed, along with a description of the roles and responsibilities of all key personnel proposed for this project(s). The chart should also differentiate between elements of the applicant's staff and sub-contractors or consultants who will be retained. (Also see requirement under Section V.B.I.c.(1). Applicants may submit only one organization chart.)

(d) Identify all key tasks and the person-days required to complete each task. Labor estimates for each task must be broken down by individuals assigned to the task, including sub-contractors and consultants. All key tasks must be charted to show time required to perform them by months or weeks.

(e) A resume for each of the key personnel to be assigned to the program. At a minimum, each resume must include: the individual's current employment status and previous work experience, including position title, duties performed, dates in position, employing organizations and educational background, including local language skills (if any). Duties must be clearly defined in terms of role performed, *i.e.,* manager, team leader, consultant, *etc.* (Resumes must be included as attachments, which do not count toward the page limitation.)

(f) The special capabilities of staff that demonstrate prior experience in

organization, managing and performing similar efforts.

4. Budget Plan (10 points)

The applicant must develop one proposed budget for the implementation of the entire program, including pilot projects in localities. This section of the application must explain the costs for performing all of the requirements presented in this solicitation and for producing all required reports and other deliverables presented in this solicitation; costs must include labor, training, material production and dissemination, equipment, travel and other related costs. The budget plan will be evaluated to determine the efficient and effective allocation of funding for proposed program implementation. Preference may be given to applicants with low administrative costs. Administrative costs shall be reflected separately on the budget plan from programmatic costs. The budget must comply with Federal cost principles (which can be found in the applicable OMB Circulars).

5. Leveraging of Funding (extra 5 points)

USDOL will give up to five (5) additional rating points to applications that include non-Federal resources that significantly expand the dollar amount, non-monetary resources, size and scope of the proposal, or capitalize upon previous U. S. government or private investments. The applicant may include any leveraging or co-funding anticipated. To be eligible for additional points under this criterion, the applicant must list the source(s) of funds, the nature, and activities anticipated with these funds under this cooperative agreement, and any partnerships, linkages or coordination of activities, and/or cooperative funding.

The earlier paragraphs will be incorporated into the text of the cooperative agreement with the selected applicant(s).

Signed in Washington, DC, on this 9th day of August, 2002.

**Lawrence J. Kuss,**

*Grant Officer.*

**Appendix A: Application for Federal Assistance (SF424)**

**Appendix B: Budget Information (SF424A)**

BILLING CODE 4510–28–P

## APPLICATION FOR FEDERAL ASSISTANCE

OMB Approval No. 0348-0043

| | | |
|---|---|---|
| | **2. DATE SUBMITTED** | Applicant Identifier |
| **1. TYPE OF SUBMISSION:** Application ☐ Construction ☐ Non-Construction; Preapplication ☐ Construction ☐ Non-Construction | **3. DATE RECEIVED BY STATE** | State Application Identifier |
| | **4. DATE RECEIVED BY FEDERAL AGENCY** | Federal Identifier |

**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

## 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:<br>-- "New" means a new assistance award.<br>-- "Continuation" means an extension for an additional funding/budget period for a project with a projected completion date.<br>-- "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 (1) | (2) | (3) | (4) | Total (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.



[FR Doc. 02–20584 Filed 8–13–02; 8:45 am]
BILLING CODE 4510–28–C

## DEPARTMENT OF LABOR

### Employment and Training Administration

**[TA–W–41,047]**

### C.G. Bretting Manufacturing Corporation, Inc., Ashland, WI; Notice of Termination of Certification

This notice terminates the Certification Regarding Eligibility to Apply For Worker Adjustment Assistance issued by the Department on June 19, 2002, applicable to workers of C.G. Bretting Manufacturing Corporation, Inc., in Ashland, Wisconsin. The notice was published in the **Federal Register** on July 9, 2002 (67 FR 45544).

The Department, on its own motion, reviewed the worker certification. Workers at the subject firm produce paper folding machines. The review of the investigation findings show that the survey of C.G. Bretting's major declining customers was conducted for paper holding machines instead of paper folding machines. Another survey was undertaken for the same customers for the same time periods. The survey revealed that none of the customers purchased imported paper folding machines.

Based on this new information, the Department is terminating the certification for petition number TA–W–41,047. Further coverage for workers under this certification would serve no purpose, and the certification has been terminated.

Signed at Washington, DC, this 6th day of August, 2002.

**Linda G. Poole,**

*Certifying Officer, Division of Trade Adjustment Assistance.*

[FR Doc. 02–20616 Filed 8–13–02; 8:45 am]

**BILLING CODE 4510–30–P**

## DEPARTMENT OF LABOR

### Employment and Training Administration

**[TA–W–41,015 and TA–W–41,015A]**

### E.J. Footwear LLC, Franklin, Tennessee, and E.J. Footwear LLC, Endicott, New York; Notice of Termination of Certification

Pursuant to section 223 of the Trade Act of 1974, on June 4, 2002, the Department of Labor issued a Certification of Eligibility to Apply for Worker Adjustment Assistance applicable to workers of the subject firm. The notice was published in the **Federal Register** on June 21, 2002 (67 FR 42285).

The State agency requested that the Department review the certification for workers of the subject firm engaged in the production of work boots. Information shows that the E.J. Footwear LLC certification, TA–W–40,899, was amended on July 15, 2002 to include workers at the Franklin, Tennessee and Vestal (Endicott), New York locations of the subject firm.

Consequently, continuance of this certification would serve no purpose and the certification is terminated.

Signed in Washington, DC, this 6th day of August, 2002.

**Linda G. Poole,**

*Certifying Officer, Division of Trade Adjustment Assistance.*

[FR Doc. 02–20615 Filed 8–13–02; 8:45 am]

**BILLING CODE 4510–30–P**

## DEPARTMENT OF LABOR

### Employment and Training Administration

**[TA–W–41,614 and TA–W–41,614A]**

### Great Northern Paper, Inc., Millinocket, ME, Great Northern Paper, Inc., East Millinocket, ME; Amended Certification Regarding Eligibility to Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 (19 U.S.C. 2273) the Department Labor issued a Certification of Eligibility to Apply for Worker Adjustment Assistance on July 15, 2002, applicable to workers of Great Northern Paper, Inc., Millinocket, Maine. The notice was published in the **Federal Register** on July 29, 2002 (67 FR 49039).

At the request of the State agency, the Department reviewed the certification for workers of the subject firm. New findings show that workers engaged in employment related to the production of groundwood pulp were separated from employment at the subject firm's East Millinocket, Maine facility. A meaningful portion of the groundwood pulp produced at Great Northern Paper, Inc., East Millinocket, Maine was consumed by the subject firm's mill in Millinocket, Maine, for its production of coated and uncoated specialty paper.

Workers at Great Northern Paper, Inc., East Millinocket, Maine, also produce paper for telephone directories and are separately identifiable from those producing groundwood pulp. There was no allegation that imports of paper for telephone directories contributed to worker separations.

The Department is amending the certification to cover workers at Great Northern Paper, Inc., East Millinocket, Maine, engaged in employment related to the production of groundwood pulp.

The amended notice applicable to TA-W–41,614 is hereby issued as follows:

''All workers of Great Northern Paper, Inc., Millinocket, Maine (TA-W–41,614); and workers engaged in employment related to the production of groundwood pulp at Great Northern Paper, East Millinocket (TA–W–41,616A) who became totally or partially separated from employment on or after May 17, 2001, through July 15, 2004, are eligible to apply for adjustment assistance under Section 223 of the Trade Act of 1974.''

Signed at Washington DC, this 31st day of July, 2002.

**Linda G. Poole,**

*Certifying Officer, Division of Trade Adjustment Assistance.*

[FR Doc. 02–20617 Filed 8–13–02; 8:45 am]

**BILLING CODE 4510–30–P**

## DEPARTMENT OF LABOR

### Employment and Training Administration

**[TA–W–40,983]**

### Symbol Techologies, Telxon Corporation, Houston, TX; Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 (19 U.S.C. 2273) the Department of Labor issued a Certification of Eligibility to Apply for Worker Adjustment Assistance on May 7, 2002, applicable to workers of Symbol Technologies, Houston, Texas. The notice was published in the **Federal Register** on May 17, 2002 (67 FR 35141).

At the request of the State agency, the Department reviewed the certification for workers of the subject firm. The workers are engaged in the production of bar code scanners and handheld computers used for retail sales.

Information received from the State shows that Symbol Technologies merged with Telxon Corporation in 2000. Information also shows that some workers separated from employment at the subject firm had their wages reported under a separate unemployment insurance (UI) tax account for Telxon Corporation.

Accordingly, the Department is amending the certification to properly reflect this matter.

The intent of the Department's certification is to include all workers of Symbol Technologies, Houston Texas who were adversely affected by increased imports.

The amended notice applicable to TA–W–40,983 is hereby issued as follows:

''All workers of Symbol Technologies, Telxon Corporation, Houston, Texas, engaged in the production of bar code scanners and handheld computers, who became totally or partially separated from employment on or after January 3, 2001, through May 7, 2004, are eligible to apply for adjustment assistance under Section 223 of the Trade Act of 1974.''

Signed at Washington, DC, this 6th day of August, 2002.

**Linda G. Poole,**

*Certifying Officer, Division of Trade Adjustment Assistance.*

[FR Doc. 02–20614 Filed 8–13–02; 8:45 am]

**BILLING CODE 4510–30–P**

## DEPARTMENT OF LABOR

## Employment and Training Administration

## Temporary Extended Unemployment Compensation Program Reports; 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 and Training Administration (ETA) is soliciting comments concerning the proposed extension of approval for the collection of reports concerning the Temporary Extended Unemployment Compensation (TEUC) program. A copy of the proposed information collection request (ICR) 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 addresses section below on or before October 15, 2002.

**ADDRESSES:** Thomas Stengle, U.S. Department of Labor, Employment and Training Administration, Room S–4231, 200 Constitution Ave. NW., Washington, DC 20210. Phone number: 202–693–2991. Fax: 202–693–3229. (These are not toll free numbers.) e-mail: *tstengle@doleta.gov*.

**SUPPLEMENTARY INFORMATION:**

### I. Background

The TEUC program was created under Public Law 107–147. This program allows for the application for and receipt of additional weeks of unemployment compensation under certain circumstances. This program is scheduled to expire December 31, 2002. In order to track participation in the program, plan for workloads, and plan for and distribute budget allocations, it is essential that certain basic data be collected and maintained. The collection of this information has previously been approved through an emergency clearance process through November 30, 2002. The TEUC program is currently due to expire December 28, 2002, and ETA is requesting that reporting for all reports continue for twelve full months or four full quarters after the last payable week of the TEUC program. However, to provide for potential congressional extensions of this program, ETA is seeking approval of a 2 year extension for this collection package.

### 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

This is a request for OMB approval under the Paperwork Reduction Act of 1995 (44 U.S.C. 3506(c)(2)(A)) for continuing an existing collection of information previously approved and assigned OMB Control No. 1205–0009.

*Type of Review:* Extension.

*Agency:* Employment and Training Administration.

*Title:* Temporary Extended Unemployment Compensation Reports

*OMB Number:* 1205–0433.

*Agency Numbers:* ETA 207, ETA 218, ETA 227, ETA 539, ETA 2112, ETA 5130, ETA 5159.

*Affected Public:* State Government.

*Cite/Reference/Form/etc:* ETA 207, ETA 218, ETA 227, ETA 539, ETA 2112, ETA 5130, ETA 5159.

*Total Respondents:* 53.

*Frequency:* Monthly.

*Total Responses:* 5300.

*Average Time per Response:* .33 hours.

*Estimated Total Burden Hours:* 1,787 hours per year.

*Total Burden Cost (capital/startup):* $0.

*Total Burden Cost (operating/maintaining):* $0.

Comments submitted in response to this comment request 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: August 8, 2002.

**Grace A. Kilbane,**

*Administrator, Office of Workforce Security.*

[FR Doc. 02–20611 Filed 8–13–02; 8:45 am]

**BILLING CODE 4510–30–P**

## DEPARTMENT OF LABOR

## Employment and Training Administration

## Investigations Regarding Certifications of Eligibility To Apply for NAFTA Transitional Adjustment Assistance

Petitions for transitional adjustment assistance under the North American Free Trade Agreement-Transitional Adjustment Assistance Implementation Act (Pub. L. 103–182), hereinafter called (NAFTA–TAA), have been filed with State Governors under section 250(b)(1) of Subchapter D, Chapter 2, Title II, of the Trade Act of 1974, as amended, are identified in the Appendix to this Notice. Upon notice from a Governor that a NAFTA–TAA petition has been received, the Director of the Division of Trade Adjustment Assistance (DTAA), Employment and Training Administration (ETA), Department of Labor (DOL), announces the filing of the petition and takes action pursuant to paragraphs (c) and (e) of section 250 of the Trade Act.

The purpose of the Governor's actions and the Labor Department's investigations are to determine whether the workers separated from employment on or after December 8, 1993 (date of enactment of Pub. L. 103–182) are eligible to apply for NAFTA–TAA under Subchapter D of the Trade Act because of increased imports from or the shift in production to Mexico or Canada.

The petitioners or any other persons showing a substantial interest in the subject matter of the investigations may request a public hearing with the Director of DTAA at the U.S. Department of Labor (DOL) in Washington, DC, provided such request if filed in writing with the Director of DTAA not later than August 26, 2002.

Also, interested persons are invited to submit written comments regarding the subject matter of the petitions to the Director of DTAA at the address shown below not later than August 26, 2002.

Petitions filed with Governors are available for inspection at the Office of the Director, DTAA, ETA, DOL, Room C–5311, 200 Constitution Avenue, NW., Washington, DC 20210.

Signed at Washington, DC, this 7th day of August, 2002.

**Edward A. Tomchick,**

*Director, Division of Trade Adjustment Assistance.*

APPENDIX

| Subject firm | Location | Date received at governor's office | Petition number | Articles produced |
|---|---|---|---|---|
| Aerus LLC (Co.) | Piney Flats, TN | 07/10/2002 | NAFTA–6,352 | vacuum cleaner power nozzle wands. |
| American Meter (Co.) | Erie, PA | 06/21/2002 | NAFTA–6,353 | diaphram meters. |
| E and A Technology (Wkrs) | El Paso, TX | 07/10/2002 | NAFTA–6,354 | computer chassis. |
| Donaldson Co., Inc. (Co.) | Baldwin, WI | 07/10/2002 | NAFTA–6,355 | metal fabrication. |
| Breed Technologies, Inc. (Co.) | Knoxville, TX | 07/10/2002 | NAFTA–6,356 | automatic seat belt components. |
| Tecumseh Product (Co.) | Grafton, WI | 07/09/2002 | NAFTA–6,357 | compressors. |
| Dana Corporation (Co.) | Columbia City, IN | 06/14/2002 | NAFTA–6,358 | hoses and tubing. |
| Agrium US Inc. (Co.) | Soda Springs, ID | 06/12/2002 | NAFTA–6,359 | phosphate fertilizer. |
| Neoplan USA Corp. (Wkrs) | Brownsville, TX | 07/09/2002 | NAFTA–6,360 | bus manufacturer. |
| Encana (Co.) | Butte, MT | 07/08/2002 | NAFTA–6,361 | oil and gas. |
| D and L Tool, Inc. (Co.) | Meadville, PA | 06/20/2002 | NAFTA–6,362 | molds. |
| Corning Frequency Control (Co.) | Mercersburg, PA | 06/20/2002 | NAFTA–6,363 | crystal blanks. |
| Computer Sciences Corp. (Co.) | Houston, TX | 07/11/2002 | NAFTA–6,364 | mailroom operations. |
| Oki Data Americas (Co.) | Mount Laurel, NJ | 07/15/2002 | NAFTA–6,365 | ribbon and toner cartridges. |
| Sitel Corp. (Wkrs) | Longview, TX | 07/15/2002 | NAFTA–6,366 | call center. |
| Harvard Industries (UAW) | Albion, MI | 07/08/2002 | NAFTA–6,367 | iron casting for automotive. |
| Penske Truck Leasing (Wkrs) | Chesterfield, MO | 07/12/2002 | NAFTA–6,368 | trucking leasing. |
| Holloway Sportswear (Wkrs) | Ville Platte, LA | 07/15/2002 | NAFTA–6,369 | sportswear. |
| Bee Paper (Wkrs) | Wayne, NU | 07/01/2002 | NAFTA–6,370 | paper. |
| Dura Automotive Systems (Co.) | Pikeville, TN | 07/12/2002 | NAFTA–6,371 | power windows. |
| Jam'ng Five (Wkrs) | Medley, FL | 07/15/2002 | NAFTA–6,372 | children wear. |
| Oxford Automotive (Wkrs) | Argos, IN | 07/12/2002 | NAFTA–6,373 | stamped metal auto parts. |
| IBM Global Services (Wkrs) | Jacksonville, FL | 07/15/2002 | NAFTA–6,374 | computer system and support. |
| VF Imagewear (Co.) | Mt. Pleasant, TN | 07/15/2002 | NAFTA–6,375 | uniforms (shirts and pants). |
| Tellabs Operations (Wkrs) | Hawthorne, NY | 07/12/2002 | NAFTA–6,376 | hardware modules. |
| Cummins (Co.) | Montello, WI | 07/03/2002 | NAFTA–6,377 | gas Turbins. |
| Willamette Industries-Weyerhaeuser (Co.) | Albany, OR | 07/12/2002 | NAFTA–6,378 | lumber. |
| American Technical Ceramics (Wkrs) | Jacksonville, FL | 07/16/2002 | NAFTA–6,379 | electronic capacitors. |
| Klaussner Furniture (Wkrs) | Asheboro, NC | 07/16/2002 | NAFTA–6,380 | cloth and leather upholstery furniture. |
| Mountain High Timber (Co.) | LaPine, OR | 07/17/2002 | NAFTA–6,381 | wood chips. |
| Tom Harmon Logging (Co.) | LaPine OR | 07/17/2002 | NAFTA–6,382 | wood chips. |
| New York Air Brake Corporation (Co.) | Akron, OH | 07/19/2002 | NAFTA–6,383 | train line hose. |
| Southern Transformer Co. (Co.) | East Point, GA | 07/20/2002 | NAFTA–6,384 | transformers. |
| Plantronics (Wkrs) | Garden Grove, CA | 07/10/2002 | NAFTA–6,385 | hearing aides. |
| Nova bus (Wkrs) | Niskayuna, NY | 07/16/2002 | NAFTA–6386 | transit buses. |
| Susquehanna Pfaltzgraff Co. (Wkrs) | York, PA | 07/19/2002 | NAFTA–6,387 | dinnerware. |
| IBM Corp. (Wkrs) | Rochester, MN | 07/19/2002 | NAFTA–6,388 | AS/400 computer systems. |
| Federal-Mogul Corporation (Wkrs) | Winchester, VA | 07/19/2002 | NAFTA–6,389 | friction products. |
| McManus Wyatt Produce (Wkrs) | Weslaco, TX | 07/22/2002 | NAFTA–6,390 | produce. |
| Krone, Inc. (Co.) | El Paso, TX | 07/18/2002 | NAFTA–6,391 | wire termination products. |
| Copeland Corp. (Wkrs) | Ava, MO | 07/16/2002 | NAFTA–6,392 | scroll sets. |
| Ergo Systems, Inc. (Co.) | Green Lane, PA | 07/18/2002 | NAFTA–6,393 | computer support equipment. |
| General Cable (IUE) | Sanger, CA | 07/10/2002 | NAFTA–6,394 | datacom wire and cable. |
| Switching Systems International (Wkrs) | Anaheim, CA | 07/10/2002 | NAFTA–6,395 | power supplies. |
| Aermotor Pumps, Inc. (Co.) | Conway, AR | 07/12/2002 | NAFTA–6,396 | sump pumps. |
| Johnson and Johnson Apparel (UNITE) | Bailey, NC | 07/16/2002 | NAFTA–6,397 | children's dresses. |
| American Uniform Co. (Co.) | Blue Ridge, GA | 07/15/2002 | NAFTA–6,398 | shirts, flat goods, and aprons. |

APPENDIX—Continued

| Subject firm | Location | Date received at governor's office | Petition number | Articles produced |
|---|---|---|---|---|
| United Plastics Group, Inc. (Wkrs) | Brooksville, FL | 07/16/2002 | NAFTA–6,399 | automotive injections. |
| Komatsu America Corp. (Co.) | Peoria, IL | 06/26/2002 | NAFTA–6,400 | ball studs, pins and castings. |
| Volant Ski (Wkrs) | Wheatridge, Co | 06/10/2002 | NAFTA–6,401 | alpine skis. |
| National Electrical Carbon (Wkrs) | Birmingham, AL | 07/23/2002 | NAFTA–6,402 | carbon brushes. |
| Coper Wiring Devices (Eagle Electric) (Wkrs) | Long Island City, NY | 07/23/2002 | NAFTA–6,403 | switches, adapters, etc. |
| Clark Alabma (Co.) | Pell City, AL | 07/23/2002 | NAFTA–6,404 | Industrial material handling equipment. |
| Saint Gobain Abrasives North America (PACE) | Niagara Falls, NY | 07/23/2002 | NAFTA–6,405 | abrasive products. |
| Don Alleson Athletic (Co.) | Toccoa, GA | 07/24/2002 | NAFTA–6,406 | athletic apparel, gym shorts. |
| Amcoe Speciality Packaging (Co.) | Newport News, VA | 07/08/2002 | NAFTA–6,407 | plastic food containers. |
| Emerson Electric (Co.) | Vernon, AL | 07/25/2002 | NAFTA–6,408 | electric heating/residential appliances. |
| Skyworks Solutions (Co.) | Havenhill, MA | 07/16/2002 | NAFTA–6,409 | semiconductor components. |
| Goodyear Tire and Rubber (The) (USWA) | Green, OH | 07/26/2002 | NAFTA–6,410 | air springs. |
| Carolina Mills (Co.) | Gastonia, NC | 07/25/2002 | NAFTA–6,411 | spur synthetic yarns. |
| U.S. Precision Glass (Co.) | Lewisburg, OH | 07/11/2002 | NAFTA–6,412 | glass for furniture. |
| Kelly Springfield (Wkrs) | Fayetteville, NC | 07/29/2002 | NAFTA–6,413 | tires. |
| Harris Welco—J.W. Harris (Co.) | Kings Mountain, NC | 07/29/2002 | NAFTA–6,414 | machinery. |
| MEL, Inc. (Co.) | Winchester, MA | 07/29/2002 | NAFTA–6,415 | dyeing of materials. |
| Norscan, Inc. (Co.) | Conover, NC | 07/30/2002 | NAFTA–6,416 | cable protection devices. |
| Gate City Printing (Wkrs) | Greensboro, NC | 07/25/2002 | NAFTA–6,417 | printed packaging. |
| Lapcor Plastic—Mirro/Wearever. Co. (Wkrs) | Manitowoc, WI | 07/29/2002 | NAFTA–6,418 | cookware sets. |

[FR Doc. 02–20612 Filed 8–13–02; 8:45 am]
BILLING CODE 4510–30–M

## DEPARTMENT OF LABOR

### Employment and Training Administration

**[NAFTA–6124]**

### Holophane, a Division of Acuity Lighting Group, Inc., Springfield, OH; Notice of Negative Determination Regarding Application for Reconsideration

By application dated July 9, 2002, the International Union, UAW, Region 2B and Local Union No. 1876 requested administrative reconsideration of the Department's negative determination regarding eligibility to apply for North American Free Trade Agreement-Transitional Adjustment Assistance (NAFTA–TAA), applicable to workers and former workers of the subject firm. The denial notice was signed on May 22, 2002, and was published in the **Federal Register** on June 11, 2002 (67 FR 40005).

Pursuant to 29 CFR 90.18(c) reconsideration may be granted under the following circumstances:

(1) If it appears on the basis of facts not previously considered that the determination complained of was erroneous;

(2) if it appears that the determination complained of was based on a mistake in the determination of facts not previously considered; or

(3) if in the opinion of the Certifying Officer, a mis-interpretation of facts or of the law justified reconsideration of the decision.

The denial of NAFTA–TAA for workers engaged in activities related to the production of castings which are sold within the corporation at Holophane, a Division of Acuity Lighting Group, Inc., Springfield, Ohio was based on the finding that criteria (3) and (4) of the group eligibility requirements of paragraph (a)(1) of Section 250 of the Trade Act, as amended, were not met. There were no company imports of castings from Mexico or Canada, nor did the subject firm shift production from Springfield, Ohio to Mexico or Canada. The subject firm has decided to outsource castings domestically and transfer some other secondary functions to another company facility in the United States.

The petitioner alleges that the subject firm shifted subject plant machinery and equipment to a warehouse located in Brownsville, Texas and then shipped the machinery to an affiliated plant located in Matamoros, Mexico that produces outdoor architectural lighting fixtures and poles. The petitioner also supplied pictures and various shipping information (printed and handwritten) pertaining to the shifts in plant machinery to Mexico.

A review of the company data supplied in the initial decision shows the subject plant was an internal component supplier of Aluminum Die-Castings, Low Pressure Castings and Sand Casting to an affiliated Holophane manufacturing plant located in Newark, New Jersey. As part of a business diagnostics project, an evaluation was made by the company to determine if Holophane should continue to produce its own castings since manufacturing Aluminum castings is not a core competency of Holophane. Consequently, the building and Die Cast equipment was sold to a domestic company located in Arkansas with a production plant located in Tennessee. The plant located in Tennessee will supply the Die cast component parts to Holophane. With regard to the Low-pressure Castings and Sand Casting, other firms located in Ohio are now supplying Holophane products produced by the subject plant. All secondary operations previously performed at the Springfield facility have been transferred to affiliated plants located in Utica, Ohio. Therefore, all of the work performed at the subject plant prior to the closure is still being

produced in the United States, either at Company facilities or by various domestic suppliers.

Further review of the initial decision shows that a very small amount of the foundry equipment from Springfield was transferred to the company's existing foundry operation at the Cast Light de Mexico S. A. plant located in Matamoros, Mexico. The transferred equipment to Mexico shows the machinery was not being used and therefore has not replaced any of the production previously performed at the Springfield, Ohio plant during the relevant period.

**Conclusion**

After review of the application and investigative findings, I conclude that there has been no error or misinterpretation of the law or of the facts which would justify reconsideration of the Department of Labor's prior decision. Accordingly, the application is denied.

Signed at Washington, DC, this 6th day of August, 2002.

**Edward A. Tomchick,**

*Director, Division of Trade Adjustment Assistance.*

[FR Doc. 02–20619 Filed 8–13–02; 8:45 am]

**BILLING CODE 4510–30–P**

## DEPARTMENT OF LABOR

### Employment and Training Administration

**[NAFTA—05977]**

### Progress Lighting, Philadelphia, PA; Notice of Termination of Investigation

Pursuant to Title V of the North American Free Trade Agreement Implementation Act (Pub. L. 103–182) concerning transitional adjustment assistance, hereinafter called (NAFTA–TAA), and in accordance with section 250(a), subchapter D, chapter 2, Title II, of the Trade Act of 1974, as amended (19 U.S.C. 2273), an investigation was initiated on March 12, 2002, in response to a petition filed on behalf of workers at Progress Lighting, Philadelphia, Pennsylvania.

An active certification covering the petitioning group of workers is already in effect (NAFTA–04208A, as amended). Consequently, further investigation in this case would serve no purpose, and the investigation has been terminated.

Signed at Washington, DC, this 25th day of July, 2002.

**Edward A. Tomchick,**

*Director, Division of Trade Adjustment Assistance.*

[FR Doc. 02–20618 Filed 8–13–02; 8:45 am]

**BILLING CODE 4510–30–P**

## DEPARTMENT OF LABOR

### Employment and Training Administration

**[NAFTA–6205]**

### ZF-Meritor, LLC, Meritor Clutch Company, Maxton, North Carolina; Dismissal of Application for Reconsideration

Pursuant to 29 CFR 90.18(C) an application for administrative reconsideration was filed with the Director of the Division of Trade Adjustment Assistance for workers at ZF Meritor, LLC, Meritor Clutch Company, Maxton, North Carolina. The application contained no new substantial information which would bear importantly on the Department's determination. Therefore, dismissal of the application was issued.

NAFTA–6205; ZF Meritor, LLC, Meritor Clutch Company Maxton, North Carolina (August 6, 2002)

Signed at Washington, DC this 8th day of August, 2002.

**Edward A. Tomchick,**

*Director, Division of Trade Adjustment Assistance.*

[FR Doc. 02–20620 Filed 8–13–02; 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, Wage and Hour Division, is soliciting comments concerning the proposed collection ''Application for Federal Certificate of Age''(WH–14).'' 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 October 15, 2002.

**ADDRESSES:** Ms. Patricia A. Forkel, U.S. Department of Labor, 200 Constitution Ave., NW., Room S–3201, Washington, DC 20210, telephone (202) 693–0339, fax (202) 693–1451, e-mail *pforkel@fenix2.dol-esa.gov.* Please use only one method of transmission for comments (mail, fax, or e-mail).

**SUPPLEMENTARY INFORMATION:**

**I. Background**

Section 3(1) of the Fair Labor Standards Act (FLSA) provides, in part, that an employer may protect against unwitting employment of ''oppressive child labor'' [as defined in section 3(1)], by having on file a certificate issued pursuant to Department of Labor (DOL) regulations certifying that the named person meets the FLSA minimum wage requirements for employment. Section 11(c) of the FLSA requires that all employers covered by the Act make, keep, and preserve records of wages, hours, and other conditions and practices of employment with respect to their employees. Regulations 29 CFR part 570, subpart B, set forth the requirements for obtaining certifications of age. State age, employment or working certificates which substantially meet the Federal regulatory requirements for certificates of age are an acceptable alternative to obtaining a Federal Certificate of Age. Form WH–14 is the application which is to be completed by the youth and prospective employer to obtain a Federal Certificate of Age in those States where no State certificates are issued or State certificates do not meet the Federal regulatory requirements. This information collection is currently approved by the Office of Management and Budget (OMB) for use through January 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 seeks an extension of approval of the information collection to protect employers from unwitting violation of the minimum age standards of the Fair Labor Standards Act. There is no change to the form or method of collection.

*Type of Review:* Extension.

*Agency:* Employment Standards Administration.

*Title:* Application for Federal Certificate of Age.

*OMB Number:* 1215–0083.

*Agency Number:* WH–14.

*Affected Public:* Businesses or other for-profit; individuals or households; not-for-profit institutions; farms; State, Local or Tribal Government.

*Total Respondents:* 10.

*Total Responses:* 10.

*Burden Hours per Response(Reporting):* 10 minutes.

*Burden Hours Per Response:* (Recordkeeping): ½ minute.

*Total Burden Hours:* (Reporting and Recordkeeping): 2.

*Total Burden Cost:* (capital/startup): $0.

*Total Burden Cost:* (operation/maintenance): $4.00.

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: August 8, 2002.

**Margaret J. Sherrill,**

*Chief, Branch of Management Review and Internal Control, , Division of Financial Management, Office of Management, Administration and Planning, Employment Standards Administration.*

[FR Doc. 02–20609 Filed 8–13–02; 8:45 am]

**BILLING CODE 4510–27–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 extension collection: Agreement and Undertaking (OWCP–1). 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 October 15, 2002.

**ADDRESSES:** Ms. Patricia A. Forkel, U.S. Department of Labor, 200 Cnstitution Ave., NW., Room S–3201, Washington, DC 20210, telephone (202) 693–0339, fax (202) 693–1451, e-mail *pforkel@fenix2.dol-esa.gov.* Please use only one method of transmission for comments (mail, fax, or e-mail).

**I. Background**

Coal mine operators and longshore companies desiring to be self-insurers are required by law (30 U.S.C. 933, Black Lung Benefits Act) and 33 U.S.C. 932 (Longshore and Harbor Workers' Compensation Act) to produce security in terms of an indemnity bond, security deposit, or, for Black Lung only, a letter of credit or 501(c)(21) trust. Once a company's application to become self-insured is reviewed by the Division of Coal Mine Workers' Compensation (DCMWC) or by the Division of Longshore and Harbor Workers' Compensation (DLHWC) and it is determined the company is potentially eligible, an amount of security is determined to guarantee the payment of benefits required by the Act. The OWCP–1 form is executed by the self-insurer who agrees to abide by the Department's rules and authorizes the Secretary, in the event of default, to file suit to secure payment from a bond underwriter or, in the case of a Federal Reserve account, to sell the securities for the same purpose. Regulations establishing this requirement are at 20 CFR 726.110 for DCMWC and 20 CFR 703.304 for DLHWC. A company cannot be authorized to self-insure until this requirement is met. This information collection is currently approved for use through January 31, 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 seeks the extension of approval to collect this information in order to determine if a coal mine or longshore company is potentially eligible to become self-insured. The information is reviewed to deposited, indemnity bond is purchased, letter of credit is obtained, or 501(c)(21) trust assets are available; and that in case of default, OWCP has the authority to utilize the securities or bond. If this Agreement and Undertaking were not required, OWCP would not be empowered to utilize the

company's security deposit to meet its financial responsibilities for the coal mine or longshore benefits in case of default. There is no change in this information collection since the last OMB clearance.

*Type of Review:* Extension.

*Agency:* Employment Standards Administration.

*Title:* Agreement and Undertaking.

*OMB Number:* 1215–0034.

*Agency Number:* OWCP–1.

*Affected Public:* Businesses or other for-profit.

*Total Respondents:* 300.

*Frequency:* On occasion.

*Total Responses:* 300.

*Average Time per Response:* 15 minutes.

*Estimated Total Burden Hours:* 75.

*Total Burden Cost (capital/startup):* $0.

*Total Burden Cost (operating/maintenance):* $120.

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: August 8, 2002.

**Margaret J. Sherrill,**

*Chief, Branch of Management Review and Internal Control, , Division of Financial Management, Office of Management, Administration and Planning, Employment Standards Administration.*

[FR Doc. 02–20610 Filed 8–13–02; 8:45 am]

**BILLING CODE 4510–CK–P**

## DEPARTMENT OF LABOR

### Office of Federal Contract Compliance Programs

### Goya de Puerto Rico, Inc., Debarment

**AGENCY:** Office of Federal Contract Compliance Programs, Labor.

**ACTION:** Notice of Debarment: Goya de Puerto Rico, Inc., Bayamon, P.R. 00959.

**SUMMARY:** This notice advises of the debarment of Goya de Puerto Rico, Inc., as an eligible bidder on Government contracts or extensions or modifications of existing contracts. The debarment is effective immediately.

**EFFECTIVE DATE:** August 14, 2002.

**FOR FURTHER INFORMATION CONTACT:** Charles E. James, Sr., Deputy Assistant Secretary for Federal Contract Compliance, U.S. Department of Labor, 200 Constitution Ave., NW., Room C–3325, Washington, DC 20210 (202–693–1062).

**SUPPLEMENTARY INFORMATION:** This notice pertains to Goya de Puerto Rico, Inc., Road No. 28, Corner Road No. 5, Luchetti Industrial Park, Bayamon, P.R. 00959. (It is not applicable to Goya Foods, Inc., a separate entity.) On March 21, 2002, the U.S. Department of Labor Administrative Review Board (''ARB'') issued a Final Decision and Order, pursuant to Executive Order 11246, the Vietnam Era Veterans' Readjustment Assistance Act of 1974, Section 503 of the Rehabilitation Act of 1973 and their implementing regulations (41 CFR Parts 60–1 to 60–50, 41 CFR Part 60–250, and 41 CFR Part 60–741), *OFCCP* v. *Goya de Puerto Rico, Inc.,* No. 99–104. The Final Decision provides that Goya de Puerto Rico, Inc., its officers, agents, employees, successors, divisions, subsidiaries, and all persons in active concert or participation with them, are permanently enjoined from failing or refusing to comply with the requirements of the Executive Order, Section 503, and VEVRAA. The decision further ordered that Goya de Puerto Rico, Inc. be debarred from having or entering into government contracts, or from extensions or modifications of existing contracts, until the later of the expiration of six months or the fulfillment of the following three conditions: (1) That Goya de Puerto Rico, Inc. submit a complete affirmative action plan to OFCCP; (2) that OFCCP has the opportunity to complete an on-site investigation and to conduct a full compliance review to confirm the accuracy of the affirmative action program and to verify compliance with all regulations; and (3) that the Secretary of Labor, through OFCCP, declares Goya de Puerto Rico Inc.'s affirmative action plan acceptable. Finally, the ARB ordered that Goya de Puerto Rico's existing government contracts, subcontracts and blanket purchase agreements, and all of the contracts, subcontracts, and blanket purchase agreements of Goya de Puerto Rico Inc.'s officers, agents, employees, successors, divisions, subsidiaries, and all persons in active concert or participation with it, be canceled and terminated. Pursuant to Section 209(a)(5) of Executive Order 11246, as amended, the process of consultation with Federal contracting agencies has been initiated, and existing contracts, subcontracts and blanket purchase agreements may be terminated thereafter.

Signed August 8, 2002, Washington, DC.

**Harold M. Busch,**

*Acting Deputy Director, Office of Federal Contract Compliance Programs.*

[FR Doc. 02–20607 Filed 8–13–02; 8:45 am]

**BILLING CODE 4510–CM–P**

## DEPARTMENT OF LABOR

### Bureau of Labor Statistics

### 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 pre-clearance 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 Bureau of Labor Statistics (BLS) is soliciting comments concerning the proposed revision of the ''Cognitive and Psychological Research.'' A copy of the proposed information collection request (ICR) can be obtained by contacting the individual listed below in the **ADDRESSES** section of this notice.

**DATES:** Written comments must be submitted to the office listed in the Addresses section below on or before October 15, 2002.

**ADDRESSES:** Send comments to Amy A. Hobby, BLS Clearance Officer, Division of Management Systems, Bureau of Labor Statistics, Room 3255, 2 Massachusetts Avenue, NE., Washington, DC 20212, telephone number 202–691–7628 (this is not a toll free number).

**FOR FURTHER INFORMATION CONTACT:** Amy A. Hobby, BLS Clearance Officer, telephone number 202–691–7628. (See **ADDRESSES** section.)

**SUPPLEMENTARY INFORMATION:**

#### I. Background

The Bureau of Labor Statistics' (BLS) Behavior Science Research Laboratory (BSRL) conducts theoretical, applied and evaluative research aimed at improving the quality of data collected and published by the Bureau. Since its creation in 1988, the BSRL has advanced the study of survey methods research, approaching issues of non-sampling error within a framework that draws heavily on the theories and methods of the cognitive, statistical and social sciences. The BSRL research focuses primarily on the assessment of

survey instrument design and survey administration, as well as on issues related to interviewer training, and on the interaction between interviewer and respondent in the interview process. Improvements in these areas result in better accuracy and response rates of BLS surveys, frequently reduce costs in training and survey administration, and further ensure the effectiveness of the Bureau's overall mission.

**II. Desired Focus of Comments**

The Bureau of Labor Statistics is particularly interested in comments that:

- 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 Action**

The purpose of this clearance request by the BSRL is to conduct cognitive and psychological research for the purpose of enhancing the quality of the Bureau's data collection and data management procedures. The BLS is committed to producing the most accurate and complete data under high quality assurance guidelines. For the past 15 years, research conducted by the BSRL has led to substantial improvements in BLS estimates and procedures. Over the next few years, demand for BSRL consultation is expected to rise, as information processing approaches to survey methods research become even more common and visible. In addition, as data collection methods involving computers and web-based surveys become increasing wide-spread, careful instrument design and testing will be required. The BSRL is uniquely equipped with both the skills and facilities to accommodate these demands.

The revisions in the accompanying clearance package reflect an attempt to accommodate an increasing interest by BLS program offices and other agencies in the methods used, and the results obtained, by the BSRL. This package reflects planned research and development activities for FY2003 through FY2005. Its approval will enable the continued productivity of a state-of-the-art, multi-disciplinary program of behavioral science research to improve BLS survey methodology.

*Type of Review:* Revision of a currently approved collection.

*Agency:* Bureau of Labor Statistics.

*Title:* Cognitive and Psychological Research.

*OMB Number:* 1220–0141.

*Affected Public:* Individuals and households.

*Total Respondents:* 4,000.

*Frequency:* One time.

*Total Responses:* 4,000.

*Average Time Per Response:* 60 minutes.

*Estimated Total Burden Hours:* 4,000 hours.

*Total Burden Cost (capital/startup):* $0.

*Total Burden Cost (operating/maintenance):* $0

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 also will become a matter of public record.

Signed at Washington, DC, this 30th day of July, 2002.

**Jesús Salinas,**

*Acting Chief, Division of Management Systems, Bureau of Labor Statistics.*

[FR Doc. 02–20613 Filed 8–13–02; 8:45 am]

**BILLING CODE 4510–24–P**

## NUCLEAR REGULATORY COMMISSION

### Agency Information Collection Activities: Submission for the Office of Management and Budget (OMB) Review; Comment Request

**AGENCY:** Nuclear Regulatory Commission (NRC).

**ACTION:** Notice of the OMB review of information collection and solicitation of public comment.

**SUMMARY:** The NRC has recently submitted to OMB for review the following proposal for the collection of information under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). The NRC hereby informs potential respondents that an agency may not conduct or sponsor, and that a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

1. *Type of submission, new, revision, or extension:* Extension request with burden revisions.

2. *The title of the information collection:* 10 CFR part 26, ''Fitness for Duty Program'.

3. *The form number if applicable:* Not applicable.

4. *How often the collection is required:* On occasion.

5. *Who will be required or asked to report:* All licensees authorized to construct or operate a nuclear power reactor and all licensees authorized to possess, use, or transport unirradiated Category 1 nuclear materials.

6. *An estimate of the number of responses:* 1514 (1440 responses plus 74 recordkeepers).

7. *The estimated number of annual respondents:* 74.

8. *An estimate of the total number of hours needed annually to complete the requirement or request:* 64,446 (6273 hours of reporting burden or an average of 85 hours per licensee and 58,173 hours of recordkeeping burden or an average of 786 hours per licensee).

9. *An indication of whether Section 3507(d), Public Law 104–13 applies:* Not applicable.

10. *Abstract:* 10 CFR part 26, ''Fitness for Duty Program,'' requires licensees of nuclear power plants and licensees authorized to possess, use, or transport unirradiated Category 1 nuclear material to implement fitness-for-duty programs to assure that personnel are not under the influence of any substance or mentally or physically impaired, to retain certain records associated with the management of these programs, and to provide reports concerning significant events and program performance. Compliance with these program requirements is mandatory for licensees subject to 10 CFR part 26.

A copy of the final supporting statement may be viewed free of charge at the NRC Public Document Room, One White Flint North, 11555 Rockville Pike, Room O–1 F21, Rockville, MD 20852. OMB clearance requests are available at the NRC World Wide Web site: *http://www.nrc.gov/public-involve/doc-comment/omb/index.html.* The document will be available on the NRC home page site for 60 days after the signature date of this notice.

Comments and questions should be directed to the OMB reviewer listed below by September 13, 2002. Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given to comments received after this date.

Bryon Allen, Office of Information and Regulatory Affairs (3150–0146),

NEOB–10202, Office of Management and Budget, Washington, DC 20503.

Comments can also be submitted by telephone at (202) 395–3087.

The NRC Clearance Officer is Brenda Jo. Shelton, 301–415–7233.

Dated at Rockville, Maryland, this 8th day of August, 2002.

For the Nuclear Regulatory Commission.

**Brenda Jo. Shelton,**

*NRC Clearance Officer, Office of the Chief Information Officer.*

[FR Doc. 02–20564 Filed 8–13–02; 8:45 am]

**BILLING CODE 7590–01–P**

## SECURITIES AND EXCHANGE COMMISSION

**[Investment Company Act Release No. 25694, 812–12692]**

## Commonfund Institutional Funds, et al.; Notice of Application

August 7, 2002.

**AGENCY:** Securities and Exchange Commission (''Commission'').

**ACTION:** Notice of an application under: (a) Section 6(c) of the Investment Company Act of 1940 (''Act'') requesting an exemption from sections 12(d)(3) and 17(e) of the Act and rule 17e–1 under the Act; (b) sections 6(c) and 17(b) of the Act requesting an exemption from section 17(a) of the Act; and (c) section 10(f) of the Act requesting an exemption from section 10(f) of the Act.

**SUMMARY OF APPLICATION:** Applicants request an order to permit certain registered open-end management investment companies advised by several investment advisers to engage in principal and brokerage transactions with a broker-dealer affiliated with one of the investment advisers and to purchase securities in certain underwritings. The transactions would be between the broker-dealer and a portion of the investment company's portfolio not advised by the adviser affiliated with the broker-dealer. The order also would permit these investment companies not to aggregate certain purchases from an underwriting syndicate in which an affiliated person of one of the investment advisers is a principal underwriter. Further, applicants request relief to permit a portion of an investment company's portfolio to purchase securities issued by a broker-dealer that is an affiliated person of an investment adviser to another portion, subject to the limits in rule 12d3–1 under the Act.

**APPLICANTS:** Commonfund Institutional Funds (the ''Company'') and Commonfund Asset Management Company, Inc. (''COMANCO'').

**FILING DATES:** The application was filed on November 21, 2001 and amended on August 6, 2002.

**HEARING OR NOTIFICATION OF HEARING:** An order granting the requested relief will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Commission's Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be received by the Commission by 5:30 p.m. on September 3, 2002 and should be accompanied by proof of service on applicants, in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons may request notification of a hearing by writing to the Commission's Secretary.

**ADDRESSES:** Secretary, Commission, 450 5th Street, NW., Washington, DC 20549–0609. Applicants, c/o John W. Auchincloss, Commonfund Institutional Funds, 15 Old Danbury Road, Wilton, CT 06897.

**FOR FURTHER INFORMATION CONTACT:** Jaea F. Hahn, Senior Counsel, at (202) 942–0614, or Todd F. Kuehl, Branch Chief, at (202) 942–0564 (Division of Investment Management, Office of Investment Company Regulation).

**SUPPLEMENTARY INFORMATION:** The following is a summary of the application. The complete application may be obtained for a fee at the Commission's Public Reference Branch, 450 5th Street, NW., Washington, DC 20549–0102 (tel. 202–942–8090).

### Applicants' Representations

1. The Company is an open-end management investment company registered under the Act and currently consists of eight investment portfolios (the ''CIF Portfolios''). COMANCO, an indirect, wholly owned subsidiary of The Common Fund for Nonprofit Organizations, is an investment adviser registered under the Investment Advisers Act of 1940, as amended (''Advisers Act''). COMANCO serves as investment adviser to each of the CIF Portfolios, including CIF Portfolios (''Multi-Managed Portfolios'') that are advised by COMANCO and investment sub-advisers (''Sub-Advisers''). Each Sub-Adviser is registered under the Advisers Act or is exempt from registration. Each Sub-Adviser is responsible for making independent investment and brokerage allocation decisions for a discrete portion of a Multi-Managed Portfolio (''Portion'') based on its own research and credit evaluations. Each Sub-Adviser is paid a fee by COMANCO out of the management fee received by COMANCO from the Multi-Managed Portfolios, which fee is based on a percentage of the value of assets allocated to the Sub-Adviser. COMANCO may also directly advise a Portion of a Multi-Managed Portfolio.

2. Applicants request relief to permit: (a) A broker-dealer that serves as a Sub-Adviser or is an affiliated person of a Sub-Adviser (the broker-dealer, an ''Affiliated Broker-Dealer''; the Sub-Adviser, an ''Affiliated Sub-Adviser'') to engage in principal transactions with a Portion of a Multi-Managed Portfolio that is advised by another Sub-Adviser that is not an affiliated person of the Affiliated Broker-Dealer or Affiliated Subadviser (the Portion, an ''Unaffiliated Portion''; the other Sub-Adviser, an ''Unaffiliated Sub-Adviser''); (b) an Affiliated Broker-Dealer to provide brokerage services to an Unaffiliated Portion, and the Unaffiliated Portion to use such brokerage services, without complying with rule 17e–1(b) or (d) under the Act; (c) an Unaffiliated Portion to purchase securities during the existence of an underwriting syndicate, a principal underwriter of which is an Affiliated Sub-Adviser or a person of which an Affiliated Sub-Adviser is an affiliated person (''Affiliated Underwriter''); (d) a Portion advised by an Affiliated Sub-Adviser (''Affiliated Portion'') to purchase securities during the existence of an underwriting syndicate, a principal underwriter of which is an Affiliated Underwriter, in accordance with the conditions of rule 10f–3 under the Act, except that paragraph (b)(7) of the rule would not require the aggregation of purchases by the Affiliated Portion with purchases by Unaffiliated Portions; and (e) an Unaffiliated Portion to purchase securities issued by an Affiliated Sub-Adviser, or an affiliated person of an Affiliated Sub-Adviser engaged in securities-related activities (''Securities Affiliate''), subject otherwise to the limits in rule 12d3–1 under the Act.[1]

[1] The terms ''Unaffiliated Subadviser'' and ''Subadviser'' include COMANCO and the term ''Unaffiliated Portion'' includes the Portion of a Multi-Managed Portfolio directly advised by COMANCO provided that it manages its Portion of the Multi-Managed Portfolio independently of the Portions managed by other Sub-Advisers to the Multi-Managed Portfolio, and COMANCO does not control or influence any other Sub-Adviser's investment decisions for its portion of the Multi-Managed Portfolio. COMANCO does not currently directly manage a Portion of any Multi-Managed Portfolio.

3. Applicants request that the exemptive relief apply to the Company or any existing or future open-end management investment company registered under the Act, or series thereof, for which COMANCO or any entity controlling, controlled by, or under common control with (within the meaning of section 2(a)(9) of the Act) COMANCO currently or in the future acts as investment adviser. The Company is the only registered investment company that currently intends to rely on the order. COMANCO will take steps designed to ensure that any other existing or future entity that relies on the order will comply with the terms and conditions of the application.

**Applicants' Legal Analysis**

*A. Principal Transactions between Unaffiliated Portions and Affiliated Broker-Dealers*

1. Section 17(a) of the Act generally prohibits sales or purchases of securities between a registered investment company and an affiliated person of, promoter of, or principal underwriter for such company, or any affiliated person of an affiliated person, promoter, or principal underwriter (''second-tier affiliate''). Section 2(a)(3)(E) of the Act defines an affiliated person to be any investment adviser of an investment company, and section 2(a)(3)(C) of the Act defines an affiliated person of another person to include any person directly or indirectly controlling, controlled by, or under common control with such person. Applicants state that an Affiliated Sub-Adviser would be an affiliated person of a Multi-Managed Portfolio, and an Affiliated Broker-Dealer would be either an Affiliated Sub-Adviser or an affiliated person of the Affiliated Sub-Adviser to the same Multi-Managed Portfolio, and thus a second-tier affiliate of a Multi-Managed Portfolio, including the Unaffiliated Portions. Accordingly, applicants state that any transactions to be effected by an Unaffiliated Sub-Adviser on behalf of an Unaffiliated Portion of a Multi-Managed Portfolio with an Affiliated Broker-Dealer are subject to the prohibitions of section 17(a).

2. Applicants seek relief under sections 6(c) and 17(b) of the Act, to exempt principal transactions prohibited by section 17(a) where an Affiliated Broker-Dealer is deemed to be an affiliated person or a second-tier affiliate of an Unaffiliated Portion solely because an Affiliated Sub-Adviser is the Sub-Adviser to another Portion of the same Multi-Managed Portfolio.

3. Section 17(b) of the Act authorizes the Commission to grant an order permitting a transaction otherwise prohibited by section 17(a) if it finds that the terms of the proposed transaction are reasonable and fair and do not involve overreaching on the part of any person concerned, and the proposed transaction is consistent with the policy of each registered investment company concerned and the general purposes of the Act. Section 6(c) of the Act permits the Commission to exempt any person or transaction from any provisions of the Act if the exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policies and provisions of the Act.

4. Applicants contend that section 17(a) is intended to prevent persons who have the power to control an investment company from using that power to the person's own pecuniary advantage. Applicants assert that when the person acting on behalf of an investment company has no direct or indirect pecuniary interest in a party to a principal transaction, the abuses that section 17(a) was designed to prevent are not present. Applicants state that if an Unaffiliated Sub-Adviser were to purchase securities on behalf of an Unaffiliated Portion in a principal transaction with an Affiliated Broker-Dealer, any benefit that might inure to the Affiliated Broker-Dealer would not be shared by the Unaffiliated Sub-Adviser. Applicants state that Sub-Advisers are paid on the basis of a percentage of the value of the assets under their management. The execution of a transaction to the disadvantage of an Unaffiliated Portion would also disadvantage the Unaffiliated Sub-Adviser to the extent that it diminishes the value of the Unaffiliated Portion. Applicants further state that COMANCO's power to dismiss Sub-Advisers or to change the Portion of a Multi-Managed Portfolio allocated to each Sub-Adviser reinforces a Sub-Adviser's incentive to maximize the investment performance of its own Portion of the Multi-Managed Portfolio.

5. Applicants state that each Sub-Adviser's contract assigns it responsibility to manage a discrete Portion of the Multi-Managed Portfolio. Each Sub-Adviser is responsible for making independent investment and brokerage allocation decisions based on its own research and credit evaluations. Applicants state that COMANCO does not dictate brokerage allocation or investment decisions for any Multi-Managed Portfolio, or have the contractual right to do so, except for any Portion of a Multi-Managed Portfolio advised directly by COMANCO. Applicants submit that, in managing a discrete Portion of a Multi-Managed Portfolio, each Sub-Adviser acts for all practical purposes as though it is managing a separate investment company.

6. Applicants state that the proposed transactions will be consistent with the policies of the Multi-Managed Portfolios, since each Unaffiliated Sub-Adviser is required to manage the Unaffiliated Portion in accordance with the investment objectives and related investment policies of the Multi-Managed Portfolio as described in its prospectus and statement of additional information. Applicants assert that permitting the transactions will be consistent with the general purposes of the Act and in the public interest because the ability to engage in such transactions increases the likelihood of the Multi-Managed Portfolio achieving best price and execution on its principal transactions, while giving rise to none of the abuses that the Act was designed to prevent.

*B. Payment of Brokerage Compensation by an Unaffiliated Portion to an Affiliated Broker-Dealer*

1. Section 17(e)(2) of the Act prohibits an affiliated person or a second-tier affiliate of a registered investment company from receiving compensation for acting as a broker in connection with the sale of securities to or by the investment company if the compensation exceeds the limits prescribed by the section unless otherwise permitted by rule 17e–1 under the Act. Rule 17e–1 sets forth the conditions under which an affiliated person or a second-tier affiliate of an investment company may receive a commission that would not exceed the ''usual and customary broker's commission'' for purposes of section 17(e)(2) of the Act. Rule 17e–1(b) requires the investment company's board of directors, including a majority of the directors who are not interested persons under section 2(a)(19) of the Act, to adopt certain procedures and to determine at least quarterly that all transactions effected in reliance on the rule complied with the procedures. Rule 17e–1(d) specifies the records that must be maintained by each investment company with respect to any transaction effected pursuant to rule 17e–1.

2. As discussed above, applicants state that an Affiliated Broker-Dealer is either an affiliated person (as Sub-Adviser to another Portion of a Multi-Managed Portfolio) or a second-tier affiliate of an Unaffiliated Portion and thus subject to section 17(e). Applicants request relief under section 6(c) of the

Act from section 17(e) of the Act and rule 17e–1 under the Act to the extent necessary to permit the Unaffiliated Portion to pay brokerage compensation to an Affiliated Broker-Dealer acting as broker in the ordinary course of business without complying with the requirements of rule 17e–1(b) and (d). The requested exemption would apply only where an Affiliated Broker-Dealer is deemed to be an affiliated person or a second-tier affiliate of an Unaffiliated Portion solely because an Affiliated Sub-Adviser is the Sub-Adviser to another Portion of the same Multi-Managed Portfolio.

3. Applicants believe that the proposed brokerage transactions involve no conflicts of interest or possibility of self-dealing and will meet the standards of section 6(c) of the Act. Applicants assert that the interests of an Unaffiliated Sub-Adviser are directly aligned with the interests of the Unaffiliated Portion it advises, and an Unaffiliated Subadviser will enter into brokerage transactions with Affiliated Broker-Dealers only if the fees charged are reasonable and fair, as required by rule 17e–1(a). Applicants note that an Unaffiliated Sub-Adviser has a fiduciary duty to obtain best price and execution for the Unaffiliated Portion.

*C. Purchases of Securities From Offerings With Affiliated Underwriters*

1. Section 10(f) of the Act, in relevant part, prohibits a registered investment company from knowingly purchasing or otherwise acquiring, during the existence of any underwriting or selling syndicate, any security (except a security of which the company is the issuer) when a principal underwriter of the security, or an affiliated person of the principal underwriter, is an officer, director, member of an advisory board, investment adviser or employee of the investment company. Section 10(f) also provides that the Commission may exempt by order any transaction or classes of transactions from any of the provisions of section 10(f), if and to the extent that such exemption is consistent with the protection of investors. Rule 10f–3 under the Act exempts certain transactions from the prohibitions of section 10(f) if specified conditions are met. Paragraph (b)(7) of rule 10f–3 limits the securities purchased by the investment company, or by two or more investment companies having the same investment adviser, to 25% of the principal amount of the offering of the class of securities.

2. Applicants state that each Sub-Adviser, although under contract to manage only a Portion of a Multi-Managed Portfolio, is an investment adviser to the entire Multi-Managed Portfolio. Therefore, all purchases of securities by an Unaffiliated Portion from an underwriting syndicate, a principal underwriter of which is an Affiliated Underwriter, would be subject to section 10(f).

3. Applicants request relief under section 10(f) to permit an Unaffiliated Portion to purchase securities during the existence of an underwriting or selling syndicate, a principal underwriter of which is an Affiliated Underwriter. Applicants request relief from section 10(f) only to the extent those provisions apply solely because an Affiliated Sub-Adviser is an investment adviser to the Multi-Managed Portfolio. Applicants also seek relief from section 10(f) to permit an Affiliated Portion to purchase securities during the existence of an underwriting syndicate, a principal underwriter of which is an Affiliated Underwriter, provided that the purchase is in accordance with the conditions of rule 10f–3, except that paragraph (b)(7) of the rule will not require the aggregation of purchases by the Affiliated Portion with purchases by an Unaffiliated Portion.

4. Applicants state that section 10(f) was adopted in response to concerns about the ''dumping'' of otherwise unmarketable securities on investment companies, either by forcing the investment company to purchase unmarketable securities from its underwriting affiliate, or by forcing or encouraging the investment company to purchase the securities from another member of the syndicate. Applicants submit that these abuses are not present in the context of the Multi-Managed Portfolios because a decision by an Unaffiliated Sub-Adviser to a Portion of a Multi-Managed Portfolio to purchase securities during the existence of an underwriting syndicate, a principal underwriter of which is an Affiliated Underwriter, involves no potential for ''dumping.'' In addition, applicants state that aggregating purchases would serve no purpose because there is no collaboration among Sub-Advisers, and any common purchases by an Affiliated Sub-Adviser and an Unaffiliated Sub-Adviser would be coincidence.

*D. Purchases of Securities Issued by Securities Affiliates*

1. Section 12(d)(3) of the Act generally prohibits a registered investment company from acquiring any security issued by any person who is a broker, dealer, investment adviser, or engaged in the business of underwriting. Rule 12d3–1 under the Act exempts certain transactions from the prohibitions of section 12(d)(3) if certain conditions are met. One of these conditions, set forth in paragraph (c) of rule 12d3–1, provides that the exemption provided by the rule is not available when the issuer of the securities is the investment company's investment adviser, promoter, or principal underwriter, or an affiliated person of the investment adviser, promoter, or principal underwriter.

2. Applicants state that because each Sub-Adviser to a Multi-Managed Portfolio is considered to be an investment adviser to the entire Multi-Managed Portfolio, an Unaffiliated Portion may not purchase securities of a Securities Affiliate in reliance on rule 12d3–1. Applicants request an exemption under section 6(c) from section 12(d)(3) to permit an Unaffiliated Portion to acquire securities issued by a Securities Affiliate subject to the limits in rule 12d3–1, except for paragraph (c) to the extent that the paragraph applies solely because the Securities Affiliate is an Affiliated Sub-Adviser, or an affiliated person of an Affiliated Sub-Adviser. The requested relief would not extend to securities issued by the Sub-Adviser making the purchase, COMANCO, or a Securities Affiliate of any of these entities.

3. Applicants state that their proposal does not raise the conflicts of interest that rule 12d3–1(c) was designed to address because of the nature of the affiliation between a Securities Affiliate and the Unaffiliated Portion. Applicants submit that each Sub-Adviser acts independently of the other Sub-Advisers in making investment decisions for the assets allocated to its portion of the Multi-Managed Portfolio. Further, applicants assert that prohibiting the Unaffiliated Portions from purchasing securities issued by Securities Affiliates could harm the interests of shareholders by preventing the Unaffiliated Sub-Adviser from achieving optimal investment results.

**Applicants' Conditions**

Applicants agree that any order granting the requested relief will be subject to the following conditions:

1. Each Multi-Managed Portfolio relying on the requested order will be advised by an Affiliated Subadviser and at least one Unaffiliated Sub-Adviser, and will be operated in the manner described in the application.

2. No Affiliated Sub-Adviser, Affiliated Broker-Dealer, Affiliated Underwriter or Securities Affiliate (except by virtue of serving as Sub-Adviser to a Portion of a Multi-Managed Portfolio) will be an affiliated person or second-tier affiliate of (a) COMANCO; (b) the Unaffiliated Sub-Adviser making

the investment decision with respect to the Unaffiliated Portion of the Multi-Managed Portfolio; (c) any principal underwriter or promoter of a Multi-Managed Portfolio, or (d) any officer, director or employee of the Multi-Managed Portfolio engaging in the transaction.

3. No Affiliated Sub-Adviser will directly or indirectly consult with any Unaffiliated Sub-Adviser concerning allocation of principal or brokerage transactions or concerning the purchase of securities issued by Securities Affiliates. Sub-Advisers may consult with COMANCO in order to monitor compliance with the limits in rule 12d3–1.

4. No Affiliated Sub-Adviser will participate in any arrangement whereby the amount of its sub-advisory fees will be affected by the investment performance of an Unaffiliated Sub-Adviser.

5. With respect to purchases of securities by an Affiliated Portion during the existence of any underwriting or selling syndicate, a principal underwriter of which is an Affiliated Underwriter, the conditions of rule 10f–3 will be satisfied except that paragraph (b)(7) will not require the aggregation of purchases by the Affiliated Portion with purchases by an Unaffiliated Portion.

6. With respect to purchases by an Unaffiliated Portion of securities issued by a Securities Affiliate, the conditions of rule 12d3–1 will be satisfied except for paragraph (c) of such rule to the extent such paragraph is applicable solely because such issuer is an Affiliated Sub-Adviser or an affiliated person of an Affiliated Sub-Adviser.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

**Margaret H. McFarland,**

*Deputy Secretary.*

[FR Doc. 02–20524 Filed 8–13–02; 8:45 am]

**BILLING CODE 8010–01–P**

## SECURITIES AND EXCHANGE COMMISSION

### Sunshine Act Meeting

Federal Register Citation of Previous Announcement: [67 FR 51900, August 9, 2002]

*Status:* Closed Meeting.

*Place:* 450 Fifth Street, NW., Washington, DC.

*Date and Time of Previously Announced Meeting:* Tuesday, August 13, 2002 at 10:00 a.m.

*Change in the Meeting:* Date Change.

The closed meeting scheduled for Tuesday, August 13, 2002 at 10 a.m. has been changed to Monday, August 12, 2002, at 3 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: August 9, 2002.

**Margaret H. McFarland,**

*Deputy Secretary.*

[FR Doc. 02–20681 Filed 8–9–02; 4:09 pm]

**BILLING CODE 8010–01–P**

## SECURITIES AND EXCHANGE COMMISSION

**[Release No. 34–46320; File No. SR–NASD–2002–84]**

### Self-Regulatory Organizations; Notice of Filing and Immediate Effectiveness of Proposed Rule Change and Amendment Nos. 1 and 2 Thereto by the National Association of Securities Dealers, Inc. Relating to Display Requirements When Using Reserve Size Functionality in Nasdaq's Future Order Display and Collector Facility

August 6, 2002.

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 June 18, 2002, 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, II, and III below, which Items have been prepared by Nasdaq. On July 25, 2002, Nasdaq submitted Amendment No. 1 to the proposed rule change.[3] On August 5, 2002, Nasdaq submitted Amendment No. 2 to the proposed rule change.[4] 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**

Nasdaq proposes to alter the display requirement when using the reserve size feature in Nasdaq's future Order Display and Collector Facility (''SuperMontage'').

The text of the proposed rule change, as amended, appears below. New text is in italics. Deleted text is in brackets.

**4710. Participant Obligations in NNMS**

(a) No Change.

(b)(1)(A) through (b)(1)(D) No Change.

(2) Refresh Functionality

(A) Reserve Size Refresh—Once a Nasdaq Quoting Market Participant's Displayed Quote/Order size on either side of the market in the security has been decremented to zero due to NNMS processing Nasdaq will refresh the displayed size out of Reserve Size to a size-level designated by the Nasdaq Quoting Market Participant, or in the absence of such size-level designation, to the automatic refresh size. To utilize the Reserve Size functionality, a minimum of [1,000] *100* shares must initially be displayed in the Nasdaq Quoting Market Participant's Displayed Quote/Order, and the Displayed Quote/Order must be refreshed to at least [1000] *100* shares. This functionality will not be available for use by UTP Exchanges.

(B) No Change.

(3) through (8) No Change.

(c) through (e) No Change.

**II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change**

In its filing with the Commission, Nasdaq included statements concerning the purpose of and basis for the proposed rule change, as amended, 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

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* letter from Mary M. Dunbar, Vice President, Nasdaq, to Katherine A. England, Assistant Director, Division of Market Regulation (''Division''), Commission, dated July 24, 2002 (''Amendment No.1''). Amendment No. 1 replaced in its entirety the original rule proposal filed on June 18, 2002. In Amendment No. 1, Nasdaq, in part, made a minor technical correction to its rule text and clarified that only Nasdaq Quoting Market Participants would be permitted to use the reserve size functionality on SuperMontage.

[4] *See* letter from Thomas P. Moran, Associate General Counsel, Nasdaq, to Katherine A. England, Assistant Director, Division, Commission, dated August 5, 2002 (''Amendment No. 2''). In Amendment No. 2, Nasdaq requested that the Commission waive the 30-day waiting period for the proposed rule change to become operative, and removed a sentence containing an inadvertent error regarding the possibility of decrementing a displayed quote to below 100 shares. For purposes of determining the effective date and calculating the 60-day period within which the Commission may summarily abrogate the proposed rule change under Section 19(b)(3)(C) of the Act, the Commission considers August 5, 2002 to be the effective date of the proposed rule change, the date Nasdaq filed Amendment No. 2. 15 U.S.C. 78s(b)(3)(C).

forth in Sections A, B, and C below, of the most significant aspects of such statements.

*A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change*

1. Purpose

As part of its ongoing preparation for the launch of SuperMontage, Nasdaq is engaging in a continuing review of the system's functionality and rules with a view to constant improvement. As a result of this review, and in consultation with industry professionals, Nasdaq has determined to reduce, from 1000 shares to 100 shares, the initial display requirement when using the reserve size feature of SuperMontage.

Background

SuperMontage allows Nasdaq Quoting Market Participants to divide quoted share amounts submitted to the system between those shares they direct to display publicly in the Nasdaq montage and the shares they desire to keep in reserve. Known as ''reserve size,'' shares kept in reserve are available for execution through SuperMontage but are not shown to the marketplace.[5] Nasdaq asserts that reserve size is an important tool for market participants seeking to execute large securities transactions while limiting negative market price impacts associated with public knowledge of those attempted sales or purchases.

Currently, the rules of Nasdaq's SuperMontage system prohibit the use of its reserve size functionality unless a Nasdaq Quoting Market Participant is displaying at least 1000 shares in its public quote. To Nasdaq's knowledge, it is the only market or trading venue that imposes such a display obligation. The 1000 share display requirement in SuperMontage was initially proposed to be consistent with a similar 1000 share display obligation applicable to trading in Nasdaq's SuperSoes system. Recent experience in the post-decimals SuperSoes environment, however, caused Nasdaq to re-examine the 1000 share display obligation and file with the Commission a proposal, since approved, to reduce, from 1000 to 100 shares, the display amount required to use reserve size in SuperSoes.[6] In this filing, Nasdaq seeks to adopt the same 100-share display standard in SuperMontage.

Under the rule change proposed here, Nasdaq Quoting Market Participants would be allowed to use SuperMontage reserve size any time they displayed a quote of at least one round lot (100 shares). Nasdaq states that the elimination of the 1000-share display requirement makes SuperMontage reserve size functionality available to market makers on terms similar to the reserve size facilities of competing trading systems while continuing to encourage the display of trading interest through SuperMontage's ''displayed size first'' execution algorithm.

2. Statutory Basis

Nasdaq believes that the proposed rule change, as amended, is consistent with the provisions of Section 15A of the Act,[7] in general, and Section 15A(b)(6) of the Act,[8] in particular, in that the proposal is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.

*B. Self-Regulatory Organization's Statement on Burden on Competition*

Nasdaq does not believe that the proposed rule change, 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*

Nasdaq neither solicited nor received written comments with respect to the proposed rule change, as amended.

**III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action**

Because the foregoing proposed rule change, as amended, does not:

(1) Significantly affect the protection of investors or the public interest;

(2) Impose any significant burden on competition; and

(3) Become operative for 30 days after the date of filing, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act[9] and Rule 19b-4(f)(6)[10] thereunder. At any time within 60 days of August 5, 2002, 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.[11]

Nasdaq requested that the Commission waive the five-day pre-filing notice requirement and the 30-day operative delay. The Commission believes waiving the 5-day pre-filing notice requirement and the 30-day operative delay is consistent with the protection of investors and the public interest. The Commission notes that it has already approved a reduction of the minimum display size to 100 shares for use of reserve size in SuperSOES and believes that the proposal to implement the same change in SuperMontage raises no new regulatory issues.[12] As a result, the Commission designates the proposal to be effective and operative upon filing with the Commission.[13]

**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, as amended, 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

[5] Under SuperMontage's various execution algorithms, the system generally executes against all publicly displayed shares at the same price level before executing in time priority against reserve size at that same price. Telephone conversation between Thomas Moran, Office of General Counsel, Nasdaq, and Terri Evans, Assistant Director, and Ira Brandriss, Special Counsel, Division, Commission, on July 8, 2002.

[6] *See* Securities Exchange Act Release No. 45998 (May 29, 2002), 67 FR 39759 (June 10, 2002) (File No. SR–NASD–2001–66).

[7] 15 U.S.C. 78*o*–3.

[8] 15 U.S.C. 78*o*–3(b)(6).

[9] 15 U.S.C. 78s(b)(3)(A).

[10] 17 CFR 240.19b–4(f)(6).

[11] *See* Section 19(b)(3)(C) of the Act, 15 U.S.C. 78s(b)(3)(C).

[12] *See* Securities Exchange Act Release No. 45998 (May 29, 2002), 67 FR 39759 (June 10, 2002).

[13] 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).

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–2002–84 and should be submitted by September 4, 2002.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[14]

**Margaret H. McFarland,**

*Deputy Secretary.*

[FR Doc. 02–20525 Filed 8–13–02; 8:45 am]

**BILLING CODE 8010–01–P**

## OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

### Trade Policy Staff Committee; Notice of Availability and Request for Public Comment on Draft Environmental Review of United States-Singapore Free Trade Agreement

**AGENCY:** Office of the United States Trade Representative.

**ACTION:** Notice of availability and request for public comment.

**SUMMARY:** The Office of the U.S. Trade Representative (USTR), on behalf of the Trade Policy Staff Committee (TPSC), seeks comment on the draft environmental review of the proposed U.S.-Singapore Free Trade Agreement (FTA). The draft environmental review is available at *http://www.ustr.gov/environment/environmental.shtml.* Copies of the review will also be sent to interested members of the public by mail upon request.

**DATES:** Comments on the draft environmental review are requested by September 20, 2002.

**FOR FURTHER INFORMATION CONTACT:** For procedural questions concerning public comments, contact Gloria Blue, Executive Secretary, TPSC, Office of the USTR, 1724 F Street, NW., Washington, DC 20508, telephone (202) 395–3475. Questions concerning the environmental review, or requests for copies, should be addressed to Alice Mattice or David Brooks, Environment and Natural Resources Section, Office of the USTR, telephone 202–395–7320.

**SUPPLEMENTARY INFORMATION:** Executive Order 13121—*Environmental Review of Trade Agreements* (64 FR 63,169, Nov. 18, 1999) and its implementing guidelines (65 FR 79,442, Dec. 19, 2000) require environmental reviews of certain major trade agreements. The Trade Act of 2002, signed by the President on August 6, 2002, provides that the President shall conduct environmental reviews consistent with the Order and its relevant guidelines, and report on such reviews to the Committee on Ways and Means of the House of Representatives and the Committee on Finance of the Senate. The Order and guidelines are available at *http://www.ustr.gov/environment/environmental.shtml.*

On November 29, 2000, at the outset of the negotiations, the TPSC initiated the environmental review of the Singapore FTA and requested public comments on the scope of the review, including the potential environmental effects that might flow from the FTA and the potential implications for environmental laws and regulations. *See* 65 FR 71,197 (Nov. 29, 2000); 65 FR 80,982 (Dec. 22, 2000) (extending public comment period). Because the negotiating schedule proved to be more extended than originally anticipated, the TPSC provided a supplemental opportunity for public comments. *See* 67 FR 8833 (Feb. 26, 2002). The TPSC also held a public hearing to discuss issues raised in connection with the Singapore FTA, including environmental issues. *See* 67 FR 9349 (Feb. 28, 2002).

**Written Comments**

In order to facilitate prompt processing of submissions of comments, the Office of the Unites States Trade Representative strongly urges and prefers e-mail submissions in response to this notice. Persons submitting comments by e-mail should use the following e-mail address: *FR0029@ustr.gov* with the subject line: ''Singapore Draft Environmental Review.'' Documents should be submitted as either WordPerfect, MSWord, or text (.TXT) files. Persons who make submissions by e-mail should not provide separate cover letters; information that might appear in a cover letter should be included in the submission itself. To the extent possible, any attachments to the submission should be included in the same file as the submission itself, and not as separate files. If submission by e-mail is impossible, comments should be made by facsimile to (202) 395–6143, attention: Gloria Blue.

Written comments will be placed in a file open to public inspection in the USTR Reading Room at 1724 F Street, NW., Washington DC. An appointment to review the file may be made by calling (202) 395–6186. The Reading Room is open to the public from 10–12 a.m. and from 1–4 p.m., Monday through Friday.

**Carmen Suro-Bredie,**

*Chair, Trade Policy Staff Committee.*

[FR Doc. 02–20505 Filed 8–13–02; 8:45 am]

**BILLING CODE 3190–01–P**

## DEPARTMENT OF TRANSPORTATION

### Office of the Secretary

### Notice on Honoring Tickets of Insolvent Airlines Pursuant to Section 145 of the Aviation and Transportation Security Act

August 8, 2002.

**AGENCY:** Office of the Secretary, DOT.

**SUMMARY:** The Department is publishing the following notice regarding the obligation of carriers to honor the tickets of insolvent airlines pursuant to the requirements of section 145 of the Aviation and Transportation Security Act.

**FOR FURTHER INFORMATION CONTACT:** Dayton Lehman, Jr., Deputy Assistant General Counsel, Office of Aviation Enforcement and Proceedings (C–70), 400 7th Street, SW.,Washington, DC 20590, (202) 366–9349.

The purpose of this notice is to clarify the obligation of airlines under section 145 of the Aviation and Transportation Security Act (''Act'') to provide transportation to passengers of airlines that have ceased operations due to insolvency or bankruptcy. (Pub. L. 107–71, 115 Stat. 645 (November 19, 2001).) This notice is needed because of numerous consumer complaints received by the Department regarding the treatment of passengers holding Vanguard Airline tickets by other airlines in the wake of Vanguard's July 30, 2002, cessation of operations.

In the wake of the September 11, 2001, terrorist attacks on the United States, Congress passed the Aviation and Transportation Security Act, which was signed into law on November 19, 2001. At least in part due to concerns that airlines might become insolvent, with resulting harm to consumers holding tickets on such airlines, Congress included in the law a provision to protect such consumers. The provision, section 145, requires airlines that operate on the same route as an insolvent carrier that has ceased operations to transport, ''to the extent practicable,'' the ticketed passengers of the insolvent carrier. Specifically, section 145, which applies to interruptions in air service that occur within 18 months of the enactment of the Act, states in pertinent part:

[14] 17 CFR 200.30–3(a)(12).

(a) * * * Each air carrier that provides scheduled air transportation on a route shall provide, to the extent practicable, air transportation to passengers ticketed for air transportation on that route by any other air carrier that suspends, interrupts, or discontinues air passenger service on the route by reason of insolvency or bankruptcy of the other air carrier.

(b) * * * An air carrier is not required to provide air transportation under subsection (a) to a passenger unless that passenger makes alternative arrangements with the air carrier for such transportation within 60 days after the date on which that passenger's air transportation was suspended, interrupted, or discontinued (without regard to the originally scheduled travel date on the ticket).

After the recent cessation of operations of Vanguard Airlines, there has been considerable confusion, on the part of airlines and the traveling public, over airlines' responsibilities under section 145, particularly with regard to the meaning of the phrase ''to the extent practicable'' as it relates to the carriers'' duties to transport persons holding Vanguard tickets. Carriers have implemented varying policies regarding the treatment afforded to persons holding Vanguard tickets. Some carriers are providing those passengers transportation at no additional cost, either on a confirmed or stand-by basis. Others permit passengers to fly stand-by but assess up to a $100 ''administrative fee'' each way, along with offering to drop advance purchase requirements for restricted positive-space fares, and still others offer restricted positive-space fares and do not permit stand-by travel at all. In some of the instances, carriers have announced that their accommodations for Vanguard passengers will be available for only a short period of time.

It is the Department's position that section 145 requires, at a minimum, that passengers holding valid confirmed tickets, whether paper or electronic, of the insolvent or bankrupt carrier must be transported by other carriers who operate on the route for which the passenger is ticketed on a space-available basis on the date of travel shown on the ticket or other documentation demonstrating e-ticketing, without significant additional charges. We recognize that there is a cost to airlines of transporting such passengers and we do not believe that in enacting section 145 Congress intended to prohibit carriers from recovering from accommodated passengers minimal amounts associated with the actual cost of providing such transportation, such as direct cost of rewriting a passenger's ticket, onboard meal costs, and additional fuel costs for transporting an additional passenger. However, in no case do we foresee those costs exceeding $25 each way.

We also believe that the 60-day provision in the statute is clear. Consumers holding Vanguard tickets have until 60 days after the carrier suspended operations, or until September 28, 2002, to attempt to make alternative arrangements with another carrier.

It should be noted that passengers who purchased their Vanguard tickets using a credit card are entitled under the Fair Credit Billing Act to a credit refund from their credit card issuer, under specific circumstances, to the extent they do not receive the services for which they paid. If a passenger elects to accept alternate transportation under section 145, this choice is likely to affect his or her right to a refund under the Fair Credit Billing Act. The public may obtain information on obtaining refunds for Vanguard tickets on the Department's website at *http://www.dot.gov/airconsumer/vanguard.htm.*

Questions regarding this notice may be addressed to the Office of Aviation Enforcement and Proceedings (C–70), 400 7th St., SW., Washington, DC 20590.

**Note:** An electronic version of this document is available on the World Wide Web at *http://dms.dot.gov/reports.*

Dated: August 8, 2002.

**Read C. Van de Water,**

*Assistant Secretary for Aviation and International Affairs.*

[FR Doc. 02–20627 Filed 8–13–02; 8:45 am]

**BILLING CODE 4910–62–P**

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

### Airworthiness Approval of Global Navigation Satellite System (GNSS) Equipment

**AGENCY:** Federal Aviation Administration (DOT).

**ACTION:** Notice of availability and request for public comment.

**SUMMARY:** This notice announces the availability of and requests comments on a revised draft Advisory Circular (AC) 20–138A airworthiness approach of Global Navigation Satellite System (GNSS) equipment. This AC addresses the following types of installations—

a. GNSS sensors, including those incorporating Wide Area Augmentation System (WAAS), Local Area Augmentation System (LAAS), or the Russian Global Navigation Satellite System (GLONASS).

b. GNSS stand-alone navigation equipment that provides deviations (including Category 1 precision approach).

**DATES:** Comments submitted must be received on or before September 16, 2002.

**ADDRESSES:** Send all comments on the proposed advisory circular to: Federal Aviation Administration (FAA), Aircraft Certification Service, Aircraft Engineering Division, Avionics Systems Branch, AIR–130, 800 Independence Avenue, SW., Washington, DC 20591. Or deliver comments to: Federal Aviation Administration, Room 815, 800 Independence Avenue, SW., Washington, DC 20591.

**FOR FURTHER INFORMATION CONTACT:** Bruce DeCleene, Federal Aviation Administration (FAA), Aircraft Certification Service, Aircraft Engineering Division, Avionic Systems Branch, AIR–130, 800 Independence Avenue, SW., Washington, DC 20591, Telephone: (202) 385–4640, FAX: (202) 267–5340.

**SUPPLEMENTARY INFORMATION:**

#### Comments Invited

Interested person are invited to comment on the draft AC listed in this notice by submitting such written data, views, or arguments, as they desire, to the aforementioned specified address. Comments must be marked ''Comments to AC 20–138A.'' Comments received on the draft advisory circular may be examined, both before and after the closing date, in Room 815, FAA Headquarters Building (FOB–10A), 800 Independence Avenue, SW., Washington, DC 20591, weekdays except Federal holidays, between 8:30 a.m. and 4:30 p.m. All communications received on or before the closing date for comments specified will be considered by the Director of the Aircraft Certification Service before issuing the Final AC.

#### Background

The FAA is developing a new Advisory Circular, AC 20–138A, Airworthiness Approval of Global Navigation Satellite System (GNSS) Equipment. This advisory circular (AC) provide guidance material for the airworthiness approval of all types of GNSS equipment. This revision to the current AC is in support of the deployment of the Wide Area Augmentation System (WAAS) and the local Area Augmentation System (LASS). WAAS services will be commissioned in 2003, providing en

route, terminal area, and approach navigation. WAAS avionics may be approved under an authorization to Technical Standard Order (TSO) C–1145a, GPS/WAAS Sensors, or TSO–C146a, GPS/WAAS Stand Alone Navigation Equipment. This equipment may be installed prior to the commissioning of WAAS, and this AC is needed to provide the unique policy applicable to such installations. In addition, the LAAS will become operational in 2004. LAAS guidance is included in this AC to support the early installation of the associated avionics.

***How To Obtain Copies**

A copy of the revised draft AC may be obtained via Internet (*http://www.faa.gov/avr/air/airhome.htm*) or on request from the individual listed under **FOR FURTHER INFORMATION CONTACT.**

Issued in Washington, DC, on August 8, 2002.

**David Hempe,**

*Manager, Aircraft Engineering Division, Aircraft Certification Service.*

[FR Doc. 02–20637 Filed 8–13–02; 8:45 am]

**BILLING CODE 4910–13–M**

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

### Public Notice for Waiver of Aeronautical Land-use Assurance, St. Louis Regional Airport, East Alton, IL

**AGENCY:** Federal Aviation Administration, DOT.

**ACTION:** Notice of intent of waiver with respect to land.

**SUMMARY:** The Federal Aviation Administration (FAA) is considering a proposal to change a portion of airport land from aeronautical use to non-aeronautical use and to authorize the sale of the airport property. The proposal consists of the sale of Parcel I–54A (a O.023-acre portion of Parcel I—54, also known as Lot 43 in Wayside Estates), Parcel I–56A (a 0.038-acre portion of Parcel I–56, also known as Lot 42 in Wayside Estates), Parcel I–58A (a 0.036-acre portion of Parcel I–58, also known as Lot 41 in Wayside Estates), Parcel I–99A (a 0.0370-acre portion of Parcel I–99, also known as Lot 40 in Wayside Estates), Parcel I–101A (a 0.036-acre portion of Parcel I–101, also known as Lot 39 in Wayside Estates), and Parcel I–103A (a 0.049-acre portion of Parcel I–103, also known as Lot 38 in Wayside Estates). Presently the land is vacant and used for control of FAR Part 77 surfaces and for land use and noise compatibility purposes and is not needed for appropriate use, as shown on the Airport Layout Plan. Parcel I–54 (0.293 acre, more or less) was acquired in 1996 with Federal participation under AIP grant 3–17–SBGP–12. Parcel I–56 (0.311 acre, more or less) was acquired in 1996 with Federal participation under AIP grant 3–17–SBGP–13. Parcel I–58 (0.285 acre, more or less) was acquired in 1996 with Federal participation under AIP grant 3–17–SBGP–10. Parcel I–99 (0.227 acre, more or less) was acquired in 1997 with Federal participation under AIP-grant 3–17–SBGP–16. Parcel I–101 (0.252 acre, more or less) was acquired in 1998 with Federal participation under AIP grant 3–17–SBGP–20. Parcel I–103 (0.254 acre, more or less) was acquired in 1997 with Federal participation under AIP grant 3–17–SBGP–20. It is the intent of the St. Louis Regional Airport Authority (SLRAA) to sell Parcels I–54A, I–56A, I–58A, I–99A, I–101A and I–103A in fee. This notice announces that the FAA intends to authorize the disposal of the subject airport property at St. Louis Regional Airport, East Alton, IL. Approval does not constitute a commitment by the FAA to financially assist in disposal of the subject airport property nor a determination that all measures covered by the program are eligible for grant-in-aid funding from the FAA. The disposition of proceeds from the disposal of the airport property will be in accordance with FAA Order 5100.38B ''Airport Improvement Program Handbook.''

In accordance with section 47107(h) of Title 49, United States Code, this notice is required to be published in the **Federal Register** 30 days before modifying the land-use assurance that requires the property to be used for an aeronautical purpose.

**DATES:** Comments must be received on or before September 13, 2002.

**FOR FURTHER INFORMATION CONTACT:** Richard Pur, Program Manager, 2300 East Devon Avenue, Des Plaines, IL, 60018. Telephone Number 847–294–7527/FAX Number 847–294–7046. Documents reflecting this FAA action may be reviewed at this same location by appointment or at the St. Louis Regional Airport Authority, St. Louis Regional Airport, 8 Terminal Drive, East Alton, IL 62024.

**SUPPLEMENTARY INFORMATION:** The following legal description of the proposed land sale is:

**Parcel I–54A**

That part of Lot 43 in Wayside Estates, a subdivision of part of the East Half of Section 11, Township 5 North, Range 9 West of the Third Principal Meridian in Madison County, Illinois, according to the plat thereof recorded in Plat Book 32, Page 83, described as follows:

Beginning at the northwest corner of said Lot 43; thence on an assumed bearing of North 79 degrees 02 minutes 13 seconds East, 21.18 feet on the north line of said Lot 43; thence South 01 degree 34 minutes 36 seconds East, 16.91 feet; thence South 11 degrees 36 minutes 36 seconds West, 41.52 feet to the south line of said Lot 43; thence North 58 degrees 27 minutes 11 seconds West, 12.09 feet on said south line to the southwest corner of said Lot 43; thence North 00 degrees 56 minutes 11 seconds West, 52.59 feet (52.56 feet recorded) on the west line of said Lot 43 to the Point of Beginning.

Said parcel herein described contains 0.023 acre, more or less.

**Parcel I–56A**

That part of Lot 42 in Wayside Estates, a subdivision of part of the East half of Section 11, Township 5 North, Range 9 West of the Third Principal Meridian in Madison County, Illinois, according to the plat thereof recorded in Plat Book 32, Page 83, described as follows:

Beginning at the northwest corner of said Lot 42, thence on an assumed bearing of North 79 degrees 01 minute 48 seconds East, 20.27 feet on the north line of said Lot 42: thence South 01 degree 34 minutes 36 seconds East, 81.05 feet to the south line of said Lot 42; thence South 79 degrees 02 minutes 13 seconds West, 21.18 feet on said south line to the southwest corner of said Lot 42; thence North 00 degrees 56 minutes 11 seconds West, 81.20 feet (81.15 feet recorded) on said west line to the Point of Beginning.

Said parcel herein described contains 0.038 acre, more or less.

**Parcel I–58A**

That part of Lot 41 in Wayside Estates, a subdivision of part of the East Half of Section 11, Township 5 North, Range 9 West of the Third Principal Meridian in Madison County, Illinois, according to the plat thereof recorded in Plat Book 32, Page 83, described as follows:

Beginning at the northwest corner of said Lot 41; thence on an assumed bearing of North 79 degrees 01 minute 59 seconds East, 19.35 feet on the north line of said Lot 41; thence South 01 degree 34 minutes 36 seconds East, 81.07 feet to the south line of said Lot 41; thence South 79 degrees 01 minute 48 seconds West, 20.27 feet on said south line to the southwest corner of said Lot 41; thence North 00 degrees 56

minutes 11 seconds West, 81.23 feet (81.18 feet recorded) on the west line of said Lot 41 to the Point of Beginning.

Said parcel herein described contains 0.036 acre, more or less.

**Parcel I–99A**

That part of Lot 40 in Wayside Estates, a subdivision of part of the East Half of Section 11, Township 5 North, Range 9 West of the Third Principal Meridian in Madison County, Illinois, according to the plat thereof recorded in Plat Book 32, Page 83, described as follows:

Beginning at the northwest corner of said Lot 40, thence on an assumed bearing of North 81 degrees 53 minutes 26 seconds East, 18.22 feet on the north line of said Lot 40; thence South 01 degree 34 minutes 36 seconds East, 86.92 feet to the south line of said Lot 40; thence South 79 degrees 01 minute 59 seconds West, 19.35 feet on said south line to the southwest corner of said Lot 40; thence North 00 degrees 56 minutes 11 seconds West, 88.01 feet (87.95 feet recorded) on the west line of said Lot 40 to the Point of beginning.

Said parcel herein contains 0.037 acre, more or less.

**Parcel I–101A**

That part of Lot 39 in Wayside Estates, a subdivision of part of the East Half of Section 11, Township 5 North, Range 9 West of the Third Principal Meridian in Madison County, Illinois, according to the plat thereof recorded in Plat Book 32, Page 83, described as follows:

Beginning at the northwest corner of said Lot 39; thence on an assumed bearing on North 85 degrees 58 minutes 11 seconds East, 17.12 feet on the north line of said Lot 39; thence South 01 degree 34 minutes 36 seconds East, 88.26 feet to the south line of said Lot 39; thence South 81 degrees 53 minutes 26 seconds West, 18.22 feet on said south line to the southwest corner of said Lot 39; thence North 00 degrees 56 minutes 11 seconds West, 89.61 feet (89.55 feet recorded) on the west line of said Lot 39 to the Point of Beginning.

Said parcel herein described contains 0.036 acre, more or less.

**Parcel I–103A**

That part of Lot 38 in Wayside Estates, a subdivision of part of the East Half of Section 11, Township 5 North, Range 9 West of the Third Principal Meridian in Madison County, Illinois, according to the plat thereof recorded in Plat Book 32, Page 83, described as follows:

Beginning at the northwest corner of said Lot 38; thence on an assumed bearing of South 86 degrees 20 minutes 45 seconds East, 30.89 feet on the north line of said Lot 38; thence South 09 degrees 51 minutes 07 seconds West, 74.38 feet; thence South 01 degree 34 minutes 36 seconds East, 20.33 feet to the south line of said Lot 38; thence South 85 degrees 58 minutes 11 seconds West, 17.12 feet on said south line to the southwest corner of said Lot 38; thence North 00 degrees 56 minutes 11 seconds West, 96.79 feet (96.73 feet recorded) on the west line of said Lot 38 to the Point of Beginning.

Said parcel herein described contains 0.049 acre, more or less.

This legal description does not represent a boundary survey and is based on a suggested land description provided by the Illinois Department of Transportation.

Issued in Des Plaines, Illinois on July 19, 2002.

**Philip M. Smithmeyer,**

*Manager, Chicago Airports District Office, FAA, Great Lakes Region.*

[FR Doc. 02–20640 Filed 8–13–02; 8:45 am]

**BILLING CODE 4910–13–M**

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

### Notice of Intent To Request Renewal From the Office of Management and Budget (OMB) of Two Current Public Collections of Information

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Notice.

**SUMMARY:** In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 et seq.), the FAA invites public comment on two currently approved public information collections which will be submitted to OMB for renewal.

**DATES:** Comments must be received on or before October 15, 2002.

**ADDRESSES:** Comments may be mailed or delivered to the FAA at the following address. Ms. Judy Street, Room 613, Federal Aviation Administration, Standards and Information Division, APF–100, 800 Independence Ave., SW., Washington, DC 20591.

**FOR FURTHER INFORMATION CONTACT:** Ms. Judy Street at the above address or on (202) 267–9895.

**SUPPLEMENTARY INFORMATION:** In accordance with the Paperwork Reduction Act of 1995, 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. Therefore, the FAA solicits comments on the following current collections of information in order to evaluate the necessity of the collections, the accuracy of the agency's estimate of the burden, the quality, utility, and clarity of the information to be collected, and possible ways to minimize the burden of the collection in preparation for submission to renew the clearances of the following information collections.

1. 2120–0543, Pilots Convicted of Alcohol or Drug-Related Vehicle Offenses or Subject to State Motor Vehicle Administration Procedures. The information requested from airmen is needed to mitigate potential hazards presented by airmen using alcohol or drugs in flight; it is used to identify persons possibly unsuitable for pilot certification; and it affects those pilots who have been or will be convicted of a drug or alcohol-related traffic violation. The current estimated annual reporting burden is 370 hours.

2. 2120–0653, Commercial Air Tour Limitation in the Grand Canyon National Park Special Flight Rules Area. The National Parks Overflights Act mandates that the recommendations provide for ''substantial restoration of the natural quiet and experience of the park and protection of public health and safety from adverse effects associated with aircraft overflight.'' The FAA will use the information to monitor compliance with the regulations. The current estimated annual reporting burden is 466 hours.

Issued in Washington, DC, on August 8, 2002.

**Judith D. Street,**

*FAA Information Collection Clearance Officer, APF–100.*

[FR Doc. 02–20639 Filed 8–13–02; 8:45 am]

**BILLING CODE 4910–13–M**

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

### Four Agency Information Collection Activities Under OMB Review

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Notice.

**SUMMARY:** In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.), this notice announces that the four Information Collection Requests (ICRs) abstracted below have been forwarded to the Office of Management and Budget (OMB) for extension of the currently approved collections. The ICR describes the nature of the information collections

and the expected burden. The **Federal Register** Notice with a 60-day comment period soliciting comments on the following collections of information was published on March 28, 2002.

**DATES:** Comments must be submitted on or before September 13, 2002. A comment to OMB is most effective if OMB receives it within 30 days of publication.

**ADDRESSES:** Send comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street, NW., Washington, DC 20503, Attention FAA Desk Officer.

**FOR FURTHER INFORMATION CONTACT:** Judy Street on (202) 267–9895.

**SUPPLEMENTARY INFORMATION:**

**Federal Aviation Administration (FAA)**

(1) *Title:* Pilot Schools—FAR 141.

*Type of Request:* Extension of a currently approved collection.

*OMB Control Number:* 2120–0009.

*Forms(s):* FAA Form 8420–8.

*Affected Public:* A total of 524 applicants for pilot school certification.

*Abstract:* Chapter 447, Subsection 44707, authorizes certification of civilian schools in instruction in flying. 14 CFR part 141 prescribes requirements for pilot schools certification. The information collected is used for certification and to determine compliance. The respondents are applicants who wish to be issued pilot school certificates and associated ratings.

*Estimated Annual Burden Hours:* An estimated 28,878 hours annually.

(2) *Title:* Rotorcraft External-Load Operator Certificate Application—FAR—133.

*Type of Request:* Extension of a currently approved collection.

*OMB Control Number:* 2120–0044.

*Forms(s):* FAA 8710–4.

*Affected Public:* A total of 400 applicants and rotorcraft operators.

*Abstract:* The information required by part 133 is used by the FAA to process the operating certificate as a record of aircraft authorized for use, and to monitor Rotorcraft External-Load Operations. Part 133 establishes certification and operating rules governing nonpassenger-carrying rotorcraft-external load operations conducted for compensation or hire.

*Estimated Annual Burden Hours:* An estimated 3,268 hours annually.

(3) *Title:* General Aviation/Air Taxi activity and Avionics Survey.

*Type of Request:* Extension of a currently approved collection.

*OMB Control Number:* 2120–0060.

*Forms(s):* FAA Form 1800–54.

*Affected Public:* A total of 30,000 applicants.

*Abstract:* Respondents to this survey are owners of general aviation aircraft. The information is used by the FAA, National Transportation Safety Board, and other government agencies, the aviation industry, and others for safety assessment, planning, forecasting, cost/benefit analysis, and to target areas of research

*Estimated Annual Burden Hours:* An estimated 5,500 hours annually.

(4) *Title:* Aviator Safety Studies.

*Type of Request:* Extension of a currently approved collection.

*OMB Control Number:* 2120–0587.

*Forms(s):* N/A.

*Affected Public:* A total of 3,333 applicants for pilot school certification.

*Abstract:* In order to develop effective intervention programs to improve aviation safety, data are required on the type and range of various pilot attributes related to their skill in making safety-related aeronautical decisions. The information collected is used to develop new training methods particularly suited to general aviation pilots.

*Estimated Annual Burden Hours:* An estimated 28,878 hours annually.

Comments are invited on: Whether the proposed collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; the accuracy of the Department's estimates of the burden of the proposed information collection; ways to enhance the quality, utility and clarity of the information to be collected; and ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

Issued in Washington, DC, on August 2, 2002.

**Judith D. Street,**

*FAA Information Collection Clearance Officer, Standards and Information Division, APF–100.*

[FR Doc. 02–20638 Filed 8–13–02; 8:45 am]

**BILLING CODE 4910–13–M**

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

### RTCA Government/Industry Free Flight Steering Committee Meeting

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Notice of RTCA Government/Industry Free Flight Steering Committee meeting.

**SUMMARY:** The FAA is issuing this notice to advise the public of a meeting of the RTCA Government/Industry Free Flight Steering Committee.

**DATES:** The meeting will be held August 21, 2002, from 1–3:30 p.m.

**ADDRESSES:** The meeting will be held at FAA Headquarters, 800 Independence Avenue, SW., Conference Rooms 5 ABC, Washington, DC 20591.

**FOR FURTHER INFORMATION CONTACT:** RTCA Secretariat, 1828 L Street, NW., Suite 805, Washington, DC 20036; telephone (202) 833–9339; fax (202) 833–9434; Web site *http://www.rtca.org.*

**SUPPLEMENTARY INFORMATION:** Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463, 5 U.S.C., Appendix 2), notice is hereby given for a Free Flight Steering Committee meeting. **NOTE:** *Non-Government attendees to the meeting must go through security and be escorted to and from the conference room.* The agenda will include:

- *August 21:*
  - Opening Session (Welcome and Introductory Remarks, Review/Approve Summary of Previous Meeting)
- Free Flight Select Committee Report
  - National Airspace System Concept of Operations, Revision 1
  - Concept of Equipage/Mandatory vs Voluntary Equipage
  - Recommendations
- Federal Aviation Administration Reports
  - ADS–B Link Decision and Next Steps
  - Operational Evolution Plan
- Closing Session (Other Business, Date and Place of Next Meeting)

Attendance is open to the interested public but limited to space availability. With the approval of the chairmen, members of the public may present oral statements at the meeting. Persons wishing to present statements or obtain information should contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section. Members of the public may present a written statement to the committee at any time.

Issued in Washington, DC, on August 1, 2002.

**Janice L. Peters,**

*FAA Special Assistant, RTCA Advisory Committee.*

[FR Doc. 02–20635 Filed 8–13–02; 8:45 am]

**BILLING CODE 4910–13–M**

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

### RTCA Special Committee 195: Flight Information Services Communications (FISC)

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Notice of RTCA Special Committee 195 meeting.

**SUMMARY:** The FAA is issuing this notice to advise the public of a meeting of RTCA Special Committee 195: Flight Information Services Communications (FISC).

**DATES:** The meeting will be held August 27–28, 2002, starting at 8:30 a.m.

**ADDRESSES:** The meeting will be held at ALPH Headquarters, 535 Herndon Parkway, Herndon, VA.

**FOR FURTHER INFORMATION CONTACT:** RTCA Secretariat, 1828 L Street, NW., Washington, DC 20036; telephone (202) 833–9339; fax (202) 883–9434; Web site *http://www.rtca.org.*

**SUPPLEMENTARY INFORMATION:** Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463, 5 U.S.C., Appendix 2), notice is hereby given for a Special Committee 195 meeting. The agenda will include:

- *August 27*
- Opening Plenary Session (Welcome and Introductory Remarks, Approval of Agenda, Approval of Minutes, Review of Action Items)
- *Working Group 1:* Aircraft Cockpit Weather Display
  - Use of Color Discussion
  - Progress on Change 1 to DO–267, Minimum Aviation System Performance Standards (MASPS) for Flight Information Services-Broadcast (FIS–B) Data Link
- Continue Plenary Session
- Review of Product Registry Guidance Draft Document
- Work on DO–267 Change 1
- *August 28*
- Review of Aerodrome and Airspace Product Specifications
- Review of Proposed Appendix F, Universal Access Transceiver Material
- Working Group 1 Report
- Work on DO–267 Change 1
- Closing Plenary Session (Review Action Items, Discussion of Future Workplan, Other Business, Date and Place of Next Meeting, Adjourn)

Attendance is open to the interested public but limited to space availability. With the approval of the chairmen, members of the public may present oral statements at the meeting. Persons wishing to present statements or obtain information should contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section. Members of the public may present a written statement to the committee at any time.

Dated: Issued in Washington, DC, on August 2, 2002.

**Janice L. Peters,**

*FAA Special Assistant, RTCA Advisory Committee.*

[FR Doc. 02–20636 Filed 8–13–02; 8:45 am]

**BILLING CODE 4910–13–M**

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

### Notice of Passenger Facility Charge (PFC) Approvals and Disapprovals

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Monthly Notice of PFC Approvals and Disapprovals. In May 2002, there were six applications approved. This notice also includes information on one application, approved in April 2002, inadvertently left off the April 2002 notice. Additionally, 21 approved amendments to previously approved applications are listed.

**SUMMARY:** The FAA publishes a monthly notice, as appropriate, of PFC approvals and disapprovals under the provisions of the Aviation Safety and Capacity Expansion Act of 1990 (Title IX of the Omnibus Budget Reconciliation Act of 1990) (Pub. L. 101–508) and Part 158 of the Federal Aviation Regulations (14 CFR part 158). This notice is published pursuant to paragraph d of § 158.29.

**PFC Applications Approved**

*Public Agency:* City and Borough of Juneau, Juneau, Alaska.

*Application Number:* 02–06–C–00–JNU.

*Application Type:* Impose and use a PFC.

*PFC Level:* $4.50.

*Total PFC Revenue Approved in This Decision:* $2,425,779.

*Earliest Charge Effective Date:* July 1, 2002.

*Estimated Charge Expiration Date:* May 1, 2005.

*Class of Air Carriers Not Required To Collect PFC's:* None.

*Brief Description of Projects Approved for Collection and Use:*

Rehabilitate access road.

Terminal expansion feasibility study/design, phase I.

*Brief Description of Projects Approved for Collection:*

Snow removal equipment building.

Runway safety area phase II—mitigation and construction.

Northwest quadrant development.

*Decision Date:* April 30, 2002.

**FOR FURTHER INFORMATION CONTACT:** Debbie Roth, Alaska Region Airports Division, (907) 271–5443.

*Public Agency:* Beaufort County Council, Hilton Head, South Carolina.

*Application Number:* 02–03–U–00–HXD.

*Application Type:* Use PFC revenue.

*PFC Level:* $3.00.

*Total PFC Revenue Approved for Use in This Decision:* $2,076,657.

*Charge Effective Date:* December 1, 2000.

*Estimated Charge Expiration Date:* October 1, 2007.

*Class of Air Carriers Not Required To Collect PFC's:* No change from previous decision.

*Brief Description of Projects Approved for Use:*

Land acquisition (10 acres).

General aviation development.

*Decision Date:* May 3, 2002.

**FOR FURTHER INFORMATION CONTACT:** Aimee McCormick, Atlanta Airports District Office, (404) 305–7153.

*Public Agency:* City of Dayton, Ohio.

*Application Number:* 01–04–C–00–DAY.

*Application Type:* Impose and use a PFC.

*PFC Level:* $4.50.

*Total PFC Revenue Approved in This Decision:* $64,544,267.

*Earliest Charge Effective Date:* July 1, 2003.

*Estimated Charge Expiration Date:* December 1, 2013.

*Class of Air Carriers Not Required To Collect PFC's:* All air taxi/commercial operators.

*Determination:* Approved. Based on information contained in the public agency's application, the FAA has determined that the proposed class accounts for less than 1 percent of the total annual enplanements at Dayton International Airport (DAY).

*Brief Description of Projects Approved for Collection at Day and Use at Day:*

Runway pavement rehabilitation.

Environmental impact study.

Deicing system improvements.

Back-up generator—airfield.

Aircraft rescue and firefighting (ARFF) station renovation and expansion.

Taxiways A and Z rehabilitation.

Taxiways H, K, E, C, L, and V rehabilitation.

Cargo and terminal aircraft apron rehabilitation.

Land acquisition—approach and runway protection.

Airfield snow removal equipment.
ARFF vehicle replacement (Rescue 22).
Back-up generator—terminal.
Terminal gate expansion.
Terminal Drive and related roads rehabilitation.
Southwest terminal apron, northeast deice apron, and perimeter road.
Part 150 noise study, phases 1, 2, and final.
Airport police office renovation.
*Brief Description of Projects Approved for Collection at Day and Use at Dayton-Wright Brothers Airport:*
Land acquisition and approach protection for runway 20.
Runway 2/20 and other pavement rehabilitation.
*Brief Description of Projects Approved in Part for Collection at Day and Use at Day:* Geographical information system (GIS) implementation and computerized airfield lighting and control system (CALCS).
*Determination:* Partially approved. The public agency did not provide enough information to allow the FAA to determine that the GIS is adequately justified in accordance with § 158.15(c) and paragraph 4–8 of FAA Order 5500.1, Passenger Facility Charge (August 9, 2001). Nor could the FAA determine from the information provided by the public agency that the GIS met one of the PFC objectives in accordance with § 158.15(a).
*Decision Date:* May 9, 2002.

**FOR FURTHER INFORMATION CONTACT:** Arlene B. Draper, Detroit Airports District Office, (734) 487–7282.

*Public Agency:* City of Cleveland, Ohio.
*Application Number:* 02–09–U–00–CLE.
*Application Type:* Use PFC revenue.
*PFC Level:* $3.00.
*Total PFC Revenue Approved for Use in This Decision:* $3,410,400.
*Charge Effective Date:* June 1, 1999.
*Estimated Charge Expiration Date:* December 1, 2007.
*Class of Air Carriers Not Required To Collect PFC's:* No change from previous decision.
*Brief Description of Projects Approved for Use:*
Analex office building demolition.
Installation of instrument landing system on runway 6L/24R.
*Decision Date:* May 16, 2002.

**FOR FURTHER INFORMATION CONTACT:** Arlen B. Draper, Detroit Airports District Office, (734) 487–7282.

*Public Agency:* City of Redmond, Oregon.
*Application Number:* 02–04–C–00–RDM.
*Application Type:* Impose and use a PFC.
*PFC Level:* $4.50.
*Total PFC Revenue Approved in This Decision:* $1,968,545.
*Earliest Charge Effective Date:* June 1, 2003.
*Estimated Charge Expiration Date:* April 1, 2006.
*Class of Air Carriers Not Required To Collect PFC's:* Air taxis.
*Determination:* Approved. Based on information contained in the public agency's application, the FAA has determined that the proposed class accounts for less than 1 percent of the total enplanements at Roberts Field.
*Brief Description of Projects Approved for Collection and Use:*
Expand terminal access road.
Conceptual design of terminal expansion.
Install perimeter security fence.
Wildlife mitigation.
Design and rehabilitate air carrier terminal apron.
Rock obstruction removal.
*Decision Date:* May 24, 2002.

**FOR FURTHER INFORMATION CONTACT:** Suzanne Lee-Pang, Seattle Airports District Office, (425) 227–2654.

*Public Agency:* Yakima Air Terminal Board, Yakima, Washington.
*Application Number:* 02–08–C–00–YKM.
*Application Type:* Impose and use a PFC.
*PFC Level:* $34.00.
*Total PFC Revenue Approved in This Decision:* $55,000.
*Earliest Charge Effective Date:* March 1, 2004.
*Estimated Charge Expiration Date:* July 1, 2004.
*Class of Air Carriers Not Required To Collect PFC's:* Air Taxi/commercial operators.
*Determination:* Approved. Based on information contained in the public agency's application, the FAA has determined that the proposed class accounts for less than 1 percent of the total annual enplanements at Yakima Air Terminal—McAllister Field.
*Brief Description of Project Approved for Collection and Use:* 2002 airport security improvement project.
*Decision Date:* May 24, 2002.

**FOR FURTHER INFORMATION CONTACT:** Suzanne Lee-Pang, Seattle Airports District Office, (425) 227–2654.

*Public Agency:* Monterey Peninsula Airport District, Monterey, California.
*Application Number:* 02–08–C–00–MRY.
*Application Type:* Impose and use a PFC.
*PFC Level:* $3.00.
*Total PFC Revenue Approved in This Decision:* $320,122.
*Earliest Charge Effective Date:* August 1, 2002.
*Estimated Charge Expiration Date:* May 1, 2003.
*Class of Air Carriers Not Required To Collect PFC's:* Unscheduled Part 135 Air taxi operators.
*Determination:* Approved. Based on information contained in the public agency's application, the FAA has determined that the proposed class accounts for less than 1 percent of the total annual enplanements at Monterey Peninsula Airport.
*Brief Description of Projects Approved for Collection and Use:*
Airport biological assessment for airport roadway circulation projects.
Improve airport drainage.
Improve airport emergency assess gate.
Residential soundproofing, phase 8.
*Brief Description of Disapproved Project:* Environmental impact report for airport roadway circulation project.
*Determination:* This project is not eligible as a stand-alone document in accordance with FAA Order 5050.4A, Airport Environmental Handbook (October 8, 1985).
*Brief Description of Withdrawn Project:* Airport property map.
*Determination:* This project was withdrawn by the public agency on April 28, 2002.
*Decision Date:* May 30, 2002.

**FOR FURTHER INFORMATION CONTACT:** Marlys Vandervelde, San Francisco Airports District Office, (650) 876–2806.

AMENDMENTS TO PFC APPROVALS

| Amendment No. city, state | Amendment approved date | Original approved net PFC revenue | Amended approved net PFC revenue | Original estimated charge exp. date | Amended estimated charge exp. date |
|---|---|---|---|---|---|
| 97–05–C–01–TYS, Knoxville, TN | 02/12/02 | $1,751,812 | $1,467,737 | 05/01/99 | 05/01/99 |
| [1] 00–05–C–01–SAW, Marquette, MI | 04/04/02 | 369,235 | 335,998 | 11/01/05 | 12/01/02 |
| 95–02–C–05–CVG, Covington, KY | 04/26/02 | 76,095,000 | 75,857,000 | 12/01/98 | 11/01/98 |

AMENDMENTS TO PFC APPROVALS—Continued

| Amendment No. city, state | Amendment approved date | Original approved net PFC revenue | Amended approved net PFC revenue | Original estimated charge exp. date | Amended estimated charge exp. date |
|---|---|---|---|---|---|
| 98–03–C–05–CVG, Covington, KY | 04/26/02 | 24,261,000 | 24,004,000 | 08/01/99 | 09/01/99 |
| 98–04–C–05–CVG, Covington, KY | 04/26/02 | 33,338,000 | 35,198,000 | 07/01/00 | 07/01/00 |
| 99–05–C–04–CVG, Covington, KY | 04/26/02 | 18,620,000 | 18,136,000 | 08/01/01 | 02/01/02 |
| 01–06–C–01–CVG, Covington, KY | 04/26/02 | 21,117,000 | 20,265,000 | 06/01/02 | 10/01/02 |
| 01–07–C–01–CVG, Covington, KY | 04/26/02 | 27,138,000 | 29,046,000 | 06/01/03 | 08/01/03 |
| 93–01–C–05–IAD, Chantilly, VA | 05/01/02 | 225,967,396 | 226,410,192 | 05/01/03 | 05/01/03 |
| 99–02–C–02–APF, Naples, FL | 05/08/02 | 186,606 | 158,948 | 02/01/01 | 02/01/01 |
| 01–03–C–01–APF, Naples, FL | 05/08/02 | 850,000 | 877,658 | 06/01/07 | 04/01/07 |
| 99–01–C–02–ANC, Anchorage, AK | 05/13/02 | 15,000,000 | 15,000,000 | 01/01/04 | 01/01/04 |
| 96–04–C–04–YAK, Yakima, WA | 05/15/02 | 965,075 | 965,075 | 06/01/00 | 06/01/00 |
| 01–03–C–01–FOD, Fort Dodge, IA | 05/21/02 | 284,903 | 290,193 | 04/01/08 | 04/01/08 |
| [1] 92–01–C–03–HLN, Helena, MT | 05/28/02 | 1,877,003 | 1,877,003 | 09/01/04 | 06/01/03 |
| 96–02–U–02–HLN, Helena, MT | 05/28/02 | NA | NA | 09/01/04 | 06/01/03 |
| 93–01–C–03–DCA, Arlington, VA | 05/28/02 | 166,100,974 | 166,739,069 | 02/01/02 | 04/01/02 |
| 94–02–U–03–DCA, Arlington, VA | 05/28/02 | NA | NA | 02/01/02 | 04/01/02 |
| 98–04–C–02–DCA, Arlington, VA | 05/28/02 | 73,203,813 | 73,203,813 | 09/01/06 | 09/01/06 |
| 93–01–C–06–IAD, Chantilly, VA | 05/29/02 | 226,410,194 | 225,967,400 | 05/01/03 | 01/01/04 |
| [1] 01–05–C–01–DFW, Dallas-Fort Worth, TX | 05/31/02 | 1,681,378,893 | 1,681,378,893 | 12/01/13 | 07/01/11 |

**(Note:** The amendments denoted by an asterisk (*) include a change to the PFC level charged from $3.00 per enplaned passenger to $4.50 per enplaned passenger. For Marquette, MI and Dallas, TX, this change is effective on July 1, 2002. For Helena, MT, this change is effective on August 1, 2002.)

Issued in Washington, DC, on August 5, 2002.

**Barry Molar,**

*Manager, Airports Financial Assistance Division.*

[FR Doc. 02–20634 Filed 8–13–02; 8:45 am]

**BILLING CODE 4910–13–My**

## DEPARTMENT OF THE TREASURY

### Submission for OMB Review; Comment Request

August 7, 2002.

The Department of Treasury has submitted the following public information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Copies of the submission(s) may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding this information collection should be addressed to the OMB reviewer listed and to the Treasury Department Clearance Officer, Department of the Treasury, Room 2110, 1425 New York Avenue, NW., Washington, DC 20220.

**DATES:** Written comments should be received on or before September 13, 2002 to be assured of consideration.

**Departmental Offices/International Portfolio Investment Data Systems**

*OMB Number:* 1505–0149.

*Form Number:* None.

*Type of Review:* Extension.

*Title:* Reporting of International Capital and Foreign Currency Transactions and Positions, 31 CFR Part 128.

*Description:* 31 CFR Part 128 establishes general guidelines for report on United States claims on and liabilities to foreigners; on transactions in securities with foreigners; and on monetary reserves of the United States. It also establishes guidelines for reporting on the foreign currency transactions of U.S. persons. It includes a recordkeeping requirement § 128.5.

*Respondents:* Business or other for-profit.

*Estimated Number of Recordkeepers:* 2,000.

*Estimated Burden Hours Per Recordkeeper:* 3 hours.

*Frequency of Response:* On occasion.

*Estimated Total Recordkeeping Burden:* 6,000 hours.

*Clearance Officer:* Lois K. Holland, (202) 622–1563, Departmental Offices, Room 2110, 1425 New York Avenue, NW, Washington, DC 20220.

*OMB Reviewer:* Joseph F. Lackey, Jr., (202) 395–7316, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503.

**Mary A. Able,**

*Departmental Reports, Management Officer.*

[FR Doc. 02–20552 Filed 8–13–02; 8:45 am]

**BILLING CODE 4811–16–P**

## DEPARTMENT OF THE TREASURY

### Submission for OMB Review; Comment Request

August 7, 2002.

The Department of Treasury has submitted the following public information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Copies of the submission(s) may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding this information collection should be addressed to the OMB reviewer listed and to the Treasury Department Clearance Officer, Department of the Treasury, Room 2110, 1425 New York Avenue, NW., Washington, DC 20220.

**DATES:** Written comments should be received on or before September 13, 2002 to be assured of consideration.

**Internal Revenue Service (IRS)**

*OMB Number:* 1545–1004.

*Form Number:* IRS Form 1120–REIT.

*Type of Review:* Revision.

*Title:* U.S. Income Tax Return for Real Estate Investment Trusts.

*Description:* Form 1120–REIT is filed by a corporation, trust, or association electing to be taxed as a REIT in order to report its income, and deductions, and to compute its tax liability. IRS uses Form 1120–REIT to determine whether the REIT has correctly reported its income, deductions, and tax liability.

*Respondents:* Business or other for-profit.

*Estimated Number of Respondents/ Recordkeepers:* 363.

*Estimated Burden Hours Per Respondent/Recordkeeper:*

| | |
|---|---|
| Recordkeeping ..... | 58 hr., 35 min. |
| Learning about the law or the form. | 24 hr., 7 min. |
| Preparing the form .... | 42 hr., 51 min. |
| Copying, assembling, and sending the form to the IRS. | 4 hr., 49 min. |

*Frequency of Response:* Annually.

*Estimated Total Reporting/ Recordkeeping Burden:* 46,490 hours.

*OMB Number:* 1545–1008.

*Form Number:* IRS Form 8582.

*Type of Review:* Revision.

*Title:* Passive Activity Loss Limitation.

*Description:* Under Internal Revenue Code section 469, losses from passive activities, to the extent that they exceed income from passive activities, cannot be deducted against nonpassive income. Form 8582 is used to figure the passive activity loss allowed and the loss to be reported on the tax return.

*Respondents:* Business or other for-profit, Individuals or households, Farms.

*Estimated Number of Respondents/ Recordkeepers:* 3,622,282.

*Estimated Burden Hours Per Respondent/Recordkeeper:*

| | |
|---|---|
| Recordkeeping ..... | 1 hr., 25 min. |
| Learning about the law or the form. | 1 hr., 43 min. |
| Preparing the form .... | 1 hr., 45 min. |
| Copying, assembling, and sending the form to the IRS. | 20 min. |

*Frequency of Response:* Annually.

*Estimated Total Reporting/ Recordkeeping Burden:* 19,355,758 hours.

*Clearance Officer:* Glenn Kirkland, (202) 622–3428, Internal Revenue Service, Room 6411–03, 1111 Constitution Avenue, NW, Washington, DC 20224.

*OMB Reviewer:* Joseph F. Lackey, Jr., (202) 395–7316, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503.

**Mary A. Able,**

*Departmental Reports, Management Officer.*

[FR Doc. 02–20553 Filed 8–13–02; 8:45 am]

**BILLING CODE 4830–01–P**

## DEPARTMENT OF THE TREASURY

### Internal Revenue Service

### Proposed Collection; Comment Request for Form 4361

**AGENCY:** Internal Revenue Service (IRS), Treasury.

**ACTION:** Notice and request for comments.

**SUMMARY:** The Department of the Treasury, 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 proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Form 4361, Application for Exemption From Self-Employment Tax for Use by Ministers. Members of Religious Orders and Christian Science Practitioners.

**DATES:** Written comments should be received on or before October 15, 2002 to be assured of consideration.

**ADDRESSES:** Direct all written comments to Glenn Kirkland, Internal Revenue Service, room 6411, 1111 Constitution Avenue NW., Washington, DC 20224.

**FOR FURTHER INFORMATION CONTACT:** Requests for additional information or copies of the form and instructions should be directed to Larnice Mack, (202) 622–3179, or through the internal (*Larnice.Mack@irs.gov.*), Internal Revenue Service, room 6407, 1111 Constitution Avenue NW., Washington, DC 20224.

**SUPPLEMENTARY INFORMATION:**

*Title:* Application for Exemption From Self-Employment Tax for Use by Ministers, Members of Religious Orders and Christian Science Practitioners.

*OMB Number:* 1545–0168.

*Form Number:* 4361.

*Abstract:* Form 4361 is used by ministers, members of religious orders, or Christian Science practitioners to file for an exemption from self-employment tax on certain earnings and to certify that they have informed the church or order that they are opposed to the acceptance of certain public insurance benefits.

*Current Actions:* There are no changes being made to the Form 4361 at this time.

*Type of Review:* Extension of a current OMB approval.

*Affected Public:* Individuals.

*Estimated Number of Respondents:* 10,270.

*Estimated Time Per Response:* 59 min.

*Estimated Total Annual Burden Hours:* 10,167.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

*Request for Comments:* Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the 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 of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: August 5, 2002.

**Glenn Kirkland,**

*IRS Reports Clearance Officer.*

[FR Doc. 02–20623 Filed 8–13–02; 8:45 am]

**BILLING CODE 4830–01–P**

## DEPARTMENT OF THE TREASURY

### Internal Revenue Service

### Performance Review Board

**AGENCY:** Internal Revenue Service (IRS), Treasury.

**ACTION:** Notice of Members of Senior Executive Service Performance Review Board.

**EFFECTIVE DATE:** October 1, 2002.

**FOR FURTHER INFORMATION CONTACT:** Bernie Doyle, 1111 Constitution Avenue, NW, N:ADC:H:S Room 3513, Washington, DC 20224, (202) 927–6421.

**SUPPLEMENTARY INFORMATION:** As required by Chapter 43, Subchapter II, Section 4314(4) of Title 5, U.S. Code

and Part 430, Subpart C. Section 430.310, the following executives are members of the Internal Revenue Service's Senior Executive Service Performance Review Board (PRB):

Robert E. Wenzel, Deputy Commissioner and Chairperson, Service-wide Performance Review Board
Tyrone B. Ayers, Director, Communications, Assistance, Research, and Education
Leonard Baptiste, Jr., Director, Security and Privacy Oversight
Darlene R. Berthod, Deputy Commissioner, Tax Exempt and Government Entities
Helen H. Bolton, Director, Human Resources Policy and Program
Delena D. Bratton, Deputy Chief/ National Director, Government Liaison and Disclosure
Dennis E. Crawford, Deputy Chief, Criminal Investigation
Richard J. Cronin, Director, Personnel Services
John M. Dalrymple, Commissioner, Wage and Investment
Mary E. Davis, Director, Strategy and Finance
John C. Duder, Deputy Commissioner, Wage and Investment
Fred L. Forman, Associate Commissioner for Business Systems Modernization
Linda M. Garrard, Deputy Chief, Appeals
W. Todd Grams, Chief Financial Officer
Thelma Harris, Director, EEO & Diversity Field Services
Dale F. Hart, Deputy Commissioner, Small Business and Self-Employed
Joseph G. Kehoe, Commissioner, Small Business and Self-Employed
Francis M. Keith Jr., National Director, Communication
Henry O. Lamar Jr., Deputy, National Taxpayer Advocate
Larry R. Langdon, Commissioner, Large and Mid-Size Business
David A. Mader, Assistant Deputy Commissioner
Richard J. Morgante, Director, Management and Finance
Deborah M. Nolan, Deputy Commissioner, Large and Mid-Size Business
Evelyn A. Petschek, Commissioner, Tax Exempt and Government Entities
William E. Porter, Director, Resources Allocation
John C. Reece, Deputy Commissioner Modernization & CIO
John A. Ressler, Director, Customer Account Services
David B. Robison, Chief, Appeals
Johnny C. Rose, Director, Operations Policy and Support
Gregory D. Rothwell, Deputy Chief, Agency-Wide Shared Services
Gerald J. Songy, Director, Taxpayer Education and Communication
Richard Speier Jr., Director of Field Operations, Pacific Area
Ronald Stephen, Director, Real Estate & Facilities
Linda E. Stiff, Director, Compliance
Martha Sullivan, Director, Compliance
Robert C. Turner, National Director, Strategic Planning and Client Services
John R. Watson, Director, Customer Accounts Services
Dan Whitten, Director of Field Operations, Mid-Atlantic Area
Floyd L. Williams III, National Director, Legislative Affairs Division
Toni L. Zimmerman, Deputy Director, Information Technology

This document does not meet the Department of Treasury's criteria for significant regulations.

Dated: July 25, 2002.

**Charles O. Rossotti,**

*Commissioner of Internal Revenue.*

[FR Doc. 02–20622 Filed 8–13–02; 8:45 am]

**BILLING CODE 4830–01–P**

## DEPARTMENT OF VETERANS AFFAIRS

**[OMB Control No. 2900–0067]**

## Proposed Information Collection Activity: Proposed Collection; Comment Request

**AGENCY:** Veterans Benefits Administration, Department of Veterans Affairs.

**ACTION:** Notice.

**SUMMARY:** The Veterans Benefits Administration (VBA), Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of a currently approved collection for which approval has expired and allow 60 days for public comment in response to the notice. This notice solicits comments on the information needed to determine a claimant eligibility for automobile allowance and adaptive equipment.

**DATES:** Written comments and recommendations on the proposed collection of information should be received on or before October 15, 2002.

**ADDRESSES:** Submit written comments on the collection of information to Nancy J. Kessinger, Veterans Benefits Administration (20S52), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420 or e-mail: *irmnkess@vba.va.gov.* Please refer to ''OMB Control No. 2900–0067'' in any correspondence.

**FOR FURTHER INFORMATION CONTACT:** Nancy J. Kessinger at (202) 273–7079 or FAX (202) 275–5947.

**SUPPLEMENTARY INFORMATION:** Under the PRA of 1995 (Pub. L. 104–13; 44 U.S.C., 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to Section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VBA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of VBA's functions, including whether the information will have practical utility; (2) the accuracy of VBA's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology.

*Title:* Application for Automobile or other Conveyance and Adaptive Equipment (under 38 U.S.C. 3901–3904), VA Form 21–4502.

*OMB Control Number:* 2900–0067.

*Type of Review:* Extension of a currently approved collection.

*Abstract:* VA Form 21–4502 is used to gather the necessary information to determine a veteran's entitlement to automobile allowance and adaptive equipment.

*Affected Public:* Individuals and households.

*Estimated Annual Burden:* 375.

*Estimated Average Burden Per Respondent:* 15 minutes.

*Frequency of Response:* On occasion.

*Estimated Number of Respondents:* 1,500.

Dated: July 31, 200.

By direction of the Secretary:

**Ernesto Castro,**

*Director, Records Management Service.*

[FR Doc. 02–20573 Filed 8–13–02; 8:45 am]

**BILLING CODE 8320–01–P**

## DEPARTMENT OF VETERANS AFFAIRS

**[OMB Control No. 2900–0005]**

### Proposed Information Collection Activity: Proposed Collection; Comment Request

**AGENCY:** Veterans Benefits Administration, Department of Veterans Affairs.

**ACTION:** Notice.

**SUMMARY:** The Veterans Benefits Administration (VBA), Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of a currently approved collection, and allow 60 days for public comment in response to the notice. This notice solicits comments for information needed to determine a parent's eligibility for the death benefit sought subsequent to a veteran's death.

**DATES:** Written comments and recommendations on the proposed collection of information should be received on or before October 15, 2002.

**ADDRESSES:** Submit written comments on the collection of information to Nancy J. Kessinger, Veterans Benefits Administration (20S52), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420 or e-mail: *irmnkess@vba.va.gov.* Please refer to ''OMB Control No. 2900–0005'' in any correspondence.

**FOR FURTHER INFORMATION CONTACT:** Nancy J. Kessinger at (202) 273–7079 or FAX (202) 275–5947.

**SUPPLEMENTARY INFORMATION:** Under the PRA of 1995 (Pub. L. 104–13; 44 U.S.C., 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to Section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VBA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of VBA's functions, including whether the information will have practical utility; (2) the accuracy of VBA's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology.

*Title:* Application for Dependency and Indemnity Compensation by Parent(s), (Including Accrued Benefits and Death Compensation, When Applicable), VA Form 21–535.

*OMB Control Number:* 2900–0005.

*Type of Review:* Extension of a currently approved collection.

*Abstract:* VA Form 21–535 is completed by a surviving parent or parents of a deceased veteran to file for benefits subsequent to the veteran's death. VA uses the information to determine a parent's eligibility, dependency and income, as applicable, for the death benefits.

*Affected Public:* Individuals or households.

*Estimated Annual Burden:* 25,056 hours.

*Estimated Average Burden Per Respondent:* 1 hour 12 minutes.

*Frequency of Response:* On occasion.

*Estimated Number of Respondents:* 20,880.

Dated: July 31, 2002.

By direction of the Secretary:

**Ernesto Castro,**

*Director, Records Management Service.*

[FR Doc. 02–20574 Filed 8–13–02; 8:45 am]

**BILLING CODE 8320–01–P**

## DEPARTMENT OF VETERANS AFFAIRS

**[OMB Control No. 2900–0381]**

### Proposed Information Collection Activity: Proposed Collection; Comment Request

**AGENCY:** Veterans Benefits Administration, Department of Veterans Affairs.

**ACTION:** Notice.

**SUMMARY:** The Veterans Benefits Administration (VBA), Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of a currently approved collection, and allow 60 days for public comment in response to the notice. This notice solicits comments for information needed to determine the holder's election to convey and transfer foreclosed property to VA.

**DATES:** Written comments and recommendations on the proposed collection of information should be received on or before October 15, 2002.

**ADDRESSES:** Submit written comments on the collection of information to Nancy J. Kessinger, Veterans Benefits Administration (20S52), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420 or e-mail: *irmnkess@vba.va.gov.* Please refer to ''OMB Control No. 2900–0381'' in any correspondence.

**FOR FURTHER INFORMATION CONTACT:** Nancy J. Kessinger at (202) 273–7079 or FAX (202) 275–5947.

**SUPPLEMENTARY INFORMATION:** Under the PRA of 1995 (Pub. L. 104–13; 44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to Section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VBA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of VBA's functions, including whether the information will have practical utility; (2) the accuracy of VBA's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology.

*Title:* Notice for Election to Convey and/or Invoice for Transfer of Property, VA Form 26–8903.

*OMB Control Number:* 2900–0381.

*Type of Review:* Extension of a currently approved collection.

*Abstract:* VA Form 26–8903 serves four purposes: holder's election to convey, invoice for the purchase price of the property, VA's voucher for authorizing payment to the holder, and establishment of VA's property records. When VA specifies an amount in relation to the foreclosure of a GI home loan and the holder elects to convey the property to VA, Section 3732 of Title 38, U.S.C., and 38 CFR 36.4320(a)(1), provide that if a minimum amount for credit to the borrower's indebtedness has been specified by VA in relation to the sale of the real property and the holder is the successful bidder at the sale for no more than the amount

specified by VA, the holder will credit the indebtedness with that amount. The holder may then retain the property, or not later than 15 days after the date of sale, advise VA of its election to convey and transfer the property to the VA. VA needs to know the amount bid at the sale, the type of deed to be used for transferring title from the holder to VA, occupancy information, and the hazard insurance coverage.

*Affected Public:* Business or other for-profit.

*Estimated Annual Burden:* 4,167 hours.

*Estimated Average Burden Per Respondent:* 10 minutes.

*Frequency of Response:* On occasion.

*Estimated Number of Respondents:* 25,000.

Dated: July 31, 2002.

By direction of the Secretary:

**Ernesto Castro,**

*Director, Records Management Service.*

[FR Doc. 02–20575 Filed 8–13–02; 8:45 am]

**BILLING CODE 8320–01–P**

## DEPARTMENT OF VETERANS AFFAIRS

**[OMB Control No. 2900–NEW]**

### Proposed Information Collection Activity: Proposed Collection; Comment Request

**AGENCY:** Veterans Benefits Administration, Department of Veterans Affairs.

**ACTION:** Notice.

**SUMMARY:** The Veterans Benefits Administration (VBA), Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed new collection, and allow 60 days for public comment in response to the notice. This notice solicits comments on information needed by VA to determine the process used by medical examiners and coroners to identify unclaimed persons as veterans.

**DATES:** Written comments and recommendations on the proposed collection of information should be received on or before October 15, 2002.

**ADDRESSES:** Submit written comments on the collection of information to Nancy J. Kessinger, Veterans Benefits Administration (20S52), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420 or e-mail: *irmnkess@vba.va.gov.* Please refer to ''OMB Control No. 2900–NEW'' in any correspondence.

**FOR FURTHER INFORMATION CONTACT:** Nancy J. Kessinger at (202) 273–7079 or FAX (202) 275–5947.

**SUPPLEMENTARY INFORMATION:** Under the PRA of 1995 (Public Law 104–13; 44 U.S.C., 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to Section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VBA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of VBA's functions, including whether the information will have practical utility; (2) the accuracy of VBA's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology.

*Title:* Questionnaire For Coroners and Medical Examiners, VA Form 21–0766.

*OMB Control Number:* 2900–NEW.

*Type of Review:* New collection.

*Abstract:* VA Form 21–0766 is used by medical examiners and coroners to help identify unclaimed decedents as veterans who are entitled to burial benefits. The information collected is needed to determine how often medical examiners and coroners attempt to verify veteran status, how long records of decedents are maintained and who the medical examiners and coroners contact to verify veteran status.

*Affected Public:* Business or other for-profit.

*Estimated Annual Burden:* 525 hours.

*Estimated Average Burden Per Respondent:* 10 minutes.

*Frequency of Response:* On occasion.

*Estimated Number of Respondents:* 3,158.

Dated: July 31, 2002.

By direction of the Secretary:

**Ernesto Castro,**

*Director, Records Management Service.*

[FR Doc. 02–20576 Filed 8–13–02; 8:45 am]

**BILLING CODE 8320–01–P**

## DEPARTMENT OF VETERANS AFFAIRS

**[OMB Control No. 2900–NEW (Pension and Parents DIC Participants)]**

### Agency Information Collection Activities Under OMB Review

**AGENCY:** Office of Policy and Planning, Department of Veterans Affairs.

**ACTION:** Notice.

**SUMMARY:** In compliance with the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C., 3501 *et seq.*), this notice announces that the Office of Policy and Planning (OPPA), Department of Veterans Affairs, has submitted the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden; it includes the actual data collection instrument.

**DATES:** Comments must be submitted on or before September 13, 2002.

**FOR FURTHER INFORMATION OR A COPY OF THE SUBMISSION CONTACT:** Denise McLamb, Information Management Service (045A4), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420, (202) 273–8030 or FAX (202) 273–5981 or e-mail: *denise.mclamb@mail.va.gov.* Please refer to ''OMB Control No. 2900–NEW (Pension and Parents DIC Participants)''.

Send comments and recommendations concerning any aspect of the information collection to VA's Desk Officer, OMB Human Resources and Housing Branch, New Executive Office Building, Room 10235, Washington, DC 20503 (202) 395–7316. Please refer to ''OMB Control No. 2900–NEW (Pension and Parents DIC Participants)''.

**SUPPLEMENTARY INFORMATION:**

*Title:* Survey of Department of Veterans Affairs Pension and Parents DIC Participants.

*OMB Control Number:* 2900–New.

*Type of Review:* New collection.

*Abstract:* The purpose of this evaluation is to assess the effectiveness and efficiency of the VA Pension and Parents DIC programs. These are needs-based programs that provide benefits to wartime veterans who are permanently and totally disabled due to non-service-connected causes, surviving spouses of deceased wartime veterans, and needy parents of veterans whose deaths were service-connected.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB

control number. The **Federal Register** Notice with a 60-day comment period soliciting comments on this collection of information was published on June 4, 2002, at pages 38547–38548.

*Affected Public:* Individuals or households.

*Estimated Time Per Respondent and Annual Burden:* 2,871 hours.

a. Veterans @ 45 minutes per response = 981.75 hours.

b. Spouses @ 45 minutes per response = 978 hours.

c. Parents @ 45 minutes per response = 911.25 hours.

*Frequency of Response:* One-time.

*Estimated Number of Respondents:* 3,828.

a. Veterans—1,309.

b. Spouses—1,304.

c. Parents—1,215.

Dated: August 6, 2002.

By direction of the Secretary:

**Ernesto Castro,**

*Director, Records Management Service.*

[FR Doc. 02–20571 Filed 8–13–02; 8:45 am]

**BILLING CODE 8320–01–P**

## DEPARTMENT OF VETERANS AFFAIRS

**[OMB Control No. 2900–0368]**

### Agency Information Collection Activities Under OMB Review

**AGENCY:** Veterans Benefits Administration, Department of Veterans Affairs.

**ACTION:** Notice.

**SUMMARY:** In compliance with the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C., 3501 et seq.), this notice announces that the Veterans Benefits Administration (VBA), Department of Veterans Affairs, has submitted the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden; it includes the actual data collection instrument.

**DATES:** Comments must be submitted on or before September 13, 2002.

**FOR FURTHER INFORMATION OR A COPY OF THE SUBMISSION CONTACT:** Denise McLamb, Information Management Service (045A4), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420, (202) 273–8030, FAX (202) 273–5981 or e-mail: *denise.mclamb@mail.va.gov.* Please refer to ''OMB Control No. 2900–0368.''

Send comments and recommendations concerning any aspect of the information collection to VA's OMB Desk Officer, OMB Human Resources and Housing Branch, New Executive Office Building, Room 10235, Washington, DC 20503 (202) 395–7316. Please refer to ''OMB Control No. 2900–0368'' in any correspondence.

**SUPPLEMENTARY INFORMATION:**

*Title:* Monthly Statement of Wages Paid to Trainee VA (Chapter 31, Title 38, U.S.C.), VA Form 28–1917.

*OMB Control Number:* 2900–0368.

*Type of Review:* Extension of a currently approved collection.

*Abstract:* VA Form 28–1917 is used by employers providing on-job or apprenticeship training to veterans to report each veteran's wages during the preceding month. VA uses the information to determine whether the veteran is receiving the appropriate wage increase and to ensure the veteran is receiving the correct rate of subsistence allowance.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The **Federal Register** Notice with a 60-day comment period soliciting comments on this collection of information was published on June 6, 2002, at page 39099–39100.

*Affected Public:* Business or other for-profit, Individuals or households, Not-for-profit institutions.

*Estimated Annual Burden:* 1,800 hours.

*Estimated Average Burden Per Respondent:* 30 minutes.

*Frequency of Response:* Monthly.

*Estimated Number of Respondents:* 300.

*Estimated Total Annual Responses:* 3,600.

Dated: July 31, 2002.

By direction of the Secretary:

**Ernesto Castro,**

*Director, Records Management Service.*

[FR Doc. 02–20572 Filed 8–13–02; 8:45 am]

**BILLING CODE 8320–01–P**

## DEPARTMENT OF VETERANS AFFAIRS

### Professional Certification and Licensure Advisory Committee; Notice of Meeting

The Department of Veterans Affairs (VA) gives notice under Pub. L. 92–463 (Federal Advisory Committee Act) that the Professional Certification and Licensure Advisory Committee will meet at the Department of Veterans Affairs, Veterans Benefits Administration Education Conference Room 601V, 1800 G St., NW., Washington, DC, on Wednesday, September 4, 2002, from 8:30 a.m. to 4 p.m., and from 8 a.m. to 12 p.m. on Thursday, September 5, 2002. The purpose of the Committee is to review the requirements of organizations or entities offering licensing and certification tests to individuals for which payment for such tests may be made under chapters 30, 32, 34, or 35 of Title 38, United States Code.

On September 4, the meeting will begin with opening remarks and an overview by Ms. Sandra Winborne, Committee Chair. During the morning session, the Committee will receive presentations on the National Association of State Approving Agencies Conference and the Professional Certification Advisory Board Meeting. The afternoon session will include discussion of the VA responses to previous Committee recommendations. On September 5, the Committee will discuss what the Committee's direction should be for the coming year.

Those planning to attend the open meeting should contact Mr. Giles Larrabee or Mr. Michael Yunker at (202) 273–7187. Interested persons may attend, appear before, or file statements with the Committee. Statements, if in written form, may be filed before the meeting, or within 10 days after the meeting. Oral statements will be heard at 9 a.m. Thursday, September 5, 2002.

Dated: August 7, 2002.

By Direction of the Secretary.

**Nora E. Egan,**

*Committee Management Officer.*

[FR Doc. 02–20570 Filed 8–13–02; 8:45 am]

**BILLING CODE 8320–01–M**

# Corrections

**Federal Register**

Vol. 67, No. 157

Wednesday, August 14, 2002

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 TRANSPORTATION

### Federal Motor Carrier Safety Administration

### 49 CFR Part 393

**[Docket No. FMCSA–99–6266]**

**RIN 2126–AA46**

### Brake Performance Requirements for Commercial Motor Vehicles Inspected by Performance-Based Brake Testers

*Correction*

In rule document 02–20248 beginning on page 51770 in the issue of Friday, August 9, 2002, make the following correction:

On page 51770, in the second column, under the **DATES** section, in the second line, ''February 5, 2002'' should read ''February 5, 2003''.

[FR Doc. C2–20248 Filed 8–13–02; 8:45 am]

BILLING CODE 1505–01–D


Federal Register

**Wednesday,**
**August 14, 2002**

## Part II

# Environmental Protection Agency

**40 CFR Parts 86, 90, 1045, 1051 and 1068**
**Control of Emissions From Spark-Ignition Marine Vessels and Highway Motorcycles; Proposed Rule**

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Parts 86, 90, 1045, 1051, and 1068**

**[AMS–FRL–7253–8]**

**RIN 2060–AJ90**

## Control of Emissions From Spark-Ignition Marine Vessels and Highway Motorcycles

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** In this action, we are proposing evaporative emissions standards for marine vessels that use spark-ignition engines (including sterndrive, inboard, and outboard engines and personal watercraft) and we discuss our plans to propose standards in the future regulating exhaust emissions from spark-ignition marine engines. This action also proposes new emission standards for highway motorcycles, including motorcycles of less than 50 cubic centimeters in displacement. This action is related to our proposal for emission standards for several sources that cause or contribute to air pollution. On October 5, 2001 we published proposed standards for large spark-ignition engines such as those used in forklifts and airport tugs; recreational vehicles using spark-ignition engines such as off-highway motorcycles, all-terrain vehicles, and snowmobiles; and recreational marine diesel engines.

Nationwide, marine evaporative hydrocarbon (HC) emissions contribute to ozone, and motorcycles contribute to ozone, carbon monoxide (CO), and particulate matter (PM) nonattainment. These pollutants cause a range of adverse health effects, especially in terms of respiratory impairment and related illnesses. The proposed standards would help states achieve and maintain air quality standards. In addition, the proposed evaporative emission standards would help reduce acute exposure air toxics and the proposed motorcycle exhaust standards would help reduce exposure to CO, air toxics, and PM for operators and other people close to emission sources. They would also help address other environmental problems, such as visibility impairment in our national parks.

We believe that manufacturers would be able to maintain or even improve the performance of their products in certain respects when producing engines and vessels meeting the proposed standards. In fact, we estimate that the evaporative emission standards would reduce fuel consumption by enough to offset any costs associated with the evaporative emission control technology. Overall, the gasoline fuel savings associated with the anticipated changes in technology resulting from the rule proposed in this notice are estimated to be about 31 million gallons per year once the program is fully phased in (2030). The proposal also has several provisions to address the unique limitations of small-volume manufacturers.

**DATES:** *Comments:* Send written comments on this proposal by November 8, 2002. See Section VII for more information about written comments.

*Hearings:* We will hold a public hearing on September 17, 2002 starting at 9:30 a.m. EDT. This hearing will focus on issues related to highway motorcycles. In addition, we will hold a public hearing on September 23, 2002 starting at 9:30 a.m. EDT. This hearing will focus on issues related to marine vessels. If you want to testify at a hearing, notify the contact person listed below at least ten days before the hearing. See Section VII for more information about public hearings.

**ADDRESSES:** *Comments:* You may send written comments in paper form or by e-mail. We must receive them by November 8, 2002. Send paper copies of written comments (in duplicate if possible) to the contact person listed below. You may also submit comments via e-mail to ''MCNPRM@epa.gov.'' In your correspondence, refer to Docket A–2000–02.

*Hearings:* We will hold a public hearing for issues related to highway motorcycles on September 17 at the Ypsilanti Marriott at Eagle Crest, Ypsilanti, Michigan (734–487–2000).

We will host a public hearing for issues related to marine vessels on September 23 at the National Vehicle and Fuel Emission Laboratory, 2000 Traverwood Dr., Ann Arbor, Michigan (734–214–4334). See Section VII, ''Public Participation'' below for more information on the comment procedure and public hearings.

*Docket:* EPA's Air Docket makes materials related to this rulemaking available for review in Public Docket Nos. A–2000–01 and A–2000–02 at the following address: U.S. Environmental Protection Agency (EPA), Air Docket (6102), Room M–1500 (on the ground floor in Waterside Mall), 401 M Street, SW., Washington, DC 20460 between 8 a.m. to 5:30 p.m., Monday through Friday, except on government holidays. You can reach the Air Docket by telephone at (202) 260–7548, and by facsimile (202) 260–4400. We may charge a reasonable fee for copying docket materials, as provided in 40 CFR part 2.

**FOR FURTHER INFORMATION CONTACT:** Margaret Borushko, U.S. EPA, National Vehicle and Fuels Emission Laboratory, 2000 Traverwood, Ann Arbor, MI 48105; Telephone (734) 214–4334; FAX: (734) 214–4816; E-mail: *borushko.margaret@epa.gov.*

**SUPPLEMENTARY INFORMATION:**

### Regulated Entities

This proposed action would affect companies that manufacture or introduce into commerce any of the engines or vehicles that would be subject to the proposed standards. These include: Marine vessels with spark-ignition engines and highway motorcycles. This proposed action would also affect companies buying engines for installation in vessels and motorcycles. There are also proposed requirements that apply to those who rebuild any of the affected engines. Regulated categories and entities include:

| Category | NAICS codes [a] | SIC codes [b] | Examples of potentially regulated entities |
|---|---|---|---|
| Industry | ..... | 3732 | Manufacturers of marine vessels. |
| Industry | 811310 | 7699 | Engine repair and maintenance. |
| Industry | 336991 | ..... | Motorcycles and motorcycle parts manufacturers. |
| Industry | 421110 | ..... | Independent Commercial Importers of Vehicles and Parts. |

[a] North American Industry Classification System (NAICS).
[b] Standard Industrial Classification (SIC) system code.

This list is not intended to be exhaustive, but rather provides a guide regarding entities likely to be regulated by this action. To determine whether particular activities may be regulated by this action, you should carefully

examine the proposed regulations. You may direct questions regarding the applicability of this action to the person listed in **FOR FURTHER INFORMATION CONTACT**.

### Obtaining Electronic Copies of the Regulatory Documents

The preamble, regulatory language, Draft Regulatory Support Document, and other rule documents are also available electronically from the EPA Internet Web site. This service is free of charge, except for any cost incurred for internet connectivity. The electronic version of this proposed rule is made available on the day of publication on the primary Web site listed below. The EPA Office of Transportation and Air Quality also publishes official **Federal Register** notices and related documents on the secondary Web site listed below.

1. *http://www.epa.gov/docs/fedrgstr/EPA–AIR/* (either select desired date or use Search feature)
2. *http://www.epa.gov/otaq/* (look in What's New or under the specific rulemaking topic)

Please note that due to differences between the software used to develop the documents and the software into which the document may be downloaded, format changes may occur.

**Table of Contents**



## I. Introduction

### *A. Overview*

Air pollution is a serious threat to the health and well-being of millions of Americans and imposes a large burden on the U.S. economy. Ground-level ozone, carbon monoxide, and particulate matter are linked to potentially serious respiratory health problems, especially respiratory effects and environmental degradation, including visibility impairment in our precious national parks. Over the past quarter century, state and federal representatives have established emission-control programs that significantly reduce emissions from individual sources. Many of these sources now pollute at only a small fraction of their pre-control rates. This proposal is part of a new effort that further addresses these air-pollution concerns by proposing national standards regulating emissions from several types of nonroad engines and vehicles that are currently unregulated by establishing standards for nonroad engines and vehicles, as required by Clean Air Act section 213(a)(3). The first part of this effort was a proposal published on October 5, 2001 which included industrial spark-ignition engines such as those used in forklifts and airport tugs; recreational vehicles such as off-highway motorcycles, all-terrain vehicles, and snowmobiles; and recreational marine diesel engines.[1]

This action, the second part, includes evaporative emission standards for marine vessels with spark-ignition engines and their fuel systems.[2] In addition, we are proposing new emission standards for highway motorcycles. The proposed standards for motorcycles reflect the development of emission-control technology that has occurred since we last set standards for these engines in 1978. Including highway motorcycles in this proposal is also appropriate as we consider new emission standards for the counterpart off-highway motorcycle models.

Nationwide, the sources covered by this proposal are significant contributors to mobile-source air pollution. Marine evaporative emissions currently account for 1.3 percent of mobile-source hydrocarbon (HC) emissions, and highway motorcycles currently account for about 1.1 percent of mobile-source HC emissions, 0.4 percent of mobile-source carbon monoxide (CO) emissions, 0.1 percent of mobile-source oxides of nitrogen ($NO_X$) emissions, and 0.1 percent of mobile-source particulate matter (PM) emissions.[3] The proposed standards would reduce exposure to these emissions and help avoid a range of adverse health effects associated with ambient ozone and PM levels, especially in terms of respiratory impairment and related illnesses. In addition, the proposed standards would help reduce acute exposure air toxics and PM for persons who operate or who work with or are otherwise active in close proximity to these sources. They would also help address other environmental problems associated with these sources, such as visibility impairment in our national parks and other wilderness areas where recreational vehicles and marine vessels are often used.

This proposal follows EPA's Advance Notice of Proposed Rulmaking (ANRPM) published on December 7, 2000 (65 FR 76797). In that Advance Notice, we provided an initial overview of possible regulatory strategies for nonroad vehicles and engines and invited early input to the process of developing standards. We received comments on the Advance Notice from a wide variety of stakeholders, including the engine industry, the equipment industry, various governmental bodies, environmental groups, and the general public. These comments are available for public viewing in Docket A–2000–01. The Advance Notice, the related comments, and other new information provide the framework for this proposal.

[1] See 66 FR 51098.

[2] Diesel-cycle engines, referred to simply as ''diesel engines'' in this document, may also be referred to as compression-ignition (or CI) engines. These engines typically operate on diesel fuel, but other fuels may also be used. Otto-cycle engines (referred to here as spark-ignition or SI engines) typically operate on gasoline, liquefied petroleum gas, or natural gas.

[3] While we characterize emissions of hydrocarbons, this can be used as a surrogate for volatile organic compounds (VOC), which is broader group of compounds.

*B. How Is This Document Organized?*

This proposal covers both marine vessels and highway motorcycles and many readers may only be interested in one or the other of theses applications. We have attempted to organize the document in a way that allows each reader to focus on the application of particular interest. The Air Quality discussion in Section II is general in nature, however, and applies to the proposal as a whole.

The next three sections contain our proposal for the marine vessels and highway motorcycles that are the subject of this action. Section III presents the proposed evaporative emission program for marine vessels using spark-ignition engines. Section IV discusses our intentions for controlling exhaust emissions from spark-ignition marine engines in the future. Section V contains our proposed highway motorcycle standards.

Section VI summarizes the projected impacts and a discussion of the benefits of this proposal. Finally, Sections VII and VIII contain information about public participation, how we satisfied our administrative requirements, and the statutory provisions and legal authority for this proposal.

The remainder of this Section I summarizes important background information about this proposal, including the engines covered, the proposed standards, and why we are proposing them.

*C. What Categories of Vessels and Vehicles Are Covered in This Proposal?*

1. Which Marine Vessels Are Covered in This Proposal?

We are proposing evaporative emission requirements for marine vessels that use any kind of spark ignition (SI) engine, including boats using sterndrive, inboard, and outboard engines and personal watercraft. These vessels are currently unregulated for evaporative emissions. Although we are not proposing exhaust emission standards for SI marine, we discuss our intent for a future emission control program.

This proposal covers new vessels that are used in the United States, whether they are made domestically or imported.[4] A more detailed discussion of the meaning of the terms ''new,'' ''imported,'' as well as other terms that help define the scope of application of this proposal, is contained in Section III.B of this preamble.

2. Which Highway Vehicles Are Covered in This Proposal?

We are proposing standards for new highway motorcycles, including those with engines with displacements of less than 50 cubic centimeters (cc). The federal emission standards for highway motorcycles were established over twenty years ago. Technology has advanced significantly over the last two decades, and many advancements are currently being used on highway motorcycles in California and elsewhere in the world. Despite these advancements, highway motorcycles currently produce more harmful emissions per mile than driving a car, or even a large SUV. (This discrepancy will become even larger when the Tier 2 emissions standards for passenger cars and SUVs take effect starting in 2004, when SUVs will have to meet the same set of standards as passenger cars.) Present technology already in use on highway motorcycles can be applied easily and cost-effectively to achieve additional improvements in emissions. California, which has separately regulated motorcycles, recently adopted more advanced emissions standards in several stages. New emission standards and test procedures have also been proposed or finalized internationally. Proposing more stringent standards nationwide will reduce emissions from these engines, which operate predominantly in warmer weather when ozone formation is a greater concern. In addition, we believe it is important to consider the emissions standards for highway motorcycles in the context of setting standards for off-highway motorcycles. Some degree of consistency between the standards for these related products may allow manufacturers to transfer technologies across product lines. (At the same time, we recognize that there are other factors which may argue for treating these categories differently.)

*D. What Requirements Are We Proposing?*

Clean Air Act section 213 directs EPA to establish standards which achieve the greatest degree of emission reductions from nonroad engines and vehicles achievable through the application of technology that will be available, giving appropriate consideration to cost, noise, energy, and safety factors. Other requirements such as certification procedures, engine and vehicle labeling, and warranty requirements are necessary for implementing the proposed program in an effective way.

For vessels that use spark-ignition marine engines, we are proposing emission standards, beginning in 2008, that would reduce evaporative hydrocarbon emissions by more than 80 percent. To meet these standards, manufacturers would need to design and produce fuel systems that prevent gasoline vapors from escaping. While we are not proposing exhaust emission standards for spark-ignition marine engines at this time, we are participating with California and industry representatives in a technology development program that is evaluating the feasibility of using catalyst controls on these engines. We considered setting emission standards for sterndrive and inboard marine engines in this rulemaking, but have decided not to pursue these standards at this time. We instead intend to propose exhaust emission standards for these engines after the results of this development program are available. We also intend at that time to review, and if appropriate, propose to update emission standards for outboard and personal watercraft engines based on the results of the ongoing catalyst test program.

With respect to highway motorcycles, section 202(a)(3)(E) of the Clean Air Act states, in part: ''In any case in which such standards are promulgated for such emissions from motorcycles as a separate class or category, the Administrator, in promulgating such standards, shall consider the need to achieve equivalency of emission reductions between motorcycles and other motor vehicles to the maximum extent practicable.'' Given that it has been more than twenty years since the first (and only) federal emission regulations for motorcycles were implemented, we believe it is consistent with the Act to set new standards for highway motorcycles. Thus, for highway motorcycles we are proposing to harmonize with the California program, but with some additional flexibilities. This is a two-phase program that would result in reductions of $HC+NO_X$ of about 50 percent when fully phased in.

*E. Why Is EPA Taking This Action?*

There are important public health and welfare reasons supporting the standards proposed in this document. As described in Section II, these sources contribute to air pollution which causes public health and welfare problems. Emissions from these engines contribute to ground level ozone and ambient CO and PM levels. Exposure to ground level ozone, CO, and PM can cause serious respiratory problems. These emissions also contribute to other serious

[4] For this proposal, we consider the United States to include the States, the District of Columbia, the Commonwealth of Puerto Rico, the Commonwealth of the Northern Mariana Islands, Guam, American Samoa, the U.S. Virgin Islands, and the Trust Territory of the Pacific Islands.

environmental problems, including visibility impairment.

*F. Putting This Proposal Into Perspective*

This proposal should be considered in the broader context of EPA's nonroad and highway vehicle emission-control programs; state-level programs, particularly in California; and international efforts. Each of these are described in more detail below.

1. EPA's Emission-Control Programs

a. EPA's nonroad process. Clean Air Act section 213(a)(1) directs us to study emissions from nonroad engines and vehicles to determine, among other things, whether these emissions ''cause, or significantly contribute to, air pollution that may reasonably be anticipated to endanger public health or welfare.'' Section 213(a)(2) further required us to determine whether emissions of CO, VOC, and $NO_X$ from all nonroad engines significantly contribute to ozone or CO emissions in more than one nonattainment area. If we determine that emissions from all nonroad engines were significant contributors, section 213(a)(3) then requires us to establish emission standards for classes or categories of new nonroad engines and vehicles that in our judgment cause or contribute to such pollution. We may also set emission standards under section 213(a)(4) regulating any other emissions from nonroad engines that we find contribute significantly to air pollution.

We completed the Nonroad Engine and Vehicle Emission Study, required by Clean Air Act section 213(a)(1), in November 1991.[5] On June 17, 1994, we made an affirmative determination under section 213(a)(2) that nonroad emissions are significant contributors to ozone or CO in more than one nonattainment area. We also determined that these engines make a significant contribution to PM and smoke emissions that may reasonably be anticipated to endanger public health or welfare. In the same document, we set a first phase of emission standards (now referred to as Tier 1 standards) for land-based nonroad diesel engines rated at or above 37 kW. We recently added a more stringent set of Tier 2 and Tier 3 emission levels for new land-based nonroad diesel engines at or above 37 kW and adopted Tier 1 standards for land-based nonroad diesel engines less than 37 kW. Our other emission-control programs for nonroad engines are listed in Table I.F–1. This proposal takes another step toward the comprehensive nonroad engine emission-control strategy envisioned in the Act by proposing an emission-control program for the remaining unregulated nonroad engines.

TABLE I.F–1.—EPA'S NONROAD EMISSION-CONTROL PROGRAMS

| Engine category | Final rule | Date |
|---|---|---|
| Land-based diesel engines ≥ 37 kW—Tier 1 | 56 FR 31306 | June 17, 1994. |
| Spark-ignition engines ≤19 kW—Phase 1 | 60 FR 34581 | July 3, 1995. |
| Spark-ignition marine | 61 FR 52088 | October 4, 1996. |
| Locomotives | 63 FR 18978 | April 16, 1998. |
| Land-based diesel engines—Tier 1 and Tier 2 for engines < 37 kW—Tier 2 and Tier 3 for engines ≥ 37 kW. | 63 FR 56968 | October 23, 1998. |
| Commercial marine diesel | 64 FR 73300 | December 29, 1999. |
| Spark-ignition engines ≤19 kW (Non-handheld)—Phase 2 | 64 FR 15208 | March 30, 1999. |
| Spark-ignition engines ≤19 kW (Handheld)—Phase 2 | 65 FR 24268 | April 25, 2000. |

b. National standards for marine engines. In the October 1996 final rule for spark-ignition marine engines, we set standards only for outboard and personal watercraft engines. We decided not to finalize emission standards for sterndrive or inboard marine engines at that time. Uncontrolled emission levels from sterndrive and inboard marine engines were already significantly lower than the outboard and personal watercraft engines. We did, however, leave open the possibility of revisiting the need for emission standards for sterndrive and inboard engines in the future.

c. National standards for highway motorcycles. National standards for highway motorcycles were first established in the 1978 model year. Interim standards were effective for the 1978 and 1979 model years, and final standards took effect with the 1980 model year. These standards remain in effect today, unchanged from more than two decades ago. These standards, which have resulted in the phase-out of two-stroke engines for highway motorcycles above 50cc displacement, achieved significant reductions in emissions. The level of technology required to meet these standards is widely considered to be comparable to the pre-catalyst technology in the automobile. However, for the past two decades, other agencies in Europe, Asia, and California have caused motorcycle emission controls to keep some pace with the available technology. It is clear that the impact of the current federal standards on technology was fully realized by the mid-1980's, and that the international and other efforts have been the recent driving factor in technology development for motorcycle emissions control.

2. State Initiatives

Under Clean Air Act section 209, California has the authority to regulate emissions from new motor vehicles and new motor vehicle engines. California may also regulate emissions from nonroad engines, with the exception of new engines used in locomotives and new engines used in farm and construction equipment rated under 130 kW.[6] So far, the California Air Resources Board (California ARB) has adopted requirements for four groups of nonroad engines: (1) Diesel- and Otto-cycle small off-road engines rated under 19 kW; (2) new land-based nonroad diesel engines rated over 130 kW; (3) land-based nonroad recreational engines, including all-terrain vehicles, off-highway motorcycles, go-carts, and other similar vehicles; and (4) new nonroad SI engines rated over 19 kW. They have approved a voluntary registration and control program for existing portable equipment.

Other states may adopt emission standards set by California ARB, but are otherwise preempted from setting

[5] This study is avaialble in docket A–92–28.

[6] The Clean Air Act limits the role states may play in regulating emissions from new motor vehicles and nonroad engines. California is permitted to establish emission standards for new motor vehicles and most nonroad engines; other states may adopt California's programs (sections 209 and 177 of the Act). The Act specifies the power rating minimum in terms of horsepower for farm and construction equipment (175 hp = 130 kW).

emission standards for new engines or vehicles. In contrast, there is generally no federal preemption of state initiatives related to the way individuals use individual engines or vehicles.

a. SI Marine engines. California ARB developed exhaust emission standards for SI marine engines through two rulemakings. In 1998, they adopted standards for outboards and personal watercraft that have three stages. Beginning with the 2001 model year, manufacturers must meet the 2006 EPA national averaging standard for engines sold in California. In addition, they require two more phases in 2004 and 2008 which reduce the standards an additional 20 and 60 percent, respectively, beyond the EPA standards.

Last year, California ARB also adopted exhaust emission standards for sterndrive and inboard marine engines. These standards cap HC+$NO_X$ emissions at 15 g/kW-hr beginning in 2003. In 2007, 45 percent of each manufacturer's product line must meet 5 g/kW-hr HC+$NO_X$. This production fraction becomes 75 percent in 2008 and 100 percent in 2009. Manufacturers will likely need to use catalytic converters to meet this standard.

As part of the emission-control program for sterndrive and inboard marine engines, California ARB has committed to performing a review of emission-control technology in conjunction with the industry, U.S. Coast Guard, and EPA. They intend to hold a technology review in 2003, and if necessary, hold another technology review in 2005. The technology review will focus on applying catalytic control to marine engines operating in boats on the water. EPA is working with these groups to continue to assess technical concerns related to introducing catalysts on these marine engines.

b. Highway motorcycles. Motorcycle emission standards in California were originally identical to the federal standards. However, California ARB has revised their standards several times to bring them to their current levels. In the 1982 model year the standards were modified to tighten the HC standard from 5.0 g/km to 1.0 or 1.4 g/km, depending upon engine displacement. California adopted an evaporative emission standard of 2.0 g/test for 1983 and later model year motorcycles, and later amended the regulations for 1988 and later model year motorcycles, resulting in standards of 1.0 g/km HC for engines under 700cc and 1.4 g/km HC for 700cc and larger engines.

In 1999 California ARB finalized new standards for Class III highway motorcycles that will take effect in two phases—''Tier 1'' standards starting with the 2004 model year, followed by ''Tier 2''standards starting with the 2008 model year. The Tier 1 standard is 1.4 g/km HC+$NO_X$, and the Tier 2 standard is 0.8 g/km HC+$NO_X$. The CO standard remains at 12.0 g/km.

3. Actions in Other Countries

a. European action—Recreational Marine Engines. The European Commission has proposed emission standards for recreational marine engines, including both diesel and gasoline engines. These requirements would apply to all new engines sold in member countries. The numerical emission standards for SD/I marine engines, are shown in Table I.F–2. Table I.F–2 also presents average baseline emissions based on data that we have collected. These data are presented in Chapter 4 of the Draft Regulatory Support Document. We have received comment that we should apply these standards in the U.S., but the proposed European emission standards for SD/I marine engines may not result in a decrease in emissions, and based on emissions information we now have, would in some cases allow an increase in emissions from current designs of engines operated in the U.S.

TABLE I.F–2.—PROPOSED EUROPEAN EMISSION STANDARDS FOR FOUR-STROKE SPARK-IGNITION MARINE ENGINES

| Pollutant | Emission standard (g/kW-hr) | Baseline emissions (g/kW–hr) |
|---|---|---|
| $NO_X$ | 15.0 | 9.7 |
| HC | [a]7.2 | 5.8 |
| CO | [a]154 | 141 |

[a] For a 150 kW engine; decreases slightly with increasing engine power rating.

b. Highway motorcycles. Under the auspices of the United Nations/Economic Commission for Europe (UN/ECE) there is an ongoing effort to develop a global harmonized world motorcycle test cycle (WMTC). The objective of this work is to develop a scientifically supported test cycle that accurately represents the in-use driving characteristics of motorcycles. The United States is also a participating member of UN/ECE. This is an ongoing process that EPA is actively participating in, but that will not likely result in an action until sometime in 2003 or 2004. If an international test procedure is agreed upon by the participating nations, we plan to initiate a rulemaking process to propose adopting the global test cycle as part of the U.S. regulations.

The European Union (EU) recently finalized a new phase of motorcycle standards, which will start in 2003, and are considering a second phase to start in 2006. The 2003 European standards are more stringent than the existing Federal standards, being somewhat comparable to the California Tier 1 standards taking effect in 2004. The standards being considered for 2006, along with a revised test cycle (as an interim cycle to bridge between the current EU cycle and a possible WMTC cycle in the future) are likely to be proposed soon by the EU. As of April 2002 the 2006 European standards and test cycle are being considered and debated by the European Parliament and the European Commission.

Many other nations, particularly in southeast Asia where low-displacement two-stroke motorcycles are ubiquitous, have established standards that could be considered quite stringent. Taiwan, in particular, is often noted for having some of the most stringent standards in the world, but India, China, Japan, and Thailand, are moving quickly towards controlling what is, in those nations, a significant contributor to air pollution problems.

4. Recently Proposed EPA Standards for Nonroad Engines

This proposal is the second part of an effort to control emissions from nonroad engines that are currently unregulated and for updating Federal emissions standards for highway motorcycles. The first part of this effort was a proposal published on October 5, 2001 for emission control from large spark-ignition engines such as those used in forklifts and airport tugs; recreational

vehicles using spark-ignition engines such as off-highway motorcycles, all-terrain vehicles, and snowmobiles; and recreational marine diesel engines. The October 5, 2001 proposal includes general provisions in proposed 40 CFR part 1068 that address the applicability of nonroad engine standards, which could be relevant to commenters.

With regard to Large SI engines, we proposed a two-phase program. The first phase of the standards, to go into effect in 2004, are the same as those recently adopted by the California Air Resources Board. In 2007, we propose to supplement these standards by setting limits that would require optimizing the same technologies but would be based on a transient test cycle. New requirements for evaporative emissions and engine diagnostics would also start in 2007.

For recreational vehicles, we proposed emission standards for snowmobiles separately from off-highway motorcycles and all-terrain vehicles. For snowmobiles, we proposed a first phase of standards for HC and CO emissions based on the use of clean carburetion or 2-stroke electronic fuel injection (EFI) technology, and a second phase of emission standards for snowmobiles that would involve use of direct fuel injection 2-stroke and some 4-stroke technology. For off highway motorcycles and all-terrain vehicles, we proposed standards based mainly on moving these engines from 2-stroke to 4-stroke technology. In addition, we proposed a second phase of standards for all-terrain vehicles that could require some catalyst use.

For marine diesel engines, we proposed to extend our commercial marine diesel engine standards to diesel engines used on recreational vessels. These standards would phase in beginning in 2006.

## II. Public Health and Welfare Effects of Emissions From Covered Engines

### *A. Background*

This proposal contains regulatory strategies to control evaporative emissions from marine vessels that use spark ignition engines. Spark-ignition marine vessels include vessels that use sterndrive and inboard engines as well as outboards and personal watercraft. Most of these vessels are recreational, but there are some commercial vessels that use spark-ignition engines as well. The standards we are proposing in this document for marine vessels may require changes to the fuel system or fuel tank. We are also proposing revised standards for highway motorcycles. The current HC and CO emission standards for highway motorcycles were set in 1978 and are based on 1970s technology. The proposed standards are harmonized to California's emission limits, but also include new requirements for under 50 cc motorcycles.

Nationwide, marine vessels and on-highway motorcycles are an important source of mobile-source air pollution (see section II–C). We determined that marine vessels that use spark-ignition engines cause or contribute to ozone and carbon monoxide pollution in more than on nonattainment area in an action dated February 7, 1996 (61 FR 4600). These engines continue to contribute to these problems because they are primarily used in warm weather and therefore their HC, $NO_X$, CO, and PM emissions contribute to ozone formation and ambient PM and CO levels, and because they are primarily used in marinas and commercial ports that are frequently located in nonattainment areas such as Chicago and New York. Evaporative emissions from marine vessels are also significant for similar reasons and because the emissions occur all the time rather than just when the engine is running. Similarly, on-highway motorcycles are typically used in warm, dry weather when their HC and $NO_X$ emissions are most likely to form ozone, thus adding to ground-level ozone levels and contributing to ozone nonattainment.

We expect that implementation of the proposed standards would result in about a 50 percent reduction in HC emissions and $NO_X$ emissions from highway motorcycles in 2020. We expect that the proposed standards would result in about a 56 percent reduction in evaporative HC emissions from marine vessels using spark-ignition engines in 2020 (see Section VI below for more details). These emission reductions would reduce ambient concentrations of ozone, and fine particles, which is a health concern and contributes to visibility impairment. The standards would also reduce personal exposure for people who operate or who work with or are otherwise in close proximity to these engines and vehicles. As summarized below and described more fully in the Draft Regulatory Support Document for this proposal, many types of hydrocarbons are air toxics. By reducing these emissions, the proposed standards would provide assistance to states facing ozone air quality problems, which can cause a range of adverse health effects, especially in terms of respiratory impairment and related illnesses. States are required to develop plans to address visibility impairment in national parks, and the reductions proposed in this rule would assist states in those efforts.

### *B. What Are the Public Health and Welfare Effects Associated With Emissions From Nonroad Engines and Motorcycles Subject to the Proposed Standards?*

Marine vessels that use spark-ignition engines and highway motorcycles generate emissions that contribute to ozone formation and ambient levels of PM, and air toxics. This section summarizes the general health effects of these pollutants. National inventory estimates are set out in Section II.C, and estimates of the expected impact of the proposed control programs are described in Section VI. Interested readers are encouraged to refer to the Draft Regulatory Support Document for this proposal for more in-depth discussions.

#### 1. Health and Welfare Effects Associated with Ground Level Ozone and its Precursors

Volatile organic compounds (VOC) and $NO_X$ are precursors in the photochemical reaction which forms tropospheric ozone. Ground-level ozone, the main ingredient in smog, is formed by complex chemical reactions of VOCs and $NO_X$ in the presence of heat and sunlight. Hydrocarbons (HC) are a large subset of VOC, and to reduce mobile-source VOC levels we set maximum emissions limits for hydrocarbon and particulate matter emissions.

A large body of evidence shows that ozone can cause harmful respiratory effects including chest pain, coughing, and shortness of breath, which affect people with compromised respiratory systems most severely. When inhaled, ozone can cause acute respiratory problems; aggravate asthma; cause significant temporary decreases in lung function of 15 to over 20 percent in some healthy adults; cause inflammation of lung tissue; produce changes in lung tissue and structure; may increase hospital admissions and emergency room visits; and impair the body's immune system defenses, making people more susceptible to respiratory illnesses. Children and outdoor workers are likely to be exposed to elevated ambient levels of ozone during exercise and, therefore, are at a greater risk of experiencing adverse health effects. Beyond its human health effects, ozone has been shown to injure plants, which has the effect of reducing crop yields and reducing productivity in forest ecosystems.

There is strong and convincing evidence that exposure to ozone is associated with exacerbation of asthma-related symptoms. Increases in ozone concentrations in the air have been associated with increases in hospitalization for respiratory causes for individuals with asthma, worsening of symptoms, decrements in lung function, and increased medication use, and chronic exposure may cause permanent lung damage. The risk of suffering these effects is particularly high for children and for people with compromised respiratory systems.

Ground level ozone today remains a pervasive pollution problem in the United States. In 1999, 90.8 million people (1990 census) lived in 31 areas designated nonattainment under the 1-hour ozone NAAQS.[7] This sharp decline from the 101 nonattainment areas originally identified under the Clean Air Act Amendments of 1990 demonstrates the effectiveness of the last decade's worth of emission-control programs. However, elevated ozone concentrations remain a serious public health concern throughout the nation.

Over the last decade, declines in ozone levels were found mostly in urban areas, where emissions are heavily influenced by controls on mobile sources and their fuels. Twenty-three metropolitan areas have realized a decline in ozone levels since 1989, but at the same time ozone levels in 11 metropolitan areas with 7 million people have increased.[8] Regionally, California and the Northeast have recorded significant reductions in peak ozone levels, while four other regions (the Mid-Atlantic, the Southeast, the Central and Pacific Northwest) have seen ozone levels increase.

The highest ambient concentrations are currently found in suburban areas, consistent with downwind transport of emissions from urban centers. Concentrations in rural areas have risen to the levels previously found only in cities. Particularly relevant to this proposal, ozone levels at 17 of our National Parks have increased, and in 1998, ozone levels in two parks, Shenandoah National Park and the Great Smoky Mountains National Park, were 30 to 40 percent higher than the ozone NAAQS over part of the last decade.[9]

To estimate future ozone levels, we refer to the modeling performed in conjunction with the final rule for our most recent heavy-duty highway engine and fuel standards.[10] We performed ozone air quality modeling for the entire Eastern U.S. covering metropolitan areas from Texas to the Northeast.[11] This ozone air quality model was based upon the same modeling system as was used in the Tier 2 air quality analysis, with the addition of updated inventory estimates for 2007 and 2030. The results of this modeling were examined for those 37 areas in the East for which EPA's modeling predicted exceedances in 2007, 2020, and/or 2030 and the current 1-hour design values are above the standard or within 10 percent of the standard. This photochemical ozone modeling for 2020 predicts exceedances of the 1-hour ozone standard in 32 areas with a total of 89 million people (1999 census) after accounting for light- and heavy-duty on-highway control programs.[12] We expect the $NO_X$ and HC control strategies contained in this proposal for marine vessels that use spark-ignition engines and highway motorcycles will further assist state efforts already underway to attain and maintain the 1-hour ozone standard.

In addition to the health effects described above, there exists a large body of scientific literature that shows that harmful effects can occur from sustained levels of ozone exposure much lower than 0.125 ppm.[13] Studies of prolonged exposures, those lasting about 7 hours, show health effects from prolonged and repeated exposures at moderate levels of exertion to ozone concentrations as low as 0.08 ppm. The health effects at these levels of exposure include transient pulmonary function responses, transient respiratory symptoms, effects on exercise performance, increased airway responsiveness, increased susceptibility to respiratory infection, increased hospital and emergency room visits, and transient pulmonary respiratory inflammation.

Prolonged and repeated ozone concentrations at these levels are common in areas throughout the country, and are found both in areas that are exceeding, and areas that are not exceeding, the 1-hour ozone standard. Areas with these high concentrations are more widespread than those in nonattainment for that 1-hour ozone standard. Monitoring data indicates that 334 counties in 33 states exceeded these levels in 1997–99.[14] The Agency's most recent photochemical ozone modeling forecast that 111 million people are predicted to live in areas that are at risk of exceeding these moderate ozone levels for prolonged periods of time in 2020 after accounting for expected inventory reductions due to controls on light- and heavy-duty on-highway vehicles.[15]

### 2. Health and Welfare Effects Associated With Particulate Matter

Highway motorcycles contribute to ambient particulate matter through direct emissions of particulate matter in the exhaust. Both marine vessels and highway motorcycles contribute to indirect formation of PM through their emissions of organic carbon, especially HC. Organic carbon accounts for between 27 and 36 percent of fine particle mass depending on the area of the country.

[7] National Air Quality and Emissions Trends Report, 1999, EPA, 2001, at Table A–19. This document is available at *http://www.epa.gov/oar/aqtrnd99/*. The data from the Trends report are the most recent EPA air quality data that have been quality assured. A copy of this table can also be found in Docket No. A–2000–01, Document No. II–A–64.

[8] National Air Quality and Emissions Trends Report, 1998, March, 2000, at 28. This document is available at *http://www.epa.gov/oar/aqtrnd98/*. The data from the Trends report are the most recent EPA air quality data that have been quality assured. A copy of this table can also be found in Docket No. A–2000–01, Document No. II–A.–63.

[9] National Air Quality and Emissions Trends Report, 1998, March, 2000, at 32. This document is available at *http://www.epa.gov/oar/aqtrnd98/*. The data from the trends report are the most recent EPA air quality data that have been quality assured. A copy of this table can also be found in Docket No. A–2000–01, Document No. II–A–63.

[10] Additional information about this modeling can be found in our Regulatory Impact Analysis: Heavy-Duty Engine and Vehicle Standards and Highway Diesel Fuel Sulfur Contro Requirements, document EPA420–R–00–026, December 2000. This document is available at *http://www.epa.gov/otaq/diesel.htm#documents* and in Docket No. 1–2000–01, Document No. II–A–13.

[11] We also performed ozone air quality modeling for the western United States but, as described further in the air quality technical support document, model predictions were well below corresponding ambient concentrations for out heavy-duty engine standards and fuel sulfur control rulemaking. Because of poor model performance for this region of the country, the results of the Western ozone modeling were not relied on for that rule.

[12] Regulatory Impact Analysis: Heavy-Duty Engine and Vehicle Standards and Highway Diesel Fuel Sulfur Control Requirements, US EPA, EPA420–R–00–026, December 2000, at II–14, Table II.A–2. Docket No. A–2000–01, Document Number II–A–13. This document is also available at *http://www.epa.gpa.gov/otaq/diesel/htm#documents.*

[13] Additional information about theses studies can be found in Chapter 2 of ''Regulatory Impact Analysis: Heavy-Duty Engine and Vehicle Standards and Highway Diesel Fuel Sulfur Control Requirements,'' December 2000, EPA420–R–00–026. Docket No. A–2000–01, Document Number II–A–13. This document is also available at *http://www.epa.gov/otaq/diesel.htm#documents.*

[14] A copy of this data can be found in Air Docket A–2000–01, Document No. II–A–80.

[15] Memorandum to Docket A–99–06 from Eric Ginsburg, EPA, ''Summary of Model-Adjusted Ambient Concentrations for Certain Levels of Ground-Level Ozone over Prolonger Periods,'' November 22, 2000, at Table C, Control Scenario—2020 Populations In Eastern Metropolitan Counties with Predicted Daily 8-Hour Ozone greater than or equal to 0.080 ppm. Docket A–2000–01, Document Number II–B–13.

Particulate matter represents a broad class of chemically and physically diverse substances. It can be principally characterized as discrete particles that exist in the condensed (liquid or solid) phase spanning several orders of magnitude in size. All particles equal to and less than 10 microns are called $PM_{10}$. Fine particles can be generally defined as those particles with an aerodynamic diameter of 2.5 microns or less (also known as $PM_{2.5}$), and coarse fraction particles are those particles with an aerodynamic diameter greater than 2.5 microns, but equal to or less than a nominal 10 microns.

Particulate matter, like ozone, has been linked to a range of serious respiratory health problems. Scientific studies suggest a likely causal role of ambient particulate matter (which is attributable to several of sources including mobile sources) in contributing to a series of health effects. The key health effects categories associated with ambient particulate matter include premature mortality, aggravation of respiratory and cardiovascular disease (as indicated by increased hospital admissions and emergency room visits, school absences, work loss days, and restricted activity days), aggravated asthma, acute respiratory symptoms, including aggravated coughing and difficult or painful breathing, chronic bronchitis, and decreased lung function that can be experienced as shortness of breath. Observable human noncancer health effects associated with exposure to diesel PM include some of the same health effects reported for ambient PM such as respiratory symptoms (cough, labored breathing, chest tightness, wheezing), and chronic respiratory disease (cough, phlegm, chronic bronchitis and suggestive evidence for decreases in pulmonary function). Symptoms of immunological effects such as wheezing and increased allergenicity are also seen. Epidemiology studies have found an association between exposure to fine particles and such health effects as premature mortality or hospital admissions for cardiopulmonary disease.

PM also causes adverse impacts to the environment. Fine PM is the major cause of reduced visibility in parts of the United States, including many of our national parks. Other environmental impacts occur when particles deposit onto soils, plants, water or materials. For example, particles containing nitrogen and sulphur that deposit on to land or water bodies may change the nutrient balance and acidity of those environments. Finally, PM causes soiling and erosion damage to materials, including culturally important objects such as carved monuments and statues. It promotes and accelerates the corrosion of metals, degrades paints, and deteriorates building materials such as concrete and limestone.

The NAAQS for $PM_{10}$ were established in 1987. The most recent $PM_{10}$ monitoring data indicate that 14 designated $PM_{10}$ nonattainment areas with a projected population of 23 million violated the $PM_{10}$ NAAQS in the period 1997–99. In addition, there are 25 unclassifiable areas that have recently recorded ambient concentrations of $PM_{10}$ above the $PM_{10}$ NAAQS.[16]

Current 1999 $PM_{2.5}$ monitored values, which cover about a third of the nation's counties, indicate that at least 40 million people live in areas where long-term ambient fine particulate matter levels are at or above 16 $\mu g/m^3$ (37 percent of the population in the areas with monitors).[17] According to our national modeled predictions, there were a total of 76 million people (1996 population) living in areas with modeled annual average $PM_{2.5}$ concentrations at or above 16 $\mu g/m^3$ (29 percent of the population).[18] This 16 $\mu g/m^3$ threshold is the low end of the range of long term average $PM_{2.5}$ concentrations in cities where statistically significant associations were found with serious health effects, including premature mortality.[19]

We expect the PM reductions that result from control strategies contained in this proposal will further assist state efforts already underway to attain and maintain the PM NAAQS.

3. Health Effects Associated with Air Toxics

In addition to the human health and welfare impacts described above, emissions from the engines covered by this proposal also contain several Mobile Source Air Toxics, including benzene, 1,3-butadiene, formaldehyde, acetaldehyde, and acrolein.[20] The health effects of these air toxics are described in more detail in Chapter 1 of the Draft Regulatory Support Document for this rule. Additional information can also be found in the Technical Support Document for our final Mobile Source Air Toxics rule.[21] The hydrocarbon controls contained in this proposal are expected to reduce exposure to air toxics and therefore may help reduce the impact of these engines on cancer and noncancer health effects.

### *C. What Is the Inventory Contribution of These Sources?*

The spark-ignition marine vessels and highway motorcycles that would be subject to the proposed standards contribute to the national inventories of pollutants that are associated with the health and public welfare effects described in Section II.B. To estimate nonroad engine and vehicle emission contributions, we used the latest version of our NONROAD emissions model. This model computes nationwide, state, and county emission levels for a wide variety of nonroad engines, and uses information on emission rates, operating data, and population to determine annual emission levels of various pollutants. Emission estimates for highway motorcycles were developed using information on the certification levels of current motorcycles and updated information on motorcycle use provided by the motorcycle industry. A more detailed description of the modeling and our estimation methodology can be found in the

[16] EPA adopted a policy in 1996 that allows areas with $PM_{10}$ exceedances that are attributable to natural events to retain their designation as unclassifiable if the State is taking all reasonable measures to safeguard public health regardless of the sources of $PM_{10}$ emissions.

[17] Memorandum to Docket A–99–06 from Eric O. Ginsburg, Senior Program Advisor, ''Summary of 1999 Ambient Concentrations of Fine Particulate Matter,'' November 15, 2000. Air Docket A–2000–01, Docket No. II–B–12. For information regarding estimates for future $PM_{2.5}$ levels, See information about the Regulatory Model System for Aerosols and Deposition (REMSAD) and our modeling protocols, which can be found in the Regulatory Impact Analysis: Heavy-Duty Engine and Vehicle Standards and Highway Diesel Fuel Sulfur Controls Requirements, document EPA 420–R–00–026, December 2000. Docket No. A–2000–01, Document No. A–II–13. This document is also available at *http://www.epa.gov/otaq/diesel.htm#documents.* Also see Technical Memorandum, EPA Air Docket A–99–06, Eric O. Ginsburg, Senior Program Advisor, Emissions Monitoring and Analysis Division, OAQPs, Summary of Absolute Modeled and Model-Adjusted Estimates of Fine Particulate Matter for Selected Years, December 6, 2000, Table P–2. Docket Number 2000–01, Document Number II–B–14.

[18] Memorandum to Docket A–99–06 from Eric O. Ginsburg, Senior Program Advisor, ''Summary of Absolute Modeled and Model-Adjusted Estimates of Fine Particulate Matter for Selected Years,'' December 6, 2000. Air Docket A–2000–01, Docket No. II–B–14.

[19] EPA (1996) Review of the National Ambient Air Quality Standards for Particulate Matter: Policy Assessment of Scientific and Technical Information OAQPS Staff Paper. EPA–452/R–96–013. Docket Number A–99–06, Documents Nos. II–A–18, 19, 20, and 23. The particulate matter air quality criteria documents are also available at *http://www.epa.gov/ncea/partmatt.htm.*

[20] EPA recently finalized a list of 21 Mobile Source Air Toxics, including VOCS, metals, and diesel particulate matter and diesel exhaust organic gases (collectively DPM+DEOG). 66 FR 17230, March 29, 2001.

[21] See our Mobile Source Air Toxics final rulemaking, 66 FR 17230, March 29, 2001, and the Technical Support Document for that rulemaking. Docket No. A–2000–01, Documents Nos. II–A–42 and II–A–30.

Chapter 6 of the Draft Regulatory Support Document.

Baseline emission inventory estimates for the year 2000 for the marine vessels and highway motorcycles covered by this proposal are summarized in Table II.C–1. This table shows the relative contributions of the different mobile-source categories to the overall national mobile-source inventory. Of the total emissions from mobile sources, evaporative emissions from spark-ignition marine vessels contribute about 1.3 percent of HC. Highway motorcycles contribute about 1.1 percent, 0.1 percent, 0.4 percent, and 0.1 percent of HC, $NO_X$, CO, and PM emissions, respectively, in the year 2000.

Our draft emission projections for 2020 for the spark-ignition marine vessels and highway motorcycles that would be subject to the proposed standards show that emissions from these categories are expected to increase over time if left uncontrolled. The projections for 2020 are summarized in Table II.C–2 and indicate that the evaporative emissions from marine vessel are expected to contribute 1.8 percent of mobile source HC, and motorcycles are expected to contribute 2.3 percent, 0.2 percent, 0.6 percent, and 0.1 percent of mobile source HC, $NO_X$, CO, and PM emissions in the year 2020. Population growth and the effects of other regulatory control programs are factored into these projections.

TABLE II.C–1.—MODELED ANNUAL EMISSION LEVELS FOR MOBILE-SOURCE CATEGORIES IN 2000

[Thousand short tons]

| Category | $NO_X$ | | HC | | CO | | PM | |
|---|---|---|---|---|---|---|---|---|
| | Tons | Percent of mobile source | Tons | Percent of mobile source | Tons | Percent of mobile source | Tons | Percent of mobile source |
| Highway Motorcycles | 8 | 0.1 | 35 | 0.5 | 331 | 0.4 | 0.4 | 0.1 |
| Marine SI Evaporative | 0 | 0.0 | 108 | 1.3 | 0 | 0.0 | 0 | 0.0 |
| Marine SI Exhaust | 32 | 0.2 | 708 | 9.6 | 2,144 | 2.8 | 38 | 5.4 |
| Nonroad Industrial SI > 19 kW | 306 | 2.3 | 247 | 3.2 | 2,294 | 3.0 | 1.6 | 0.2 |
| Recreational SI | 13 | 0.1 | 737 | 9.6 | 2,572 | 3.3 | 5.7 | 0.8 |
| Recreation Marine CI | 24 | 0.2 | 1 | 0.0 | 4 | 0.0 | 1 | 0.1 |
| Nonroad SI < 19 kW | 106 | 0.8 | 1,460 | 19.1 | 18,359 | 23.6 | 50 | 7.2 |
| Nonroad CI | 2,625 | 19.5 | 316 | 4.1 | 1,217 | 1.6 | 253 | 36.2 |
| Commercial Marine CI | 977 | 7.3 | 30 | 0.4 | 129 | 0.2 | 41 | 5.9 |
| Locomotive | 1,192 | 8.9 | 47 | 0.6 | 119 | 0.2 | 30 | 4.3 |
| Total Nonroad | 5,275 | 39 | 3,646 | 48 | 26,838 | 35 | 420 | 60 |
| Total Highway | 7,981 | 59 | 3,811 | 50 | 49,813 | 64 | 240 | 34 |
| Aircraft | 178 | 1 | 183 | 2 | 1,017 | 1 | 39 | 6 |
| Total Mobile Sources | 13,434 | 100 | 7,640 | 100 | 77,668 | 100 | 699 | 100 |
| Total Man-Made Sources | 24,538 | ..... | 18,586 | ..... | 99,747 | ..... | 3,095 | ..... |
| Mobile Source percent of Total Man-Made Sources | 55% | ..... | 41% | ..... | 78% | ..... | 23% | ..... |

TABLE II.C–2.—MODELED ANNUAL EMISSION LEVELS FOR MOBILE-SOURCE CATEGORIES IN 2020

[Thousand short tons]

| Category | $NO_X$ | | HC | | CO | | PM | |
|---|---|---|---|---|---|---|---|---|
| | Tons | Percent of mobile source | Tons | Percent of mobile source | Tons | Percent of mobile source | Tons | Percent of mobile source |
| Highway Motorcycles | 14 | 0.2 | 58 | 0.9 | 572 | 0.6 | 0.8 | 0.1 |
| Marine SI Evaporative | 0 | 0.0 | 114 | 1.8 | 0 | 0.0 | 0 | 0.0 |
| Marine SI Exhaust | 58 | 0.9 | 284 | 4.6 | 1,985 | 2.2 | 28 | 4.4 |
| Nonroad Industrial SI > 19 kW | 486 | 7.8 | 348 | 5.6 | 2,991 | 3.3 | 2.4 | 0.4 |
| Recreational SI | 27 | 0.4 | 1,706 | 27.7 | 5,407 | 3.3 | 7.5 | 1.2 |

TABLE II.C–2.—MODELED ANNUAL EMISSION LEVELS FOR MOBILE-SOURCE CATEGORIES IN 2020—Continued

[Thousand short tons]

| Category | $NO_X$ | | HC | | CO | | PM | |
|---|---|---|---|---|---|---|---|---|
| | Tons | Percent of mobile source | Tons | Percent of mobile source | Tons | Percent of mobile source | Tons | Percent of mobile source |
| Recreation Marine CI | 39 | 0.6 | 1 | 0.0 | 6 | 0.0 | 1.5 | 0.2 |
| Nonroad SI < 19 kW | 106 | 1.7 | 986 | 16.0 | 27,352 | 30.5 | 77 | 12.2 |
| Nonroad CI | 1,791 | 28.8 | 142 | 2.3 | 1,462 | 1.6 | 261 | 41.3 |
| Commercial Marine CI | 819 | 13.2 | 35 | 0.6 | 160 | 0.2 | 46 | 7.3 |
| Locomotive | 611 | 9.8 | 35 | 0.6 | 119 | 0.1 | 21 | 3.3 |
| Total Nonroad | 3,937 | 63 | 3,651 | 59 | 39,482 | 44 | 444 | 70 |
| Total Highway | 2,050 | 33 | 2,276 | 37 | 48,906 | 54 | 145 | 23 |
| Aircraft | 232 | 4 | 238 | 4 | 1,387 | 2 | 43 | 7 |
| Total Mobile Sources | 6,219 | 100 | 6,165 | 100 | 89,775 | 100 | 632 | 100 |
| Total Man-Made Sources | 16,195 | | 16,234 | | 113,443 | | 3,016 | |
| Mobile Source percent of Total Man-Made Sources | 38% | | 38% | | 79% | | 21% | |

## III. Evaporative Emission Control From Boats

### *A. Overview*

Evaporative emissions refer to hydrocarbons released into the atmosphere when gasoline, or other volatile fuels, evaporate from a fuel system. These emissions come from four primary mechanisms: hot soak, diurnal heating, vapor displacement during refueling, and permeation from tanks and hoses. Hot soak emissions occur when fuel evaporates from hot engine surfaces such as parts of the carburetor as a result of engine operation. These are minimal on fuel-injected engines. Control of hot soak emissions involves the engine manufacturer rather than the tank manufacturer.

Currently, most fuel tanks in boats are vented to atmosphere through vent hoses. Diurnal emissions, which represent about 20 percent of the evaporative emissions from boats, occur as the fuel in the tank and fuel lines heats up due to increases in ambient temperature. As the fuel heats, it forms hydrocarbon vapor which is vented to the atmosphere. Refueling emissions are vapors that are displaced from the fuel tank to the atmosphere when fuel is dispensed into the tank and only represent a small portion of the total evaporative emissions. Permeation refers to when fuel penetrates the material used in the fuel system and is most common through plastic fuel tanks and rubber hoses. This permeation makes up the majority of the evaporative emissions from fuel tanks and hoses. Table III.A–1 presents our national estimates of the evaporative hydrocarbon emissions from boats using spark-ignition engines for 2000.

TABLE III.A–1.—ESTIMATED EVAPORATIVE EMISSIONS FROM TANKS/HOSES IN 2000

| Evaporative emission component | HC [tons] |
|---|---|
| Diurnal breathing losses | 22,700 |
| Permeation through the fuel tank | 26,600 |
| Permeation through hoses | 43,200 |
| Refueling vapor displacement | 6,700 |
| Hot Soak | 260 |
| Total evaporative emissions | 100,000 |

This section describes the new provisions proposed for 40 CFR part 1045, which would apply only to boat manufacturers and fuel system component manufacturers. This section also discusses proposed test equipment and procedures (for anyone who tests fuel tanks and hoses to show they meet emission standards) and proposed general compliance provisions (for boat manufacturers, fuel system component manufacturers, operators, repairers, and others).

We are proposing performance standards intended to reduce permeation and diurnal evaporative emissions from boats using spark-ignition engines. The proposed standards, which would apply to new boats starting in 2008, are nominally based on manufacturers reducing these sources of evaporative emissions by about 80 percent overall. Because of the many small businesses that manufacture boats and fuel tanks, we are proposing a flexible compliance program that is intended to help minimize the burden of meeting the proposed requirements.

Based on a database maintained by the U.S. Coast Guard, we estimate that there are nearly 1,700 boat builders producing boats that use engines for propulsion. At least 1,200 of these boat builders install gasoline-fueled engines and would therefore be subject to the evaporative emission-control program discussed below. Our understanding is that more than 90 percent of the boat builders identified so far would be considered small businesses as defined by the Small Business Administration for SIC code 3732. Some of these boat builders construct their own fuel tanks either out of aluminum or fiberglass reinforced plastic. However, the majority of fuel tanks used by boat builders are purchased from fuel tank manufacturers.

We have determined that fuel tank manufacturers sell approximately 550,000 fuel tanks per year for gasoline storage on boats. The market is divided into manufacturers that produce plastic tanks and manufacturers that produce aluminum tanks. We have identified

nine companies that make plastic marine fuel tanks with total sales of approximately 440,000 units per year. Of these plastic tanks, about 20 percent are portable while the rest are installed. We have determined that there are at least five companies that make aluminum marine fuel tanks with total sales of approximately 110,000 units per year. All but one of the fuel tank manufacturers that we have identified are small businesses as defined by the Small Business Administration for SIC Code 3713.

Our understanding is that there are four primary manufacturers of marine hose used in fuel supply lines and venting. At least two of these four manufacturers produce hoses for other transportation sources as well and already supply low permeation hoses that would meet our proposed standards. Only one U.S. manufacturer of fill neck hose has been identified. The rest is shipped from overseas.

*B. Boats/Fuel Systems Covered by This Proposal*

Generally speaking, this proposed rule would cover the fuel systems of all new marine vessels with spark-ignition (SI) engines. We include boats and fuel systems that are used in the United States, whether they are made domestically or imported.

In the ANPRM, we discussed exhaust and evaporative emissions from boats using only sterndrive or inboard engines. As discussed later in Section IV, we are not proposing exhaust emission standards for these engines at this time. We are, however, proposing to expand the scope of the evaporative emission standards discussed in the ANPRM, because we see no significant technological differences between fuel tanks and hoses used for sterndrive or inboard engines and those used for other SI marine engines. In fact, fuel tank and hose manufacturers often sell their products without knowing what type of marine engine will be used with it.

1. Why Does This Apply Only to Marine Vessels Using Spark-Ignition Engines?

Spark-ignition marine engines generally use gasoline fuel while compression-ignition marine engines generally use diesel fuel. We are proposing evaporative emission standards only for boats using spark-ignition engines because diesel fuel has low volatility and, therefore, does not evaporate readily. In fact, the evaporative emissions from boats using diesel fuel are already significantly lower than standards we are proposing for boats using spark-ignition marine engines.

2. Would the Proposed Standards Apply to All Vessels Using SI Engines or Only to New Vessels?

The scope of this proposal is broadly set by Clean Air Act section 213(a)(3), which instructs us to set emission standards for new nonroad engines and new nonroad vehicles. Generally speaking, the proposed rule is intended to cover all new vessels. Once the emission standards apply to these vessels, individuals or companies must get a certificate of conformity from us before selling them in the United States. This includes importation and any other means of introducing engines and vehicles into commerce. The certificate of conformity (and corresponding label) provide assurance that manufacturers have met their obligation to make engines that meet emission standards over the useful life we specify in the regulations.

3. How Do I Know if My Vessel Is New?

We are proposing to define ''new'' consistent with previous rules. Under the proposed definition, a vessel is considered new until its title has been transferred to the ultimate purchaser or the vessel has been placed into service. Imported vessels would also be considered to be new.

4. When Would Imported Vessels Need to Meet the Proposed Emission Standards?

The proposed emissions standards would apply to all new vessels in the United States. According to Clean Air Act section 216, ''new'' includes vessels that are imported by any person, whether freshly manufactured or used. All vessels imported for introduction into commerce would need an EPA-issued certificate of conformity to clear customs, with limited exemptions (as described below).

Any marine vessel built after these emission standards take effect and subsequently imported into the U.S. would be a new vessel for the purpose of the regulations proposed in this document. This means it would need to comply with the applicable emission standards. For example, a marine vessel manufactured in a foreign country in 2004, then imported into the United States in 2008, would be considered ''new.'' This provision is important to prevent manufacturers from avoiding emission standards by building vessels abroad, transferring their title, and then importing them as used vessels.

5. Would the Proposed Standards Apply to Exported Vessels?

Vessels intended for export would generally not be subject to the requirements of the proposed emission-control program. However, vessels that are exported and subsequently re-imported into the United States would need to be certified.

6. Are There Any New Vessels That Would Not Be Covered?

We are proposing to extend our basic nonroad exemptions to the engines and vehicles covered by this proposal. These include the testing exemption, the manufacturer-owned exemption, the display exemption, and the national security exemption. These exemptions are described in more detail under Section III.E.3. In addition, the Clean Air Act does not consider vessels used solely for competition to be nonroad vehicles, so they are exempt from meeting the proposed emission standards.

*C. Proposed Evaporative Emission Requirements*

Our general goal in designing the proposed standards is to develop a program that will achieve significant emission reductions. The standards are designed to ''achieve the greatest degree of emission reduction achievable through the application of technology the Administrator determines will be available for the engines or vehicles to which such standards apply, giving appropriate consideration to the cost of applying such technology within the period of time available to manufacturers and to noise, energy, and safety factors associated with the application of such technology.'' Section 213(a)(3) of the Clean Air Act also instructs us to first consider standards equivalent in stringency to standards for comparable motor vehicles or engines (if any) regulated under section 202, taking into consideration technological feasibility, costs, and other factors.

1. What are the Proposed Evaporative Emission Standards?

We are proposing to require reductions in diurnal emissions, fuel tank permeation, and fuel system hose permeation from new vessels beginning in 2008. The proposed standards are presented in Table III.C–1 and represent more than a 25 percent reduction in diurnal emissions and a 95 percent reduction in permeation from both plastic fuel tanks and from hoses. Section III.F.1 presents the test procedures associated with these proposed standards. Test temperatures

are presented in Table III.C–1 because they represent an important parameter in defining the emission levels. The proposed fuel tank venting and permeation standards are based on the total capacity of the fuel tank as described below. The proposed hose permeation standards are based on the inside surface area of the hose. We are not proposing standards for hot soak and refueling emissions, as described above, at this time.

TABLE III. C–1.—PROPOSED EVAPORATIVE STANDARDS

| Evaporative emission component | Proposed emission standard | Test temperature |
|---|---|---|
| Diurnal Venting | 1.1 g/gallon/day | 22.2–35.6°C (72–96°F) |
| Fuel tank permeation | 0.08 g/gallon/day | 40°C (104°F) |
| Hose permeation | 5 g/m$^2$/day | 23°C (73°F) |
| | (15 g/m$^2$/day with 15% methanol blend) | |

The proposed emission standards are based on our evaluation of several fuel system technologies (described in Section III.H) which vary in cost and in efficiency. The proposed implementation date gives manufacturers about five years to comply after we expect to issue final standards . As discussed in more detail in Section III.H.1, this would help minimize costs by allowing fuel tank manufacturers time to implement controls in their tanks as designs normally turnover as opposed to forcing turnover premature to normal business practice. There are a multiplicity of tank sizes and shapes produced every year and the cost and efficiency of the available emission-control technologies will vary with these different configurations. In determining the proposed standards, we considered costs and focused on straightforward approaches that could potentially be used by all businesses. As discussed in Section H.3, we believe that the approaches in this proposal would comply with U.S. Coast Guard safety requirements for fuel systems. Given all this, in the 2008 time frame, we believe an average reduction of at least 80 percent in total evaporative emissions from new boats can be achieved, considering the availability and cost of technology, lead time, noise, energy and safety. We request comment on the proposed standards and implementation dates, on the units used for the fuel tank permeation standards (*i.e.* g/gallon/day versus g/m$^2$/day), and on the certification provisions discussed below. We are also interested in comments regarding the cost of implementing the proposed standards. Commenters are encouraged to provide specific data when possible.

2. Will Averaging, Banking and Trading Be Allowed Across a Manufacturer's Product Line?

An emission-credit program is an important factor we take into consideration in setting emission standards that are appropriate under Clean Air Act section 213. An emission-credit program can reduce the cost and improve the technological feasibility of achieving standards, helping to ensure the attainment of the standards earlier than would otherwise be possible. Manufacturers gain flexibility in product planning and the opportunity for a more cost-effective introduction of product lines meeting a new standard. Emission-credit programs also create an incentive for the early introduction of new technology, which would allow certain vessels to be used to evaluate new technology. This can provide valuable information to manufacturers on the technology before they apply it throughout their product line. This early introduction of lower-emitting technology improves the feasibility of achieving the standards and can provide valuable information for use in other regulatory programs that may benefit from similar technologies.

Emission-credit programs may involve averaging, banking, and trading (ABT). Averaging allows a manufacturer to certify one or more products at an emission level less stringent than the applicable emission standard, as long as the increased emissions are offset by products certified to a level more stringent than the applicable standard. The over-complying products generate credits that can be used by the under-complying products. Compliance is determined on a total mass emissions basis to account for differences in production volume and tank sizes among emission families. The average of all emissions for a particular manufacturer's production must be at or below that level of the applicable emission standard. Early banking allows a manufacturer to certify early and generate credits for modifying their fuel system to the 2008 compliance strategy. In 2008 and later, the banking program would allow a manufacturer to generate credits and retain them for future use. Trading involves the sale of banked credits from one company to another.

We believe there is a variety of technology options that could be used to meet the proposed standards for diurnal emissions. By using different combinations of these technologies, manufacturers will be able to produce products that achieve a range of emission reductions. However, certain technologies may be more appropriate for different applications. In some cases, manufacturers may need flexibility in applying the emission-control technology to their products. For this reason, we are proposing that the 1.1 g/gallon/day diurnal emission standard be based a corporate average of a manufacturer's total production. To meet this average level, manufacturers would be able to divide their fuel tanks into different emission families and certify each of their emission families to a different Family Emissions Level (FEL). The FELs would then be weighted by sales volume and fuel tank capacity to determine the average level across a manufacturer's total production. An additional benefit of a corporate average approach is that it provides an incentive for developing new technology that can be used to achieve even larger emission reductions.

Participation in the ABT program would be voluntary. Any manufacturer could choose to certify each of its evaporative emission control families at levels which would meet the 1.1 g/gallon/day proposed standard and would then comply with the average by default. Some manufacturers may choose this approach as the could see it as less complicated to implement.

The following is an example of how the proposed averaging program for diurnal emissions could give a boat manufacturer flexibility in its production. Suppose a boat builder was selling 10 boats, three with 100-gallon fuel tanks and seven with 50-gallon fuel tanks. In this case, the boat builder constructs its own fuel tanks believes that an open-vent configuration without any emission control is necessary for the vessel application using the 100 gallon tanks. However, the manufacturer is able to use closed-vent fuel tanks with a 2.0 psi pressure relief valve in the

smaller fuel tanks. Using the design certification levels described in Section III..F.3, the 100 gallon fuel tanks would have an FEL of 1.5 g/gallon/day and the 50 gallon fuel tanks would have an FEL of 0.7 g/gallon/day. The manufacturer would generate debits for the three boats with 100 gallon fuel tanks using the following equation:

Debits = (1.5 g/gallon − 1.1 g/gallon) × 3 tanks × 100 gallon/tank = 120 g

The manufacturer would need to use credits to cover these debits. The boats certified using a closed vent with a 2.0 psi pressure relief valve in this example would generate the following credits:

Credits = (1.1 g/gallon − 0.7 g/gallon) × 7 tanks × 50 gallon/tank = 140 g

Because the credits are larger than the debits in this example, the boat builder would meet the proposed corporate average standard by certifying these ten boats.

We also propose to allow manufacturers to bank and trade emission credits. We are proposing that emission credits generated under this program have no expiration, with no discounting applied. The credits would belong to the entity that certifies the fuel tank. In the above example, the manufacturer would have 20 grams of credits (140 g − 120 g = 20 g) that it could bank, either for trading or for later model year averaging.

Beginning in 2004, we propose to allow early banking for diurnal evaporative emissions. Under this program, manufacturers generate early credits in 2004 through 2007 for adding new evaporative emission control technology which would reduce diurnal emissions. These credits could be banked and then used in 2008 and later. As a precaution against creating an opportunity for windfall credits to be generated from fuel systems already below the average baseline level we would only allow credits to be generated below the proposed standard.

The following is an example of how early emission credits could be generated. In this example, a boat builder sells 20 boats in the 2004 to 2007 time period, each with a 50 gallon fuel tank. If this boat builder decided to sell one boat per year with a sealed tank and a 1.5 psi pressure relief valve (0.9 g/gallon/test), the boat builder would be able to generate emission credits using the following equation:

Credits = (1.1 g/gallon − 0.9 g/gallon/test) × 4 tanks × 50 gallon/tank = 40 g

Over this time period, the boat builder would not generate any emission debits. Therefore, the boat builder would have 40 grams of credits that it could use in 2008 and later. We request comment on the proposed ABT program for diurnal emissions.

We are supportive of the concept of ABT in general. An ABT program can reduce cost and improve technological feasibility, and provide manufacturers with additional product planning flexibility. This allows EPA to consider emissions standards with the most appropriate level of stringency and lead time, as well as providing an incentive for the early introduction of new technology. However, while we are open to the idea of including the program in the rule, we are not at this time proposing to allow ABT for meeting the proposed fuel tank and hose permeation standards. In preliminary discussions, manufacturers indicated a desire to meet requirements directly rather than using an ABT concept. From EPA's perspective including an ABT program in the rule creates a long-term administrative burden that is not worth taking on if the industry does not intend to take advantage of the flexibility. While we believe that all fuel tanks and fuel hoses can meet the proposed permeation standards using straight forward technology as discussed in Section III.H, industry may find value in an early banking program, especially for fuel tanks. Under this concept, industry could certify some tanks early in exchange for time to delay some tanks. This could potentially be done on a one-on-one basis, or perhaps on a volumetric exchange basis. In addition, we do not preclude the value of an averaging and trading program as a compliance flexibility to meet the proposed permeation standards which represent a 95 percent reduction in permeation. We request comment on whether we should adopt an ABT program for hose and fuel tank permeation emissions.

3. Would These Standards Apply to Portable Fuel Tanks as Well?

For personal watercraft and most boats using SD/I or large outboard engines, the fuel tanks are permanently mounted in the vessel. However, small boats using outboard engines may have portable fuel tanks that can be removed from the boat and stored elsewhere. Because these fuel tanks are not sold as part of a boat, we would not require boat builders that use only portable fuel tanks to certify to the proposed evaporative emission standards described above for fuel tanks. The fuel tank manufacturer would have to certify to the fuel tank diurnal and permeation standards. For this purpose, we would consider a portable fuel tank to be one that is not permanently mounted on the boat, has a handle, and has no more than 12 gallons of fuel capacity.

Portable fuel tanks generally have a quick-connect that is used to detach the fuel line between the engine and tank. Once the fuel line is detached, this quick-connect will close. In addition, these tanks generally have a valve that either closes automatically when the tank is disconnected from the engine or a valve that can be closed by the user which will prevent vapors from escaping from the tank when it is stored.

We propose to allow design-based certification of portable fuel tanks to the diurnal emission standard based on the criteria that they seal automatically when the tank is disconnected from the engine and that they meet the proposed fuel tank permeation standard. We believe that the diurnal emissions from a typical portable fuel tank would be well below the proposed standard provided that it is sealed when not in use. Because the emission control depends on user practices, (such as disconnecting the tank after use) we propose not allowing any credits to be generated for diurnal emissions. We request comment on allowing design-based certification of portable fuel tanks that have valves that must be closed by the user.

4. Is EPA Proposing Voluntary ''Blue Sky'' Emissions Standards?

Several state and environmental groups and manufacturers of emissions controls have supported our efforts to develop incentive programs to encourage the use of emission control technologies that go beyond federal emission standards. In the final rule for land-based nonroad diesel engines, we included a program of voluntary standards for low-emitting engines, referring to these as ''Blue Sky Series'' engines (63 FR 56967, October 23, 1998). Since then, we have included similar programs in several of our other nonroad rules. The general purposes of such programs are to provide incentives to manufacturers to produce clean products as well as create market choices and opportunities for environmental information for consumers regarding such products. The voluntary aspects of these programs, which in part provides an incentive for manufacturers willing to certify their products to more stringent standards than necessary, is an important part of the overall application of ''Blue Sky Series'' programs.

We are proposing a voluntary Blue Sky Series standard for diurnal emissions from marine fuel tanks. Under this proposal we are targeting

close to a 95-percent reduction in diurnal evaporative emissions beyond the proposed mandatory diurnal emission standards as a qualifying level for Blue Sky fuel tanks. The proposed Blue Sky standard is 0.1 g/gallon/day, which, as discussed in Section III.F.3, could be met through the use of technologies such as a low permeation bladder fuel tank.

Creating a voluntary standard for low diurnal emissions will be an important step in advancing emission control technology. While these are voluntary standards, they become binding on tanks produced under that certificate once a manufacturer chooses to participate. EPA certification will therefore provide protection against false claims of environmentally beneficial products. A manufacturer choosing to certify a fuel tank under this approach must comply with all the proposed certification requirements including useful life, warranty, and other general compliance provisions. This program would become effective when we finalize this rule.

For the program to be most effective, however, incentives should also be in place to motivate the production and sale of lower emitting fuel tanks. We solicit ideas that could encourage the creation and use of these incentive programs by users and state and local governments. We believe it is important that such incentive programs lead to a net benefit to the environment; therefore, we are proposing that fuel tanks with the Blue Sky designation not generate extra ABT credits for demonstrating compliance with this proposed standard. We also request comment on additional measures we could take to encourage development and introduction of low emission control technology. Finally, we request comment on the Blue Sky approach in general as it would apply to marine fuel tanks.

5. What Is Consumer-Choice Labeling?

California ARB has recently proposed consumer/environmental label requirements for outboard and personal watercraft engines. Under this approach, manufacturers would label their engines or vehicles based on their certified emission level. California has proposed three different labels to differentiate varying degrees of emission control—one for meeting the EPA 2006 standard, one for being 20 percent lower, and one for being 65 percent below. More detail on this concept is provided in the docket.[22]

We are considering a similar approach to labeling the vessels subject to this proposal. This would apply especially to consumer products. Consumer-choice labeling would give people the opportunity to consider varying emission levels as a factor in choosing specific models. This may also give the manufacturer an incentive to produce more of their cleaner models. A difficulty in designing a labeling program is in creating a scheme that communicates information clearly and simply to consumers. Also, some are concerned that other organizations could use the labeling provisions to mandate certain levels of emission control, rather than relying on consumer choice as a market-based incentive. We request comment on this approach for marine vessels.

*D. Demonstrating Compliance*

1. How Would I Certify My Products?

We are proposing to apply our emission standards to vessels, but allow certification of fuel tanks and hoses separately. For both cases, we are proposing a certification process similar to our existing program for other mobile sources. In the existing program, manufacturers test representative prototype designs and submit the emission data along with other information to EPA in an application for a Certificate of Conformity. As discussed in Section III.F.3, we are proposing to allow manufacturers to certify based on either design (for which there is data) or emissions testing. If we approve the application, then the manufacturer's Certificate of Conformity allows the manufacturer to produce and sell the vessels or fuel systems described in the application in the U.S.

We are proposing that manufacturers certify their vessels, fuel tanks, or hoses by grouping them into emission families. Under this approach, vessels, fuel tanks, or hoses systems expected to have similar emission characteristics would be classified in the same emission family. The emission family definition is fundamental to the certification process and to a large degree determines the amount of testing required for certification. To address a manufacturer's unique product mix, we may approve using broader or narrower emission families.

Once an emission family is certified, we would require every vessel, fuel tank, or hose a manufacturer produces from the emission family to have a label with basic identifying information. The proposed regulation text details the proposed requirements for design and content of the labels. We request comment on this approach.

2. Who Will be Responsible for Certifying the Vessel or Fuel System?

Every boat powered by a spark-ignition marine engine and every portable fuel tank would have to be covered by an emissions certificate (or separate certificates for fuel tanks and hoses). The proposed regulations require that compliance to the emission standards must be demonstrated before the sale of the boat (or tank, in the case of portable fuel tanks). However, to allow additional flexibility in complying with standards, we propose to allow tank and hose manufacturers to certify their product lines separately. Therefore, if a boat builder were to use certified fuel tanks and hoses, the boat builder could rely on the tank and hose manufacturers' certificates. The boat builder would only need to state that they are using components that, combined, will meet the proposed standard and properly install the fuel system. We request comment on this approach.

3. How Long Would My Vessel or Fuel System Have To Comply?

Manufacturers would be required to build vessels that meet the emission standards over each vessel's useful life. The useful life we adopt by regulation is intended to reflect the period during which vessels are designed to properly function without being remanufactured. We propose a regulatory useful life of ten years for marine evaporative emission control. This is consistent with the regulatory useful life for outboard marine engines. We use the same useful life based on the belief that engines and boats are intended to have the same design life. We request comment on the proposed useful life requirement.

4. What Warranty Requirements Apply to Certified Vessels and Fuel Systems?

Consistent with our current emission-control programs, we are proposing that manufacturers provide a design and defect warranty covering emission-related components. For marine vessels, we propose that the fuel systems be warranted for five years for the emission related components. The proposed regulations would require that the warranty period must be longer than this minimum period we specify if the manufacturer offers a longer warranty for the fuel system or any of its components; this includes extended warranties on the fuel system or any of its components that are available for an extra price. See the proposed regulation

[22] ''Public Hearing to Consider Amendments to the Spark-Ignition Marine Engine Regulations,'' Mail Out #MSC 99–15, June 22, 1999 (Docket A–2000–01, Document II–A–27).

language for a description of which components are emission-related. We request comment on whether the warranty provisions should apply only to the certificate holder or to all manufacturers of the fuel system components used by the certificate holder.

If an operator makes a valid warranty claim for an emission-related component during the warranty period, the manufacturer is generally obligated to replace the component at no charge to the operator. The manufacturer may deny warranty claims if the operator failed to do prescribed maintenance that contributed to the warranty claim.

We are also proposing a defect reporting requirement that applies separate from the emission-related warranty (see Section III.E.6). In general, defect reporting applies when a manufacturer discovers a pattern of component failures, whether that information comes from warranty claims, voluntary investigation of product quality, or other sources. We request comment on the proposed warranty and defect reporting requirements.

*E. General Compliance Provisions*

This section describes a wide range of compliance provisions that would apply to marine vessels (or fuel tanks or hoses as appropriate) and are the same as those recently proposed for the nonroad engines September 2001 (*see* 66 FR 51098). Several of these provisions apply not only to manufacturers, but also to operators, and others.

The following discussion of the general compliance provisions reflects the organization of the proposed regulatory text. For ease of reference, the subpart designations are provided. We request comment on all these provisions.

1. Miscellaneous Provisions (Part 1068, Subpart A)

This proposed regulation contains some general provisions, including general applicability and the definitions that apply to 40 CFR part 1068. Other provisions concern good engineering judgment, how we would handle confidential information; how the EPA Administrator delegates decision-making authority; and when we may inspect a manufacturer's facilities, vessels, or records.

The process of testing for evaporative emissions (or certifying based on design) and preparing an application for certification requires the manufacturer to make a variety of judgments. Section 1068.5 of the proposed regulations describes the methodology we propose to use to evaluate concerns related to manufacturers' use of good engineering judgment in cases where the manufacturer has such discretion. If we find a problem in these areas, we would take into account the degree to which any error in judgment was deliberate or in bad faith. This subpart is consistent with provisions in the final rule for light-duty highway vehicles and commercial marine diesel engines.

2. Prohibited Acts and Related Requirements (Part 1068, Subpart B)

The proposed provisions in this subpart lay out a set of prohibitions for manufacturers and operators to ensure that vessels comply with the emission standards. These provisions are summarized below, but readers are encouraged to review the proposed regulatory text. These provisions are intended to help ensure that each new vessel or portable tank sold or otherwise entered into commerce in the United States is certified to the relevant standards.

a. General prohibitions (§ 1068.100). This proposed regulation contains several prohibitions consistent with the Clean Air Act. Under this proposal, no one may sell a vessel or portable fuel tank in the United States without a valid certificate of conformity issued by EPA, deny us access to relevant records, or keep us from entering a facility to test or inspect vessels or fuel system components. In addition, no one may remove or disable a device or design element that may affect an vessel's emission levels, or manufacture any device that will make emission controls ineffective, which we would consider tampering. We have generally applied the existing policies developed for tampering with highway engines and vehicles to nonroad engines.[23] Other proposed prohibitions reinforce manufacturers' obligations to meet various certification requirements. We would also prohibit selling parts that prevent emission-control systems from working properly. Finally, for vessels that are excluded for certain applications (i.e. solely for competition), we would generally prohibit using these vessels in other applications.

These proposed prohibitions are the same as those that apply to other applications we have regulated in previous rules. Each prohibited act has a corresponding maximum penalty as specified in Clean Air Act section 205. As provided for in the Federal Civil Penalties Inflation Adjustment Act of 1990, Pub. L. 10–410, these maximum penalties are in 1970 dollars and should be periodically adjusted by regulation to account for inflation. The current penalty amount for each violation is $27,500.[24]

b. In-service systems (§ 1068.110). The proposed regulations would prevent manufacturers from requiring owners to use any certain brand of aftermarket parts and give the manufacturer responsibility for servicing related to emissions warranty, leaving the responsibility for all other maintenance with the owner. This proposed regulation would also reserve our right to do testing (or require testing) to investigate potential defeat devices, as authorized by the Act.

3. Exemptions (Part 1068, Subpart C)

We are proposing to include several exemptions for certain specific situations. Most of these are consistent with previous rules. We highlight the new or different proposed provisions in the following paragraphs. In general, exempted vessels would need to comply with the requirements only in the sections related to the exemption. Note that additional restrictions could apply to importing exempted vessels (*see* Section III.E.4). Also, we are also proposing that we may require manufacturers (or importers) to add a permanent label describing that the vessel or fuel system component is exempt from emission standards for a specific purpose. In addition to helping us enforce emission standards, this would help ensure that imported vessels clear U.S. Customs without difficulty.

a. Testing. Anyone would be allowed to request an exemption for vessels or fuel system components used only for research or other investigative purposes.

b. Manufacturer-owned vessels and fuel systems. Vessels and fuel system components that are used by manufacturers for development or marketing purposes could be exempted from regulation if they are maintained in the manufacturers' possession and are not used for any revenue-generating service. They would no longer be exempt if they were later offered for sale.

c. Display vessels or fuel systems. Boat builders and fuel system component manufacturers would get an exemption if the vessels or fuel systems are for display only. They would no longer be exempt if they were later offered for sale.

[23] ''Interim Tampering Enforcement Policy,'' EPA memorandum from Norman D. Shulter, Office of General Counsel, June 25, 1974 (Docket A–2000–01; document II–B20).

[24] EPA acted to adjust the maximum penalty amount in 1996 (61 FR 69364, December 31, 1996). See also 40 CFR part 19.

d. National security. Manufacturers could receive an exemption for vessels or portable fuel tanks they can show are needed by an agency of the federal government responsible for national defense. For cases where the vessels will not be used on combat applications, the manufacturer would have to request the exemption with the endorsement of the procuring government agency.

e. Exported vessels. Vessels and portable fuel tanks that will be exported to countries that don't have the same emission standards as those that apply in the United States would be exempted without need for a request. This exemption would not be available if the destination country has the same emission standards as those in the United States.

f. Competition vessels. New vessels that are used solely for competition are excluded from regulations applicable to nonroad equipment. For purposes of our certification requirements, a manufacturer would receive an exemption if it can show that it produces the vessel specifically for use solely in competition. In addition, vessels that have been modified for use in competition would be exempt from the prohibition against tampering described above (without need for request). The literal meaning of the term ''used solely for competition'' would apply for these modifications. We would therefore not allow the vessel to be used for anything other than competition once it has been modified. This also applies to someone who would later buy the vessel, so we would require the person modifying the vessel to remove or deface the original label and inform a subsequent buyer in writing of the conditions of the exemption. The exemption would no longer apply.

4. Imports (Part 1068, Subpart D)

In general, the same certification requirements would apply to vessels whether they are produced in the U.S. or are imported. This proposed regulation also includes some additional provisions that would apply if someone wants to import an exempted or excluded vessel. For example, the importer would need written approval from us to import any exempted vessel; this is true even if an exemption for the same reason doesn't require approval for vessels produced in the U.S.

All the proposed exemptions described above for new vessels would also apply to importation, though some of these apply only on a temporary basis. If we approve a temporary exemption, it would be available only for a defined period and could require the importer to post bond while the vessel is in the U.S. There are several additional proposed exemptions that would apply only to imported vessels.

—*Identical configuration:* This would be a permanent exemption to allow individuals to import vessels that were designed and produced to meet applicable emission standards. These vessels may not have the emission label only because they were not intended for sale in the United States.

—*Repairs or alterations:* This would be a temporary exemption to allow companies to repair or modify vessels.

—*Diplomatic or military:* This would be a temporary exemption to allow diplomatic or military personnel to use uncertified vessels during their term of service in the U.S.

We request comment on all the proposed exemptions for domestically produced and imported vessels.

5. Selective Enforcement Audit (Part 1068, Subpart E)

Clean Air Act section 206(b) gives us the authority and discretion in any program with vehicle or engine emission standards to do selective enforcement auditing of production vessels and fuel systems. The proposed regulation text describes the audit procedures in greater detail. We intend generally to rely on inspecting manufacturers' designs to ensure they comply with emission standards. However, we would reserve our right to do selective enforcement auditing if we have reason to question the emission testing conducted or data reported by the manufacturer.

6. Defect Reporting and Recall (Part 1068, Subpart F)

We are proposing provisions for defect reporting. Specifically, we are proposing that manufacturers tell us when they learn of a defect occurring 25 times or more for emission families with annual sales up to 10,000 units. This threshold of defects would increase proportionately for larger families. While these thresholds would depend on sales, counting defects would not be limited to a single emission family. For example, if a manufacturer learns that operators reported 25 cases of problems with a limiting orifice from three different low-volume models spread over five years, that would trigger the need to file a defect report. This information could come from warranty claims, customer complaints, product performance surveys, or anywhere else. The proposed regulation language in § 1068.501 also provides information on the thresholds for triggering a further investigation for where a defect report is more likely to be necessary. We request comment on the proposed defect reporting provisions.

Under Clean Air Act section 207, if we determine that a substantial number of vessels, fuel tanks, or hoses within an emission family, although properly used and maintained, do not conform to the appropriate emission standards, the manufacturer will be required to remedy the problem and conduct a recall of the noncomplying emission family. However, we also recognize the practical difficulty in implementing an effective recall program for marine vessels. It would likely be difficult to properly identify all the affected owners. The response rate for affected owners or operators to an emission-related recall notice is also a critical issue to consider. We recognize that in some cases, recalling noncomplying marine vessels may not achieve sufficient environmental protection, so our intent is to generally allow manufacturers to nominate alternative remedial measures to address most potential noncompliance situations. We expect that successful implementation of appropriate alternative remediation would obviate the need for us to make findings of substantial nonconformity under section 207 of the Act. We would consider alternatives nominated by a manufacturer based on the following criteria; the alternatives should—

(1) Represent a new initiative that the manufacturer was not otherwise planning to perform at that time, with a clear connection to the emission problem demonstrated by the emission family in question;

(2) Cost more than foregone compliance costs and consider the time value of the foregone compliance costs and the foregone environmental benefit of the emission family;

(3) Offset at least 100 percent of the emission exceedance relative to that required to meet emission standards; and

(4) Be possible to implement effectively and expeditiously and to complete in a reasonable time.

These criteria would guide us in evaluating projects to determine whether their nature and burden is appropriate to remedy the environmental impact of the nonconformity. However, in no way would the consideration of such a provision diminish our statutory authority to direct a recall if that is deemed the best course of action. We request comment on this approach to addressing the Clean Air Act provisions related to recall. In addition, we request comment on the proposed requirement

to keep recall-related records until three years after a manufacturer completes all responsibilities under a recall order.

7. Public Hearings (Part 1068, Subpart G)

According to this regulation, manufacturers would have the opportunity to challenge our decision to suspend, revoke, or void an emission family's certificate. This also applies to our decision to reject the manufacturer's use of good engineering judgment (see § 1068.5). Part 1068, subpart G describes the proposed procedures for a public hearing to resolve such a dispute.

*F. Proposed Testing Requirements*

In order to obtain a certificate allowing sale of products meeting EPA emission standards, manufacturers generally must show compliance with such standards through emission testing. 40 CFR part 86 details specifications for test equipment and procedures that apply to highway vehicle evaporative emission testing. We propose to base the SI marine evaporative emission test procedures on this part. However, we propose to modify this test procedure somewhat to more accurately reflect the anticipated technology for meeting the evaporative emission standards proposed in this rule. We are also proposing design-based certification as an alternative to performing specific testing.

1. What Are the Proposed Test Procedures for Measuring Diurnal Emissions?

We propose that the evaporative emission test will be representative of ambient temperatures ranging from 22° C to 36° C (72° F to 96° F). Emissions would be measured in a Sealed Housing for Evaporative

Determination (SHED) over a 72-hour period. The fuel tank would be set up in the SHED and sealed except for the vent(s). The fuel tank would be set up in the SHED with all hoses, seals, and other components attached. The fuel tank would be filled completely and drained to 40-percent capacity with 9 RVP test fuel and soaked with an open vent until the fuel reached 22° C.[25] Immediately after the fuel reaches this temperature, the SHED would be purged, and the diurnal temperature cycling would begin. The temperature cycle is actually three repeats of a 24-hour diurnal trace and is described in Chapter 4 of the Draft Regulatory Support Document. During the test a minimum of 5 mph wind speed would be simulated using a fan. The final g/gallon/day result is based on the highest mass emission rate from these three 24-hour cycles, divided by the fuel tank capacity. Fuel tank capacity refers the maximum amount of fuel in the tank under in-use conditions.

These proposed test procedures are designed to simulate near worst case conditions for a typical boat. We believe that typical in-use fuel tanks will rarely be exposed to a temperature cycle larger than 24°F in a single day. However, in special applications where the fuel tank is exposed to direct sunlight, the tank temperature can change much more than 24°F over the course of a single day. Therefore, we are proposing that special test procedures that simulate the radiant effect of sunlight be used to test fuel tanks that will be exposed to direct sunlight. We would not require this for exposed fuel tanks that are shielded from the sun.

This diurnal cycle is consistent with the test requirements in 40 CFR part 86 for highway vehicles. However, the test procedure for highway vehicles includes engine operation and hot soaks.[26] One purpose of the engine operation is to purge the charcoal canister that collects evaporative emissions in highway applications. However, we are excluding engine operation from the evaporative test procedures for boats using SI marine engines because we do not anticipate the use of charcoal canisters in these applications. Another purpose of running the engine and the purpose of the hot soaks is to measure evaporative emissions due to the heating of the engine and exhaust system. However, this would significantly increase the difficulty of the SHED testing due to the large size of most boats. Because most boats are operated only 50 hours per year, these running loss and hot soak emissions are considerably smaller than diurnal and permeation emissions. In addition, most of the emission-control strategies that could be used to meet the proposed standards would also reduce running loss and hot soak emissions. We request comment on the proposed test procedures for determining evaporative emissions from boats using SI marine engines.

2. What Are the Proposed Test Procedures for Measuring Permeation Emissions?

a. Fuel tanks. We propose that tank permeation be based on a test procedure consistent with the Coast Guard requirements in 33 CFR 183.620. Specifically, the rate of permeation from the tank will be measured at 40°C using the same test fuel as for the diurnal testing. We request comment on using 40°C as the test temperature or if 23°C should be used to be consistent with the hose testing. Our understanding is that 40°C represents higher temperatures that may be seen in an engine compartment during operation while 23°C represents typical ambient conditions. If a lower test temperature were used, the standards would need to be adjusted appropriately. Based on data presented in Chapter 4 of the draft RSD, the standards would have to be reduced on the order of 50 percent for every 10°C reduction in test temperature. We also request comment on using ASTM Fuel ''C'' and a 15% methanol blend to be consistent with the hose permeation test procedures or on using 10% ethanol consistent with on-highway evaporative emission testing. The tank would have to be filled and soaked for a minimum of 60 days to ensure that permeation emissions are accurately reflected in the test procedure. The tank would be sealed during testing, and care would have to be made that the environment in which the tank was tested was continuously purged of vapor to prevent the saturation of vapor with hydrocarbons around the outside of the tank. Permeation would be measured through weight loss in the tank or using equivalent procedures.

We also request comment on whether we should require specific durability test procedures for fuel tanks. Such durability tests could include pressure vacuum cycle testing, slosh testing, and temperature cycling. Information on these tests is included in the docket.[27]

b. Hoses. We propose to use the current practices for measuring permeation from marine hoses that are specified in SAE J 1527. Under this procedure, the hose is tested at 23°C with both ASTM Fuel ''C'' (50% toluene, 50% isooctane) and with a blend on fuel ''C'' with 15% methanol. SAE J 1527 sets permeation limits for hose of 100 g/m$^2$/day for fuel C and 300 g/m$^2$/day for the 15% methanol blend. Consistent with this relationship, we propose to allow the permeation rate to

[25] Reid Vapor Pressure (psi). This is a measure of the volatility of the fuel. 9 RVP represents a typical summertime fuel in northern states.

[26] Hot soak emissions are those caused by residual heat in the engine and exhaust system immediately after the engine is shut down. Running loss emissions are those caused by engine and exhaust heat while the engine is operating.

[27] Draft SAE Information Report J1769, ''Test Protocol for Evalution of Long Term Permeation Barrier Durability on Non-Metallic Fuel Tanks,'' (Docket A–2000–01, document IV–A–24).

be three times higher than the proposed standard for fuel C when the hose is tested on the 15% methanol blend. Because permeation rates double, roughly, with every 10°C increase in temperature, the test procedure has a large effect on emissions measured for a given hose material. In addition, the temperature effects may be greater for some materials than for others. For low permeation non-metal fuel lines used in automotive applications, the current practices are specified in SAE J 2260 and SAE J 1737. Under these test procedures, the hose permeation is measured at 60°C with an 85%-15% blend of fuel ''C'' and methanol. We request comment on using the higher test temperature in the automotive test procedure. We also request comment on requiring testing using a 10% ethanol blend consistent with on-highway evaporative emission testing.

3. Could I Certify Based on Engineering Design Rather Than Through Testing?

We recognize that performing SHED testing could be cost-prohibitive for many fuel tank manufacturers or boat builders. In addition, many of the technologies that can be used to reduce evaporative emissions are straightforward design strategies. For these reasons, we propose that manufacturers have the option of certifying to the diurnal evaporative emission requirements based on fuel system designs, as described in the proposed regulations. Test data would be required to certify fuel tanks and hoses to the proposed permeation standards. However, we would allow carryover of test data from year to year for a given emission control design. We believe the cost of testing tanks and hose designs for permeation would be considerably lower than running variable temperature diurnal testing. In addition, the data could be carried over from year to year, and there is a good possibility that the broad emission family concepts under consideration could lead to minimum testing. For instance, a hose manufacturer could test its hose design once, and all the boat builders who use this hose could incorporate this data in their certification applications.

We are proposing design based certification to the tank permeation standard for one case. We would consider an aluminum fuel tank to meet the design criteria for a low permeation fuel tank. However, we would not consider this design to be any more effective than a low permeation fuel tank for the purposes of any sort of credit program. Although aluminum is impermeable, seals and gaskets used on the fuel tank may not be. The design criteria for the seals and gaskets would be that either they would not have a total exposed surface area exceeding 1000 $mm^2$, or the seals and gaskets would have to be made of a material with a permeation rate of 10 $g/m^2$/day or less at 23°C.

The rest of this section discusses designs that we propose to be acceptable for design-based certification to the proposed diurnal emission standard. The emission data we used to develop these proposed design options are presented in Chapter 4 of the Draft Regulatory Support Document. Additional testing may help us more precisely set the appropriate emission levels associated with each design. Manufacturers wanting to use designs other than those we discuss here would have to perform the above test procedures for their design. However, once a new design is proven, we could add this new design to the list of designs for this certification flexibility and assign it to the appropriate averaging bin. For example, if several manufacturers were to pool their resources to test a diurnal emission control strategy and submit this data to EPA, we would consider this particular strategy and emission level as a new design level for design based certification. We request comment on the concept of design-based certification and on the technologies and associated emission levels discussed below. Section III.H.3 presents a more detailed description of what each of these technologies are and how they can be used to reduce evaporative emissions.

We have identified several technologies for reducing diurnal emissions from marine fuel tanks. The design levels proposed below represent our understanding of the effectiveness of various emission control technologies over the proposed test procedure. Table III.F.1 summarizes design-based emission levels associated with several emission control strategies. These control strategies are discussed in more detail after the table. Manufacturers would be required to submit information demonstrating that the components they use would be durable over the useful life of the vessel. For tanks that allow pressure build-up, a low-pressure vacuum-relief valve would also be necessary for the engine to be able to draw fuel during operation. Also, in the cases where anti-siphon valves are used with these designs, the anti-siphon system would have to be designed such that fuel could not spill out through this valve when the system is under pressure.

TABLE III.F–1.—EMISSION LEVELS FOR DESIGN BASED CERTIFICATION TO THE PROPOSED DIURNAL EMISSION STANDARD

| Emission level [g/gallon/day] | Technology |
|---|---|
| 1.5 | Baseline (open vent with a normal length vent hose). |
| 1.3 | Near zero pressure limited flow orifice and insulation (R-value ≥15), or closed vent, 0.5 psi relief valve. |
| 1.1* | Closed vent, 1.0 psi relief valve. |
| 0.9 | Closed vent, 1.5 psi relief valve. |
| 0.7 | Closed vent, 2.0 psi relief valve. |
| 0.5 | Closed vent, 0.5 psi relief valve with a volume compensating air bag. |
| 0.1 | Bladder fuel tank. |

*Proposed average standard for diurnal emissions.

*1.5 g/gal/test:* Typical fuel tanks used in boats currently have an open vent to the atmosphere through a vent hose. This vent is intended to prevent pressure from building up in the fuel tank. This uncontrolled fuel tank configuration would be considered to be at this level based on the data presented in Chapter 4 of the Draft RSD.

*1.3 g/gal/test:* The design criteria for this level would be a fuel tank with a near zero pressure limited flow orifice and insulation. The limited flow orifice would be defined as having a maximum cross-sectional area defined by the following equation: Area [$mm^2$] = 0.04 x fuel tank capacity [gallons]. For example, a 20 gallon tank would need an orifice with no more than a 1 mm diameter. This size orifice is sufficient to limit diffusion of hydrocarbons without causing significant pressure to build in the fuel tank. The design criteria for the insulation would be to use insulation having at least an R-value of 15 (see section III.H.3.b).

*1.3 g/gal/test:* An alternative design criterion for this level would be a sealed fuel tank with a pressure-relief valve that would open at a pressure of 0.5 psi.

*1.1 g/gal/test:* The design criterion for this level would be a sealed fuel tank with a pressure-relief valve that would open at a pressure of 1.0 psi.

*0.9 g/gal/test:* The design criterion for this level would be a sealed fuel tank with a pressure-relief valve that would open at a pressure of 1.5 psi.

*0.7 g/gal/test:* The design criterion for this level would be a sealed fuel tank

with a pressure-relief valve that would open at a pressure of 2.0 psi.

*0.5 g/gal/test:* The design criterion for this level would be a volume-compensating air bag used in conjunction with a 0.5 psi pressure-relief valve if the bag is designed to fill 25 percent of the fuel tank capacity when inflated. This bag would have no leaks to the fuel tank and would be constructed out of a non permeable material.

*0.1 g/gal/test:* The design criterion for this level would be to use a bladder tank. The bladder would have to be sealed and built of low permeable material. This bladder would collapse as fuel was drawn out of it and expand when refueled thereby eliminating the vapor space needed for diurnal vapor generation.

*G. Special Compliance Provisions*

The scope of this proposal includes many boat and fuel tank manufacturers that have not been subject to our regulations or certification process. Many of these manufacturers are small businesses for which a typical regulatory program may be burdensome. This section describes the proposed special compliance provisions designed to address this concern. As described in Section VIII.B, the report of the Small Business Advocacy Review Panel addresses the concerns of small manufacturers of gasoline fuel tanks for marine applications and small boat builders that use these tanks.

To identify representatives of small businesses for this process, we used the definitions provided by the Small Business Administration for fuel tank manufacturers and boat builders (less than 500 employees). Twelve small businesses agreed to serve as small-entity representatives. These companies represented a cross-section of both gasoline and diesel engine marinizers, as well as boat builders.

In this industry sector, we believe some of the burden reduction approaches presented in the Panel Report should be applied to all businesses. All of the marine fuel tank manufacturers except for one qualify as small businesses. We believe the purpose of these options is to reduce the potential burden on companies for which fixed costs cannot be distributed over a large product line. For this reason, we often times also consider the production volume when making decisions regarding flexibilities. The one fuel tank manufacturer not qualifying as a small business still has low production volumes of marine fuel tanks, thus we believe some flexibilities should be made available to this manufacturer as well.

Three of the five burden reduction approaches discussed in the Panel

Report are design-based certification, allowance to use emission credits with design-based certification, and a 5-year lead time with early banking. As discussed above, we are proposing these approaches for all manufacturers certifying marine fuel tanks to the proposed evaporative emission standards. This section discusses the other two approaches in the Panel Report and how we propose to apply them to the marine industry.

1. Broadly Defined Product Certification Families

To certify to the evaporative emission standards, we propose that manufacturers would have to classify their vessels, fuel tanks, or hoses in emission families based on having similar emission characteristics. We would expect to differentiate families by fuel type, diurnal control technology, and the tank and hose material/treatment. The manufacturer would then certify each of these evaporative emission families. The purpose of emission families has traditionally been to reduce testing burden by allowing a family to be certified based on the test results from its highest-emitting member.

For highway evaporative emission requirements, each manufacturer divides its products into several evaporative emission families based on characteristics of the fuel system. These characteristics include: fuel type, charcoal canister type and capabilities, seals, valves, hoses, and tank material. The manufacturer then has to certify each of these evaporative emission families. Unlike highway vehicles, evaporative emission controls for marine vessels are not likely to rely on charcoal canisters as a control technology. Furthermore, most or all SI marine engines will use gasoline and most manufacturers do not make both plastic and aluminum fuel tanks. Most manufacturers will therefore have very few emission families and it will be unlikely that emission families could be much broader than discussed here. In addition, broadening emission families may not reduce compliance burden, considering the proposed design-based certification approach. However, we request comment on whether there are reasonable ways to broaden these engine families, and whether or not small businesses would benefit from any such broadened definitions.

2. Hardship Provisions for Small Businesses Producing Marine Fuel Tanks

There are two types of hardship provisions. The first type of hardship program would allow small businesses to petition EPA for additional lead time (*e.g.*, up to 3 years) to comply with the standards. A small manufacturer would have to make the case that it has taken all possible business, technical, and economic steps to comply but the burden of compliance costs would have a significant impact on the company's solvency. A manufacturer would be required to provide a compliance plan detailing when and how it would achieve compliance with the standards.

Hardship relief could include requirements for interim emission reductions and/or purchase and use of emission credits. The length of the hardship relief decided during review of the hardship application would be up to one year, with the potential to extend the relief as needed. The second hardship program would allow companies to apply for hardship relief if circumstances outside their control cause the failure to comply (*i.e.*, supply contract broken by parts supplier) and if the failure to sell the subject vessels would have a major impact on the company's solvency. See the proposed regulatory text in 40 CFR 1068.240 and 1068.241 for additional details.

*H. Technological Feasibility*

We believe there are several strategies that manufacturers can use to meet our proposed evaporative emission standards. We have collected and will continue to collect emission test data on a wide range of evaporative emission control technology. The design-based certification levels discussed above are based on this test data and we may amend the list of approved designs and emission levels as more data become available.

1. Implementation Schedule

There are several strategies available to reduce evaporative emissions (diurnal and permeation) from marine fuel tanks. Some of these may require changes to the tank design, structure, and material that would cause a change in the molds used to make the plastic tanks. These molds need to be replaced periodically as part of normal manufacturing practices. Small manufacturers using rotational molding to produce plastic fuel tanks have commented that the molds covering the majority of their production line have about a five-year life before replacement. However, for the low-

production fuel tanks, they may use their molds for 10 to 15 years. They have stated that their costs would be greatly reduced if they could turn over fuel tank molds in a manner more consistent with their current business practice, rather than doing so solely in response to an evaporative control requirement.

We recognize that tank manufacturers and boat builders will need time to choose and implement the evaporative emission control strategies that work best for them. We believe the implementation date of 2008, coupled with the option for early banking, provides sufficient lead time beyond the anticipated publication of the final rule. This 5-year lead time is consistent with the general turnover schedule of most molds used in plastic fuel tank production. We request comment whether there are small entities whose product line is dominated by tanks for which the molds are turned over at a slower rate.

Surface treatments to reduce tank permeation are widely used today in other container applications and the technology and production facilities needed to conduct this process exist. While there is definitely value in an organized approach to compliance on the part of the manufacturers, the lead time requirement is largely driven by modifications needed to comply with the diurnal requirements. EPA requests comment on the feasibility of implementing the tank permeation requirement in 2006 or 2007.

Low permeation marine hose is used today on some vessels that is close to meeting the proposed standards. In addition, the development time for new hose designs is on the order of 1–2 years. Therefore, we request comment on whether an earlier implementation date for the proposed permeation standards for marine hoses would be appropriate. We are proposing an implementation date for hose permeation standards of 2008, consistent with the fuel tank standards, because hose fitting modifications may be required which could affect tank design. Manufacturers have commented that low permeation hoses require special connection fittings with better tolerances than seen on many fittings today. Automotive fuel lines also already exist that meet the proposed permeation standards. However, manufacturers have raised concerns with the cost of applying these less flexible fuel lines in marine applications. In any case, using these automotive fuel lines would probably also require fitting changes. EPA requests comment on the feasibility of implementing the hose permeation requirement in 2006 or 2007.

2. Standard Levels

We tested several diurnal emission-control strategies using the procedures discussed in VI.D.1. Based on this testing we believe there are several emission-control technologies that could be used to significantly reduce diurnal emissions. Also, we have identified several strategies for reducing permeation emissions from fuel tanks and hoses. We recognize that some of these technologies may be more desirable than others for some manufacturers, and we recognize that different strategies for equal emission reductions may be better for different applications. Specific examples of technology that could be used to meet the proposed standards would be fuel tank with a 1 psi valve in the vent, a fluorinated plastic fuel tank, and hose constructed with a thermoplastic barrier. We present several other technological approaches below.

3. Technological Approaches

We believe several emission-control technologies can be used to reduce evaporative emissions from marine fuel tanks. In addition, there are a few technologies that are used in other applications that may not be as effective here. The advantages and disadvantages of various emission-control strategies are discussed below. Chapter 4 of the Draft Regulatory Support Document presents more detail on these technologies and Chapter 5 provides information on the estimated costs.

a. Closed fuel vent with pressure relief. Evaporative emissions are formed when the fuel heats up, evaporates, and passes through the vent into the atmosphere. By closing that vent, evaporative emissions are prevented from escaping. However, as vapor is generated, pressure builds up in fuel tank. Once the fuel cools back down, the pressure subsides.

The U.S Coast Guard safety regulations (33 CFR part 183) require that fuel tanks be able to withstand pressure up to 3 psi and must be able to pass a pressure-impulse test which cycles the tank from 0 to 3 psi 25,000 times. The Coast Guard also requires that these fuel tanks be vented such that the pressure in the tank in-use never exceeds 80 percent of the pressure that the tank is designed to withstand without leaking. The American Boat and Yacht Council makes the additional recommendation that the vent line should have a minimum inner diameter of 7/16 inch (H–24.13). However, these recommended practices also note that ''there may be EPA or state regulations that limit the discharge of hydrocarbon emissions into the atmosphere from gasoline fuel systems. The latest version of these regulations should be consulted.''

To prevent pressure from building too high, we first considered a 2 psi pressure-relief valve. This is a typical automotive rating and is within the Coast Guard requirements. With this valve, vapors would be retained in the tank until 2 psi of pressure is built up in the tank due to heating of the fuel. Once the tank pressure reached 2 psi, just enough of the vapor would be vented to the atmosphere to maintain 2 psi of pressure.

As the fuel cooled, the pressure would decrease. We estimate that this would achieve about a 55-percent reduction in evaporative emissions over the proposed test procedure. A 1 psi valve would achieve a reduction of about half of this over the proposed test procedure. However, in use, this reduction could be much greater because the test procedure is designed to represent a hotter than average day. On a more mild day there could be less pressure buildup in the tank and the valve may not even need to open.

As discussed in Chapter 4 of the draft RSD, we tested fuel tanks for diurnal emissions with pressure relief valves ranging from 0.4 to 2.2 psi.

With the use of a sealed system, a low-pressure vacuum-relief valve would also be necessary so air could be drawn into the tank to replace fuel drawn from the tank when the engine is running.

Manufacturers of plastic fuel tanks have expressed concern that their tanks are not designed to operate under pressure. For instance, although they will not leak at 3 psi, rotationally molded fuel tanks with large flat surfaces could begin deforming at pressures as low as 0.5 psi. At higher pressures, the deformation would be greater. This deformation would affect how the tank is mounted in the boat. Also, fuel tank manufacturers commented that some of the fittings or valves used today may not work properly under even 2 psi of pressure. Finally, they commented that backup pressure-relief valves would be necessary for safety.

We believe that, with enough lead time, fuel tank manufacturers will be able to redesign their fuel tanks to be more resistant to deformation under pressure. By reducing the size of flat areas on the tank through adding contours to the tank, or by increasing the thickness of the tank walls, the fuel tanks can be designed to resist deformation under pressure. Portable

plastic fuel tanks are generally sealed without any pressure relief and are designed to withstand any pressure that may occur under these conditions. We also believe that if certain fittings and valves cannot withstand pressure today, they can be designed to do so. In addition, we are proposing a standard which can be met with a 1 psi valve which we believe would require significantly less modification to current tanks than designing for 3 psi of pressure. In developing this level we considered first 2.0 psi valves which is consistent with on-highway fuel tanks and is below the Coast Guard tank pressure requirement. However, we proposed a standard based on a 1.0 psi pressure relief valve to give manufacturers some margin to minimize fuel tank deflection under pressure. Although we do not consider this to be a feasibility issue, we recognize that if the tank were to deflect too much in-use that either the fuel tank compartment would have to be enlarged to accommodate this expansion or a smaller fuel tank would need to be used. We request comment on this issue.

Below, we discuss strategies that could be used in conjunction with a sealed system to minimize the build-up of pressure in the fuel tank. Such technologies are insulation, volume-compensating air bags, and bladder fuel tanks. With the use of these technologies, the same emission reductions could be achieved with a pressure-relief valve set to allow lower vent pressures. Finally the structure of the proposed standards gives manufacturers the flexibility to meet the emission limits without building up pressure in the fuel tank.

b. Limited flow orifice. An alternative to using a pressure-relief valve to hold vapors in the fuel tank would be to use a limited-flow orifice. This would essentially be a plug in the vent line with a pin hole in it that would be small enough to limit vapor flow out of the fuel tank. However, the orifice size may be so small that there would be a risk of fouling. In addition, an orifice designed for a maximum of 2 psi under worst-case conditions may not be very effective at lower temperatures. We tested a 17-gallon tank with a 75-micron diameter limited-flow orifice over the proposed diurnal test procedure and saw close to a 25 percent reduction in diurnal emissions. The peak pressure in this test was 1.6 psi.

c. Insulated fuel tank. Another option we evaluated was insulating either the fuel tank or the compartment around the fuel tank. Rather than capturing the vapors in the fuel tank, we minimize the fuel heating, which therefore minimizes the vapor generation. This could be used in conjunction with a limited-flow orifice to reduce the loss of vapor through the vent line due to diffusion. Our test data suggest that a 50-percent reduction in emissions over the proposed test procedure can be achieved using insulation with an R-value of 15.[28] However, it should be noted that today's fuel tanks, when installed in boats, have some amount of ''inherent insulation.'' This is especially true for boats that remain in the water. This inherent insulation is considered in our baseline emission factors. Additional control could be achieved with the use of a pressure-relief valve coupled with an insulated tank. Note that an insulated tank could maintain the same emission control while using a pressure-relief valve that allowed lower peak pressures, compared with a tank that was not insulated.

The method of insulation would have to be consistent with U.S. Coast Guard fuel system requirements. These requirements regulate the resistance to fuels, oils and other chemicals, water adsorption, compressive strength, and density of foam used to encase fuel tanks. In addition, the Coast Guard requirements protect against corrosion of metal fuel tanks due to foam pulling away from the fuel tank causing water to be trapped or from improper drainage. There are several methods that could be used to insulate the fuel tank while maintaining safe practices. These methods include an insulation barrier within the walls of the fuel tank, insulating the compartment that the tank is in rather than the tank itself, and foaming the tank in place by filling the entire compartment the tank is in. The Coast Guard requirements and potential insulation strategies are discussed further in Chapter 3 of the Draft Regulatory Support Document.

d. Volume-compensating air bag. Another concept for minimizing pressure in a sealed fuel tank is through the use of a volume-compensating air bag. The purpose of the bag is to fill up the vapor space in the fuel tank above the fuel. By minimizing the vapor space, the equilibrium concentration of fuel vapors occupies a smaller volume, resulting in a smaller mass of vapors. As the equilibrium vapor concentration increases with increasing temperature, the vapor space expands, which forces air out of the bag through the vent to atmosphere. Because the bag volume decreases to compensate for the expanding vapor space, total pressure inside the fuel tank stays very close to atmospheric pressure.[29] Once the fuel tank cools as ambient temperature goes down, the resulting vacuum in the fuel tank will make the bag expand again by drawing air from the surrounding ambient. Our test results showed that pressure could be kept below 0.8 psi using a bag with a capacity equal to 25 percent of the fuel tank capacity. Therefore, the use of a volume-compensating air bag could allow a manufacturer to reduce the pressure limit on its relief valve.

We are still investigating materials that would be the most appropriate for the construction of these bags. The bags would have to hold up in a fuel tank for several years and resist permeation, while at the same time being light and flexible. One such material we are considering is fluorosilicon fiber. Also, the bag would have to be positioned to avoid interfering with other fuel system components such as the fuel pick-up or catching on any sharp edges in the fuel tank. We estimate that this would be more expensive than using a pressure relief valve with some reinforcement of the fuel tank for pressure; however, it is also more effective at emission control and would minimize pressure in the fuel tank.

e. Bladder fuel tank. Probably the most effective technology for reducing diurnal emissions from marine fuel tanks is through the use of a collapsible fuel bladder. In this concept, a low permeation bladder is installed in the fuel tank to hold the fuel. As fuel is drawn from the bladder, the vacuum created collapses the bladder. Therefore, there is no vapor space and no pressure build up from fuel heating. Because the bladder is sealed, there would be no vapors vented to atmosphere. This option could also significantly reduce emissions during refueling that would normally result from dispensed fuel displacing vapor in the fuel tank. We have received comments that this would be cost-prohibitive because it could increase costs from 30 to 100 percent depending on tank size. However, bladder fuel tanks have positive safety implications as well and are already sold by at least one manufacturer to meet market demand in niche applications.

f. Charcoal canister. The primary evaporative emission-control device used in automotive applications is a charcoal canister. With this technology, vapor generated in the tank is vented through a charcoal canister. The

[28] R-value measures resistance to heat flow and is defined in 16 CFR 460.5.

[29] The Ideal Gas Law states that pressure and volume are inversely related. By increasing the volume of the vapor space, the pressure can be held constant.

activated charcoal collects and stores the hydrocarbons. Once the engine is running, purged air is drawn through the canister and the hydrocarbons are burned in the engine. These charcoal canisters generally are about a liter in size and have the capacity to store three days of vapor over the test procedure conditions. This technology does not appear to be attractive for marine fuel tanks because boats may sit for weeks at a time without the engine running. Once the canister is saturated, it provides no emission control.

g. Floating fuel and vapor separator. Another concept used in some stationary engine applications is a floating fuel and vapor separator. Generally small, impermeable plastic balls are floated in the fuel tank. The purpose of these balls is to provide a barrier between the surface of the fuel and the vapor space. However, this strategy does not appear to be effective for marine fuel tanks. Because of the motion of the boat, the fuel sloshes and the barrier would be continuously broken. Even small movements in the fuel could cause the balls to rotate and transfer fuel to the vapor space. In addition, the unique geometry of many fuel tanks could cause the balls to collect in one area of the tank.

h. Low permeability fuel tanks. We estimate that more than a quarter of the evaporative emissions from boats with plastic fuel tanks come from permeation through the walls of the fuel tanks. In highway applications, non-permeable plastic fuel tanks are produced by blow molding a layer of ethylene vinyl alcohol or nylon between two layers of polyethylene. However, blow molding has high fixed costs and therefore requires high production volumes to be cost effective. For this reason, this manufacturing technique is generally only used for portable fuel tanks which are generally produced in higher volumes. For these tanks, however, multi-layer fuel tank construction may be an inexpensive and effective approach to controlling permeation emissions

Manufacturers of rotationally molded plastic fuel tanks generally have low production volumes and have commented that they could not produce their tanks with competitive pricing in any other way. Currently, they use cross-link polyethylene which is a low density material that has relatively high rate of permeation. One material that could be used as a low permeation alternative in the rotational molding process is nylon. The use of nylon in the construction of these fuel tanks would reduce permeation by more than 95 percent when compared to cross-link polyethylene such as is used today.

Another type of barrier technology for fuel tanks would be to treat the surfaces of a plastic fuel tanks with fluorine. The fluorination process causes a chemical reaction where exposed hydrogen atoms are replaced by larger fluorine atoms which a barrier on surface of the fuel tank. In this process, fuel tanks are be stacked in a steel container. The container is then be voided of air and flooded with fluorine gas. By pulling a vacuum in the container, the fluorine gas is forced into every crevice in the fuel tanks. As a result of this process, both the inside and outside surfaces of the fuel tank would be treated. As an alternative, for tanks that are blow molded, the inside surface of the fuel tank can be exposed to fluorine during the blow molding process. A similar barrier strategy is called sulfonation where sulfur trioxide is used to create the barrier by reacting with the exposed polyethylene to form sufonic acid groups on the surface. Either of these processes can be used to reduce gasoline permeation by more than 95 percent. Achieving reductions at this level repeatedly would require tanks with consistent material quality, amount, and composition including pigments and any additive packages. This would enable process and efficiency optimization and consistency in the effectiveness of surface treatment processes.

Over the first month or so of use, polyethylene fuel tanks can expand by as much as three percent due to saturation of the plastic with fuel. Manufacturers have raised the concern that this hydrocarbon expansion could affect the effectiveness of surface treatments like fluorination or sulfonation. We believe that this will not have a significant effect on the effectiveness of these surface treatments. The California Air Resources Board has performed extensive permeation testing on portable fuel containers with and without these surface treatments. Prior to the permeation testing, the tanks were prepared by first performing a durability procedure where the fuel container is cycled a minimum of 1000 times between 5 psi and -1 psi. In addition, the fuel containers are soaked with fuel for a minimum of four weeks prior to testing. Their test data, presented in Chapter 4 of the draft RSD, show that fluorination and sulfonation are still effective after this durability testing.

The U.S. Coast Guard has raised the issue that any process applied to marine fuel tanks to reduce permeation would also need to pass Coast Guard flame resistance requirements. We are not aware of any reason that a fluorination or sulfonation surface treatment would affect the flame resistance of a marine fuel tank. Since this issue was raised, we contracted to have a fluorinated fuel tank tested. This tank passed the U.S. Coast Guard flame resistance test.

Also, about a third of marine fuel tanks used today are made of aluminum. Hydrocarbons do not permeate through aluminum.

We request comment on the low-permeable materials and strategies discussed above, and other options that are available, for use in marine fuel tanks and on their cost and effectiveness.

i. Low permeability hoses. We also estimate that permeation through fuel and vapor hoses make up more 40 percent of the evaporative emissions from boats. This fraction is higher for boats using aluminum fuel tanks, because they are inherently low in tank permeation emissions. By replacing rubber hoses with low permeability hoses, evaporative emissions through the fuel supply and vent hoses can be reduced by more than 95 percent.

Marine fuel hoses are designated as either Type A or B and eitherClass 1 or 2.[30] Type A hose passes the U.S. Coast Guard fire test while Type B represents hose that has not passed this test. Class 1 hose is intended for fuel feed lines where the hose is normally in contact with fuel and has a permeation limit of 100 g/m2/day at 23°C. Class 2 hose is intended for vent lines and fuel fill necks where fuel is not continuously in contact with the hose and has a permeation limit of 300 g/m2/day at 23°C. In general practice, most boat builders use Class 1 hose for vent lines as well as fuel lines to prevent having to carry two hose types. However, most fuel fill necks, which have a much larger diameter and are constructed differently, are Class 2 hose. Marine hose with permeation rates of less than one tenth of the Class 1 permeation limit is also used by some boat builders today for fuel and vent lines. Given sufficient lead time, we believe that hose manufacturers can modify their designs to use thicker barriers or lower permeating materials to further reduce the permeation rates from this hose.

Low permeability fuel supply and vent hoses produced today are generally constructed in one of two ways: either with a low permeability layer or by using a low permeability rubber blend. One hose design, already used in some marine applications, uses a

[30] Society of Automotive Engineers Surface Vehicle Standard, ''Marine Fuel Hoses,'' SAE J 1527 (Docket A–2000–01; document IV–A–19).

thermoplastic layer between two rubber layers to control permeation. This thermoplastic barrier may either be nylon or ethyl vinyl acetate. In automotive applications, other barrier materials are used such as fluoroelastomers and fluoroplastics such as Teflon®. An added benefit of low permeability lines is that some fluoropolymers can be made to conduct electricity and therefore can prevent the buildup of static charges. Currently, fuel fill necks used in marine applications generally are not made with barrier layers and permeate more than fuel supply lines. However, hoses are produced for chemical applications by the same companies, using the same process, that include barrier layers. This same production methodology could be used for marine fuel hoses. Also, EPA also expects low permeability fill neck hoses to be used in automotive applications in the 2004 as a result of the Tier 2 motor vehicle evaporative emission standards.

An alternative approach to reducing the permeability of marine hoses would be fluorination. This process would be performed in a manner similar to discussed above for fuel tanks.

Fuel lines used to meet the proposed standards would also have to meet Coast Guard specifications in 33 CFR 183 which include a flame resistance test. Although the automotive standard, SAE J 2260, does not specifically include a flame resistance test like that included in the Coast Guard specifications, manufacturers generally design (and test) their hoses to be flame resistant.

4. Summary

EPA believes that the proposed standards for evaporative emissions from boats using spark-ignition marine engines reasonably reflect what manufacturers can achieve through the application of available technology. Marine fuel tank manufacturers and boat builders will need to use the five years of lead time to select, design, and produce evaporative emission-control strategies that will work best for their product line. We expect that meeting these requirements will pose a challenge, but one that is feasible taking into consideration the availability and cost of technology, lead time, noise, energy, and safety. The role of these factors is presented in detail in Chapters 3 and 4 of the draft RSD.

We believe there are several options that can be used to reduce diurnal emissions from marine fuel tanks. This, coupled with the proposed emission-credit program for diurnal emissions, gives manufacturers flexibility in how they choose to comply with the proposed standards. We believe the most likely approach meeting the proposed emission diurnal standard will be for manufacturers to use a closed vent with a 1 psi pressure relief valve. Although we evaluated several technologies that have the potential to achieve larger emission reductions, we believe that more stringent standards are not appropriate at this time. This industry is primarily made up of small manufacturers and would likely need more time to develop technology options for further emission control. In addition, there are a wide range of fuel tank designs and applications in the recreational marine market, and the technologies discussed above may not be appropriate for all applications. Given these issues, and U.S. Coast Guard requirements, we believe that the flexibility given in the proposed diurnal requirements is appropriate.

The proposed permeation standards are based on the effective application of low permeable materials or surface treatments. This is essentially a step change in technology; therefore, we believe that even if we were to propose a less stringent permeation standard, these technology options would likely still be used. In addition, this technology is relatively inexpensive and can achieve meaningful emission reductions. The proposed standards are expected to achieve a 95 percent reduction in permeation emissions from marine fuel tanks and hoses. We believe that more stringent standards could result in significantly more expensive materials without large additional emission reduction. We request comment on our proposed permeation emission standards.

## IV. Sterndrive and Inboard Marine Engines

This section describes our current thinking regarding exhaust emissions from sterndrive and inboard marine engines (SD/I). We are not proposing SD/I exhaust emission standards at this time. We are investigating whether the application of catalysts on marine engines could be a cost-effective way to control emissions. We believe, that setting catalyst-forcing standards now would be premature, given the open issues related to catalyst use in the marine environment. However, we are continuing our efforts to develop and demonstrate catalytic control on SD/I marine engines in the laboratory and in-use, and will place new information in the docket when it is available. In fact, we intend to follow with another rulemaking in the future that will address exhaust emissions from SD/I engines once we have collected more information. We intend to include outboards and personal watercraft in this rulemaking as well.

There are three primary approaches that we believe could be used to reduce exhaust emissions from sterndrive and inboard marine engines. The first is through lower emission calibration of the engine, especially through the use of electronic fuel injection. This could be implemented quickly, but would only result in small emission reductions. The second approach would be through the use of exhaust gas recirculation (EGR) which could be used to get a 40 to 50-percent reduction in $NO_X$. Although this would be feasible, it would not be nearly as effective at controlling emissions as the third approach of using catalytic control. We believe catalytic control could be used to achieve much larger emission reductions than either of the first two approaches; therefore, we intend to implement catalyst-based standards as soon as we believe it is feasible. We believe we can implement these stringent standards sooner if we do not set an interim standard based on EGR. Manufacturers have raised concerns that if they were to focus on designing for an EGR-based standard, it would divert resources needed for catalyst development.

We are in the process of resolving technical issues with the use of catalysts in a marine environment. Ongoing testing has shown promising results; we believe that, in the near future, continued efforts will resolve the remaining issues raised by the marine industry and by Coast Guard. One issue is that operation in the marine environment could result in unique durability problems for catalysts. Another issue to be addressed in developing this technology is ensuring that salt water does not reach the catalyst so that salt does not accumulate on the catalyst and reduce its efficiency. A third issue is addressing any potential safety concerns.

As discussed in Section I.F, California ARB has recently put into place $HC+NO_X$ exhaust emission standards for SD/I marine engines. These standards include a cap on baseline emission levels in 2003 followed by catalyst-forcing standards (5 g/kW-hr $HC+NO_X$) phased in from 2007 through 2009. These standards are contingent on technology reviews in 2003 and 2005. ARB and industry have agreed on a catalyst development program for marine engines over the next several years. We will participate in and monitor catalyst development efforts for marine engines over the next few years.

Since the ANPRM, we have collected laboratory emission data on a SD/I

marine engine through a joint effort with ARB, engine marinizers, and Southwest Research Institute.[31] We collected baseline emission data as well as emission data from closed-loop control, exhaust gas recirculation, and several catalyst concepts. This work included catalyst packaging strategies designed to prevent water reversion to the catalyst. With the combination of closed-loop electronic control and EGR, we saw a reduction of 22 percent $HC+NO_X$ and 39 percent CO from baseline. A catalyst was placed in a stock riser extension which resulted in a 74-percent reduction in $HC+NO_X$ and 46-percent reduction in CO from baseline. Other catalyst configurations were also tested with varying emissions reductions depending on their design.

In the testing discussed above, the 74 percent reduction in $HC+NO_X$ was achieved using a two catalysts with a combined volume of less than 1.5 liters on a SD/I engine with a 7.4 liter total engine displacement. SD/I marine engines sold today generally range from 3.0 to 8.1 liters of total cylinder displacement. A smaller engine would need less catalyst volume for the same emissions reduction. Further information on the emission reductions associated with SD/I emission control strategies and associated costs will be included in future rulemaking documents.

As discussed above, we are working with the marine industry, ARB, and Coast Guard on technology assessment of catalytic converters on sterndrive and inboard marine engines. However, we do not believe this technology has been sufficiently demonstrated for us to set national standards based on implementation of catalyst technology at this time. We will also need to consider other factors such as cost and energy impacts in determining appropriate levels of standards.

As we work towards low emission marine engines through catalyst technology for SD/I we also intend to investigate this technology for use on outboards and personal watercraft (OB/PWC). We believe many of the same issues with applying catalysts to SD/I marine engines also apply to OB/PWC marine engines. In addition, the annual emissions contribution of OB/PWC marine is several times larger than the contribution from SD/I marine engines so there is the potential for significant additional reductions from OB/PWC. Therefore, we intend to look into the feasibility and cost effectiveness of applying catalytic control to outboards and personal watercraft as well.

Manufacturers have argued that the development effort required for EGR may detract resources from catalyst development. We are sensitive to this issue and are not proposing EGR-based standards at this time as it could ultimately slow industry's ability to meet catalyst-based standards. Clearly, the greatest potential for emission reductions is through the use of catalysts and we wish to implement standards as soon as feasible. However, if it were to become apparent that catalysts would not be feasible for SI marine engines in the time frame of the California ARB technology reviews, we would contemplate proposal of a standard based on EGR. EGR has been used in automotive applications for decades and we believe there are no significant technical hurdles for applying this inexpensive technology to marine engines. Although current marine engines do not generally have a port for exhaust gas recirculation, the electronic fuel injection systems are capable of controlling an EGR valve and control feedback loop. Given enough lead time, we believe manufacturers could apply this technology effectively on SI marine engines.

We request comment on the feasibility of applying electronic fuel injection, exhaust gas recirculation, catalysts, or other technology that could be used to reduce emissions from SI marine engines. We also request comment on the costs and corresponding potential emission reductions from using these technologies, as well as any potential effects on engine performance, safety, and durability.

## V. Highway Motorcycles

We are proposing revised exhaust emission standards for highway motorcycles. This section includes background material, a description of the proposed standards and other important provisions, and a discussion of the technological feasibility of the proposed standards.

### *A. Overview*

In general, we are proposing to harmonize the federal exhaust emission standards for all classes of motorcycles with those of the California program, but on a delayed schedule relative to implementation in California. For Class I and Class II motorcycles, this would mean meeting exhaust emission standards that apply today in California. For Class III motorcycles, this would mean meeting the two tiers of exhaust emission standards that California ARB has put in place for future model years. The existing federal CO standard of 12.0 g/km would remain unchanged. The process by which manufacturers certify their motorcycles, the test procedures, the driving cycle, and other elements of the federal program would also remain unchanged. We are also proposing standards for the currently unregulated category of motorcycles with engines of less than 50cc displacement.

#### 1. What Are Highway Motorcycles and Who Makes Them?

Motorcycles come in a variety of two- and three-wheeled configurations and styles. For the most part, however, they are two-wheeled, self-powered vehicles. EPA regulations currently define a motorcycle as ''any motor vehicle with a headlight, taillight, and stoplight and having: two wheels, or three wheels and a curb mass less than or equal to 793 kilograms (1749 pounds)'' (See 40 CFR 86.402–98). Both EPA and California regulations sub-divide highway motorcycles into classes based on engine displacement. Table V.A–1 below shows how these classes are defined.

TABLE V.A–1.—MOTORCYCLE CLASSES

| Motorcycle class | Engine displacement (cubic centimeters) |
|---|---|
| Class I | 50*–169 |
| Class II | 170–279 |
| Class III | 280 and greater |

*This proposal would extend Class I to include <50cc.

It is important to note that this definition excludes off-highway motorcycles from the regulatory definition of motorcycle. This is because the term ''motor vehicle,'' as used in the Act, applies only to vehicles ''designed for transporting persons or property on a street or highway'' (CAA section 216). In addition, EPA has promulgated regulations, in 40 CFR 85.1703, that elaborate on the Act's definition of motor vehicles and set forth three criteria, which, if any one is met, would cause a vehicle not to be considered a motor vehicle under the regulations, and therefore not subject to requirements applicable to motor vehicles. These criteria are:

(1) The vehicle cannot exceed a maximum speed of 25 miles per hour over a level paved surface; or

(2) The vehicle lacks features customarily associated with safe and practical street or highway use, including such things as a reverse gear (except motorcycles), a differential, or

[31] Carroll, J., White, J., ''Marine Gasoline Engine Testing,'' Prepared by Southwest Research Institute for the Environmental Protection Agency and the California Air Resources Board, EPA Contract 68–C–98–169, WA 2–11, September 2001 (Docket A–2000–01; document IV–A–91).

safety features required by state and/or Federal law; or

(3) The vehicle exhibits features which render its use on a street or highway unsafe, impractical, or highly unlikely, including tracked road contact means, an inordinate size, or features ordinarily associated with military combat or tactical vehicles such as armor and/or weaponry.

Thus, vehicles not meeting the criteria noted above are not covered by the proposed emission standard for motorcycles, because they fail to meet the definition of motor vehicle in the Clean Air Act and in 40 CFR 85.1703. Vehicles that are not considered to be a motor vehicle under these statutory and regulatory provisions are generally considered under the Clean Air Act to be nonroad vehicles. In an earlier proposal, we discussed proposed emission standards for nonroad recreational vehicles, a category which includes off-highway motorcycles (66 FR 51098, October 5, 2001). Also falling into the nonroad definition category are the mopeds and scooters that do not meet the definition of ''motor vehicle,'' *i.e.,* the smaller cousins of the mopeds and scooters that are currently considered highway motorcycles and certified as Class I motorcycles. In other words, if a moped or scooter or similar ''motorbike'' cannot exceed 25 miles per hour, it is not considered a motor vehicle, but it is instead categorized as a nonroad recreational vehicle and would be subject to the emission standards recently proposed for off-highway motorcycles.

Furthermore, vehicles that otherwise meet the motorcycle definition (*i.e.,* are highway motorcycles as opposed to off-highway motorcycles) but have engine displacements less than 50 cubic centimeters (cc) (generally, youth motorcycles, most mopeds, and some motor scooters) are currently not required to meet EPA standards. Also currently excluded are motorcycles which, ''with an 80 kg (176 lb) driver, * * * cannot: (1) Start from a dead stop using only the engine; or (2) Exceed a maximum speed of 40 km/h (25 mph) on level paved surfaces'' (*e.g.,* some mopeds). Most scooters and mopeds have very small engine displacements and are typically used as short-distance commuting vehicles. Motorcycles with larger engine displacement are more typically used for recreation (racing or touring) and may travel long distances.

The currently regulated highway category includes motorcycles termed ''dual-use'' or ''dual-sport,'' meaning that their designs incorporate features that enable them to be competent for both street and nonroad use. Dual-sport motorcycles generally can be described as street-legal dirt bikes, since they often bear a closer resemblance in terms of design features and engines to true off-highway motorcycles than to highway cruisers, touring, or sport bikes. These dual-sport motorcycles tend to fall in Class I or Class II.

The larger displacement Class III motorcycles are by far the most common motorcycles in the current U.S. market. Of the 175 engine 2002 families certified as of January 2002 by manufacturers for sale in the U.S., 151 fall in the Class III category, representing more than 93 percent of projected sales. Most of these are quite far from the bottom limit of Class III motorcycles (280cc); more than three-quarters of projected 2002 highway motorcycle sales are above 700cc, with engine displacements exceeding 1000cc for the most powerful ''superbikes,'' large cruisers, and touring bikes. The average displacement of all certified engine families is about 980cc, and the average displacement of certified Class III engine families is above 1100cc. The sales-weighted average displacement of 2002 highway motorcycles is about 1100cc. Class I and Class II motorcycles, which together make up less than seven percent of projected 2002 sales and only 24 out of 175 certified 2002 engine families, consist mostly of dual-sport bikes, scooters, and entry-level sportbikes and cruisers.

According to the Motorcycle Industry Council, in 1998 there were about 5.4 million highway motorcycles in use in the United States (565,000 of these were dual-sport). Total sales in 1999 of highway motorcycles was estimated to be about 387,000, or about 69 percent of motorcycle sales. About 15,000 of these were dual-sport motorcycles.[32] Recent figures for the 2000 calendar year show that retail sales approached 438,000 highway motorcycles, about 19,000 of which were dual-sport bikes.[33]

Six companies account for about 95 percent of all motorcycles sold (Honda, Harley Davidson, Yamaha, Kawasaki, Suzuki, and BMW). All of these companies except Harley-Davidson and BMW also manufacture off-highway motorcycles and ATVs for the U.S. market. Harley-Davidson is the only company of these six that is manufacturing highway motorcycles in the U.S. for the domestic market. Dozens of other companies make up the remaining five percent. Many of these are small U.S. companies manufacturing anywhere from a few dozen to a few thousand motorcycles, although importers and U.S. affiliates of larger international companies also contribute to the remaining five percent. See the draft Regulatory Support Document for more information regarding the makeup of the industry.

As of the 2002 model year, all highway motorcycles with engines greater than 50cc displacement are powered by four-stroke engines. (Prior to the 2002 model year, Kawasaki was certifying a 100cc two-stroke dual-sport motorcycle to the federal emission standards.) In the scooter and moped segment with engines under 50cc displacement, two-stroke engines have traditionally outnumbered four-strokes, although that appears to be changing. In particular, Honda is now marketing a 2002 49cc four-stroke scooter. Of the several dozen manufacturers in the under 50cc market, about a third are offering four-stroke engines. Therefore, as of the 2002 model year, it appears that about one third of the sales of scooters and mopeds under 50cc are powered by four-stroke engines.

2. What Is the History of Emission Regulations for Highway Motorcycles?

Emissions from highway motorcycles have been regulated for more than 20 years. While the federal requirements have remained unchanged since the initial standards were adopted more than 20 years ago, regulations in California, Europe, and many nations around the world have been periodically updated to reflect the availability of technology and the need for additional emission reductions.

a. EPA regulations. In 1977 EPA issued a Final Rule (42 FR 1126, Jan. 5, 1977), which established interim exhaust emission standards effective for the 1978 and 1979 model years and ultimate standards effective starting with the 1980 model year. The interim standards ranged from 5.0 to 14.0 g/km HC depending on engine displacement, while the CO standard of 17.0 g/km applied to all motorcycles. The standards and requirements effective for 1980 and later model year motorcycles, which do not include $NO_X$ emission standards, remain in effect today. While the final standards did not differ based on engine displacement, the useful life over which these standards must be met ranged from 12,000 km (7,456 miles) for Class I motorcycles to 30,000 km (18,641 miles) for Class III motorcycles. Crankcase emissions from motorcycles have also been prohibited since 1980. There are no current federal standards for evaporative emissions from

[32] ''2000 Motorcycle Statistical Annual'', Motorcycle Industry Council (Docket A–2000–01; document II–D–192).

[33] DealerNews, volume 37, no. 2, February 2001 (Docket A–2000–01; document II–D–190).

motorcycles. The current federal standards are shown in Table V.A–2.

TABLE V.A–2.—CURRENT FEDERAL EXHAUST EMISSION STANDARDS FOR MOTORCYCLES

| Engine size | HC (g/km) | CO (g/km) |
|---|---|---|
| All | 5.0 | 12.0 |

b. California ARB regulations. Motorcycle exhaust emission standards in California were originally identical to the federal standards that applied to 1978 through 1981 model year motorcycles. The definitions of motorcycle classes used by California ARB continue to be identical to the federal definitions. However, California ARB has revised its standards several times in bringing them to their current levels (see Table V.A–3). In the 1982 model year the standards were modified to tighten the HC standard from 5.0 g/km to 1.0 or 1.4 g/km, depending on engine displacement. California adopted an evaporative emission standard of 2.0 g/test for all three motorcycle classes for 1983 and later model year motorcycles. California later amended the regulations for 1988 and later model year motorcycles to further lower emissions and to make the compliance program more flexible for manufacturers. The 1988 and later standards could be met on a corporate-average basis, and the Class III bikes were split into two separate categories: 280 cc to 699 cc and 700 cc and greater. These are the standards that apply in California now. Like the federal standards, there are currently no limits on $NO_X$ emissions for highway motorcycles in California. Under the corporate-average scheme, no individual engine family is allowed to exceed a cap of 2.5 g/km HC. Like the federal program, California also prohibits crankcase emissions.

TABLE V.A–3.—CURRENT CALIFORNIA HIGHWAY MOTORCYCLE EXHAUST EMISSION STANDARDS

| Engine size (cc) | HC (g/km) | CO (g/km) |
|---|---|---|
| 50–279 | 1.0 | 12.0 |
| 280–699 | 1.0 | 12.0 |
| 700 and above | 1.4 | 12.0 |

In November 1999, California ARB adopted new exhaust emission standards for Class III motorcycles that would take effect in two phases__Tier 1 standards starting with the 2004 model year, followed by Tier 2 standards starting with the 2008 model year (see Table V.A–4). Existing California standards for Class I and Class II motorcycles, which have been in place since 1982, remain unchanged, as does their evaporative emissions standard. As with the current standards in California, manufacturers will be able to meet the requirements on a corporate-average basis. Perhaps most significantly, California ARB's Tier 1 and Tier 2 standards control $NO_X$ emissions for the first time by establishing a combined $HC+NO_X$ standard. California ARB made no changes to the CO emission standard, which remains at 12.0 g/km, equivalent to the existing federal standard. In addition, California ARB is providing an incentive program to encourage the introduction of Tier 2 motorcycles before the 2008 model year. This incentive program allows the accumulation of emission credits that manufacturers can use to meet the 2008 standards. Like the federal program, these standards will also apply to dual-sport motorcycles.

TABLE V.A–4.—TIER 1 AND TIER 2 CALIFORNIA CLASS III HIGHWAY MOTORCYCLE EXHAUST EMISSION STANDARDS

| Model year | Engine displacement | $HC+NO_X$ (g/km) | CO (g/km) |
|---|---|---|---|
| 2004 through 2007 (Tier 1) | 280 cc and greater | 1.4 | 12.0 |
| 2008 and subsequent (Tier 2) | 280 cc and greater | 0.8 | 12.0 |

California ARB also adopted a new definition of small-volume manufacturer that will take effect with the 2008 model year. Currently and through the 2003 model year, all manufacturers must meet the standards, regardless of production volume. Small-volume manufacturers, defined in California ARB's recent action as a manufacturer with California sales of combined Class I, Class II, and Class III motorcycles not greater than 300 units annually, do not have to meet the new standards until the 2008 model year, at which point the Tier 1 standard applies. California ARB intends to evaluate whether the Tier 2 standard should be applied to small-volume manufacturers in the future.[34]

c. International regulations. The European Commission (EC) recently finalized a new phase of motorcycle standards, which will start in 2003, and the EC intends a second phase to start in 2006. Whereas the current European standards make a distinction between two-stroke and four-stroke engines, the proposed standards would apply to all motorcycles regardless of engine type. The 2003 standards would require emissions to be below the values shown in Table V.A–5, as measured over the European ECE–40 test cycle.[35] The standards considered for 2006 are still in a draft form and have not yet been officially proposed, but the expectation is that they will be considerably more stringent. In addition to taking another step in reducing motorcycle emissions, the 2006 standards may incorporate an improved motorcycle test cycle, as noted below. The standards in the following table apply to motorcycles of less than 50cc (*e.g.,* scooters and mopeds) only if the motorcycle can exceed 45 kilometers per hour (28 miles per hour). Starting in 2002 motorcycles of less than 50cc that cannot exceed 45 kilometers per hour (28 miles per hour) are subject to a new $HC+NO_X$ standard of 1.2 grams per kilometer and a CO standard of 1.0 gram per kilometer.

TABLE V.A–5.—EUROPEAN COMMISSION 2003 MOTORCYCLE EXHAUST EMISSION STANDARDS

| HC (g/km) | CO (g/km) | $NO_X$ (g/km) |
|---|---|---|
| 1.2 | 5.5 | 0.3 |

Many other nations around the world, particularly in South Asia where two-stroke mostly small displacement motorcycles can be a majority of the vehicle population, have also recently improved their emission standards or are headed that way in the next several years. For example, Taiwan has adopted an $HC+NO_X$ standard of 1.0 gram per

[34] California ARB, October 23, 1998 ''Proposed Amendments to the California On-Road Motorcycle Regulation'' Staff Report: Initial Statement of Reasons (Docket A–2000–01; document II–D–12).

[35] The ECE–40 cycle is used by several countries around the world for motorcycle emission testing. It has its origins in passenger car driving, being derived from the European ECE–15 passenger car cycle. The speed-time trace is simply a combination of straight lines, resulting in a ''modal'' cycle, rather than the transient nature of the U.S. Federal Test Procedure (FTP).

kilometer for all two-strokes starting in 2003 (as tested on the European ECE–40 test cycle). (Four-stroke motorcycle engines will have to meet at standard of 2.0 grams per kilometer.) India has proposed a standard for all motorcycles of 1.3 grams per kilometer $HC+NO_X$ in 2003 and 1.0 grams per kilometer $HC+NO_X$ in 2005 (as tested on the Indian Drive Cycle, or IDC).[36] China has adopted the European standards described above, implementing them in 2004, a year later than Europe.

d. Test cycle. In the ANPRM we requested comment on the adequacy of the current test cycle (the Federal Test Procedure, or FTP) for representing the highway motorcycle operation. We suggested that the existing US06 test cycle (more aggressive accelerations and higher speeds than the FTP) or another more representative test cycle might be appropriate for highway motorcycles. In addition, we noted the effort underway under the auspices of the United Nations/Economic Commission for Europe (UN/ECE) to develop a global harmonized world motorcycle test cycle (WMTC), and requested comment on adopting such a test cycle. The objective of the WMTC project is to develop a scientifically supported test cycle that accurately represents the in-use driving characteristics of highway motorcycles. The advantages of such a test cycle are numerous. First, the industry could have a single test cycle to meet emission standards in many countries (the process recognizes that nations will have differing emission standards due the varying air-pollution concerns). Second, the test cycle could potentially be better than the existing FTP in that it intends to better represent how a wide range of riders drive their motorcycles.

Similar comments were submitted on this issue by the Motorcycle Industry Council (MIC) and by Harley-Davidson Motor Company. In general MIC and Harley-Davidson stated that while pursuing a global emissions test procedure for motorcycles makes good business sense, the timing of the ongoing international process is not consistent with the current EPA rulemaking to establish new motorcycle standards.

At this time we are not proposing any modifications to the highway motorcycle test cycle. We continue to be involved in the WMTC process and are hopeful that a test cycle meeting the stated objectives can be agreed on by the international participants. Although a draft test cycle has been developed, several issues remain unresolved and it will likely be a couple of years before a new cycle can be issued as a global technical regulation under the process established by a 1998 international agreement. Under that process, if a test cycle is brought to a vote and the United States votes in the affirmative, we will then be committed to initiating a rulemaking that may lead to a proposal to adopt the new test cycle. We request comment on the best way to transition to a new global test cycle in the future, should that time come. Among the many options we could consider are: an immediate transition; a phasing in of the new cycle and a phasing out of the FTP; or a phasing in of the new cycle while maintaining the FTP as an option for a specified number of years.

e. Consumer modifications. Many motorcycle owners personalize their motorcycles in a variety of ways. This is one of the aspects of motorcycle ownership that is appealing to a large number of motorcycle owners, and they take their freedom to customize their bikes very seriously. However, there are some forms of customization that are not legal under the provisions of Clean Air Act section 203(a), which states that it is illegal: ''for any person to remove or render inoperative any device or element of design installed on or in a motor vehicle or motor vehicle engine in compliance with regulations under this title ... after such sale and delivery to the ultimate purchaser* * *''

In other words, under current law, owners of motor vehicles[37] cannot legally make modifications that cause the emissions to exceed the applicable emissions standards, and they cannot remove or disable emission-control devices installed by the manufacturer.[38]

We use the term ''tampering'' to refer specifically to actions that are illegal under Clean Air Act section 203; the term, and the prohibition, do not apply generally to the wide range of actions that a motorcycle enthusiast can take to personalize his or her motorcycle, but only to actions that remove or disable emission control devices or cause the emissions to exceed the standards. We know, from anecdotal reports and from some data collected from in-use motorcycles, that a portion of the motorcycle riding population has removed, replaced, or modified the original equipment on their motorcycles. This customization can include changes that can be detrimental (or, in some cases, possibly beneficial) to the motorcycle's emission levels. The ANPRM sought comments and data that could better help us understand the nature of the issue, such that our proposal could be made with the best understanding possible of current consumer practices. We did not intend to suggest that we would be revising the existing tampering restrictions to prohibit many of the things that motorcycle owners are now doing legally.

The proposed emissions standards, if adopted by EPA, would not change this ''tampering'' prohibition, which has been in place for more than 20 years. Owners would still be free generally to customize their motorcycles in any way, as long as they do not disable emission controls or cause the motorcycle to exceed the emission standards.

They would also be free, as they are now, to perform routine maintenance on their motorcycles to restore or maintain the motorcycle engine and related components in their original condition and configuration.

This proposal would increase the number of motorcycle models employing emission reduction technologies such as sequential fuel injection, pulse air injection, and catalytic converters. We request comment on the impact, if any, that these technologies could have on the difficulty and/or cost of routine maintenance or other legal modifications performed by or for the consumer. As discussed below and in the draft RSD, we do not anticipate detrimental impacts to the performance ch aracteristics of motorcycles that will meet the proposed emission standards. We request comment and supporting data on potential performance impacts (positive and negative) of these technologies.

### *B. Motorcycles Covered by This Proposal*

Highway, or ''street-legal,'' motorcycles are covered by the proposal described in this section. EPA regulations currently define a ''motorcycle'' as ''any motor vehicle with a headlight, taillight, and stoplight and having: two wheels, or three wheels and a curb mass less than or equal to 793 kilograms (1749 pounds).'' (See 40 CFR 86.402–98). This definition would continue to apply; therefore, the term ''motorcycle'' would continue to refer only to highway motorcycles. In

[36] The IDC, although not a transient cycle like the FTP, appears to be the only cycle currently in use that is based on actual measurements of motorcycles in use.

[37] A motorcycle is a ''motor vehicle'' as defined under section 216 of the Clean Air Act, which states that ''[t]he motor vehicle' means any self-propelled vehicle designed for transporting persons or property on a street or highway.''

[38] *See* Mobile Source Enforcement Memorandum No. 1A, Interim Tampering Enforcemetn Policy, Office of Enforcement and General Council, June 25, 1974 (Docket A–2000–01; document IV–A–27). (*http://www.epa.gov/oeca/aed/comp/hcomp.html*)

addition, these ''motorcycles'' that are currently subject to emissions standards would be subject to the proposed standards. However, we are also proposing to modify the regulations to include some motorcycles that are currently excluded from the emission regulations, as described below.

EPA regulations currently exclude motorcycles (*i.e.,* motor vehicles that meet the definition of ''motorcycle'' stated above) from the emission standards requirements based on several criteria laid out in 40 CFR 86.401-97. First, motorcycles are excluded if they have an engine displacement of less than 50cc. Second, a motorcycle is excluded if, with an 80 kg (176 lb) driver, it cannot start from a dead stop using only the engine or exceed 40 kph (25 mph) on a level paved surface. These provisions have the effect of excluding many mopeds, youth motorcycles, and some scooters from having to comply with any emission standards requirements. As discussed above, motorcycle-like vehicles that cannot exceed 25 miles per hour are not considered motor vehicles, and thus would be regulated under the nonroad recreational vehicle standards proposed earlier this year (66 FR 51098, October 5, 2001).

Highway motorcycles with engine displacements less than 50cc are generally most mopeds, as well as some motor scooters (''scooters,'' or sometimes, ''motorbikes''). Many of these vehicles are powered by 49cc two-stroke engines, although four-stroke engines are becoming more popular. Honda, for example, will no longer be marketing any two-stroke street-use motorcycles as of the 2003 model year; everything, including their 49cc scooter, will be powered by a four-stroke engine. We are proposing to revise two aspects of the regulations such that we would require most of these currently excluded vehicles to meet emission standards in the future. First, the general exclusion for motorcycles under 50cc would be changed such that no motorcycles would be excluded from the emission standards on the basis of engine displacement alone. Second, the definition of Class I motorcycles would be revised to accommodate motorcycles under 50cc (*i.e.,* a Class I motorcycle would be defined as a motorcycle with an engine displacement of less than 170cc). The standards that would apply to these vehicles are described in the following section. It is important to note that the motorcycle-like vehicles under 50cc that cannot be defined as a motor vehicle (*e.g.,* one that can't exceed 25 mph), continue to be excluded from these standards; they would, however, be covered by the recently proposed standards for nonroad recreational vehicles (66 FR 51098, October 5, 2001). We request comment on our proposed regulation of this previously unregulated category of motorcycle.

The cost per ton of controlling emissions from motorcycles with less than 50cc displacement engines is higher than for the proposed standards for larger motorcycles. However, the scooters and mopeds are very likely to be operated exclusively within populated urban areas. Scooters and mopeds, by virtue of their limited speeds, are not appropriate for use on highways; these small two-wheelers are often purchased for limited commuting within large urban areas or college campuses. Thus, it is likely that the air quality benefits of controlling emissions from these engines would be greater than indicated by the cost per ton comparison alone. We request comments on the merits of applying standards to these vehicles.

Parties have raised concerns regarding the potential for losses in environmental benefits from the highway use of off-highway motorcycles. Because the standards are different today (off-highway motorcycles do not currently have emissions standards) and would be somewhat different under our proposed standards, emissions reductions potentially could be lost if consumers purchased off-highway motorcycles for highway use on a widespread basis. State requirements vary considerably and in some states it may be difficult to meet requirements by modifying an off-highway motorcycle, while in others it may require only a few minor modifications. We request comment on current practices and the potential for this to occur in the future. We also request comment on steps we could reasonably take to address air pollution concerns associated with highway use of off-highway motorcycles.

*C . Proposed Standards*

1. What Are the Proposed Standards and Compliance Dates?

In general, we are proposing to harmonize the federal exhaust emission standards for all classes of motorcycles with those of the California program, but on a delayed schedule relative to implementation in California. (The exception would be motorcycles with engines of less than 50cc displacement, which are not currently regulated by California, for which we are also proposing standards.) For Class I and Class II motorcycles as currently defined, this would mean meeting exhaust emission standards that apply now in California (and have applied since 1982). For Class III motorcycles, this would mean meeting the two tiers of exhaust emission standards that California ARB has put in place for future model years. The existing federal CO standard of 12.0 g/km would remain unchanged. The process by which manufacturers certify their motorcycles, the test procedures, the driving cycle, and other elements of the federal program would remain unchanged.

In the development of this proposal following the publication of the ANPRM we considered several regulatory alternatives. These included: no revision to the standards, harmonization with one of the ''tiers'' of California standards (current, 2004 Tier-1, 2008 Tier-2), more stringent standards than those in place in California, or possibly different implementation timing. We also considered various alternatives designed to reduce the burden on small manufacturers (these are presented in section VII.B on the Regulatory Flexibility Act).

After considering comments on the ANPRM, we believe that the standards should be revised. The existing Federal standards were established more than twenty years ago, and it is clear that emission control technology has advanced a great deal in that time. California has continued to revise their standards to maintain some contact with current technology, and manufacturers have generally (but not uniformly) responded by producing motorcycles for sale nationwide that meet the more stringent California standards. Thus, in large part the existing federal standards has been superseded because of the preponderance of manufacturers that have responded in this way. Those arguing against new emission standards often cite the fact that motorcycles are typically far cleaner than the existing federal standards require. Although we agree, we see this fact as a reason for improving emission standards and as evidence that the current federal standards are out of touch with the reality of today's technology.

We believe it is most appropriate at this time to propose harmonizing with the California exhaust emission standards, as opposed to other options discussed in the ANPRM. For example, the dissimilarities between on- and off-highway motorcycles do not encourage a one-size-fits-all approach for all motorcycles (this opinion is supported by a significant number of those who commented on the ANPRM). Off-highway motorcycles are powered predominantly by two-stroke engines, whereas highway motorcycles are all powered by four-stroke engines as of the

2002 model year. On- and off-highway motorcycle engines also lie at vastly different ends of the size spectrum. The average highway motorcycle sold today has a displacement of nearly 1000cc, whereas almost 90 percent of off-highway motorcycle engines have an engine displacement of less than 350cc. In addition, on- and off-highway motorcycles are used in very different ways; finding a set of standards and a test procedure that adequately represents the typical range of operation for both types would therefore be extremely challenging. On-highway motorcycle manufacturers have commented that, to the extent the standards are revised, harmonization with California, rather than a distinctly different set of standards, is preferable because it eliminates the possibility of needing two distinct product lines for California and Federal regulations.[39]

Delaying implementation of the California standards on a nationwide basis by two years would provide an opportunity for manufacturers to gain some experience with the technology needed to meet the new standards. Two years provides time for technology optimization and cost reduction. Providing a longer delay could potentially provide the option of a further decrease in the level of the emission standards, given that the technological feasibility of the California standards has been adequately demonstrated (at least one manufacturer is already selling a motorcycle meeting the 2008 California standards). However, this would be a tradeoff against a more timely introduction of the new standards.

We also evaluated whether the federal motorcycle program should incorporate averaging provisions, as the California program does. Given the desire of most manufacturers to manufacture a motorcycle for nationwide sale, such a program without averaging would not be desirable because it would not provide the flexibility needed to meet the California and federal requirements together and could have at least potentially led to a somewhat less stringent Federal standard. Therefore, we are proposing to provide an averaging program comparable to California's.

EPA uses the term ''useful life'' to describe the period (usually years and/or miles) over which the manufacturer must demonstrate the effectiveness of the emission control system. For example, the ''useful life'' of current passenger cars is 10 years or 100,000 miles, whichever first occurs. It does not mean that a vehicle is no longer useful or that the vehicle must be scrapped or turned in once these limits are reached. The term has no effect on the owners' ability to ride their motorcycles for as long as they want. In the ANPRM we requested comment on whether the current definitions of useful life for the three motorcycle classes remains appropriate, given that these definitions were established more than 20 years ago. For example, we question whether, given that the average distance traveled per year for highway motorcycles is around 4,200 km (2,600 miles), the useful life for Class III motorcycles of 30,000 km (18,680 miles) is really appropriate. A typical motorcycle would reach the useful life mileage in about seven years at that rate. Based on data received from an industry trade group, we estimated an average operating life of 12.5 years for on-highway motorcycles. We request comment on extending the useful life by up to 10,000 km (6,200 miles) to reflect a value more consistent with actual use.

a. Class I and Class II motorcycles. We are proposing that Class I and Class II motorcycles would have to meet the current California ARB exhaust emission standards on a nationwide basis starting with the 2006 model year. These standards, which have been in place in California since 1982, are 1.0 g/km HC and 12.0 g/km CO, as measured on the existing Federal Test Procedure (FTP) for motorcycles.

In addition to applying to motorcycles currently in Class I and Class II (*i.e.,* those over 50cc), we are also proposing that these standards apply to those motorcycles encompassed by the proposed revised Class I definition, which would include the previously-excluded engines under 50cc, as described above. As discussed in further detail below, we are considering ways of including Class I and Class II motorcycles in the overall emissions averaging program, and request comment on this issue.

Class I motorcycles as currently defined are currently tested on a version of the Federal Test Procedure (FTP) that has lower top speeds and reduced acceleration rates relative to the FTP that is used for Class II and III motorcycles. The Class I FTP has a top speed of just under 60 km/hr, or around 37 mph, whereas the Class II/III FTP has a top speed of just over 90 km/hr, or just above 55 mph. By proposing to define motorcycles with engine displacements of less than 50cc as Class I motorcycles, these ''new'' Class I motorcycles would likewise be tested on the Class I FTP. We believe that this use of this test cycle is feasible and appropriate for the new Class I motorcycles (many are advertised with a top speed in the range of 40–50 mph). We request comment on the feasibility of the proposed test cycle for motorcycles with engine displacements of less than 50cc; in particular, we request comment on whether experience in meeting existing European or Asian requirements provides any insight on this issue. We request comment on alternative test cycles and certification options, including whether the cycle required for low-speed, small-displacement scooters and mopeds in Europe should be used or allowed by EPA.

Despite the fact that virtually all Class I and Class II motorcycles already meet and certify to these standards,[40] we are proposing nationwide implementation in 2006 for two reasons. First, there are those motorcycles under 50cc that require some lead time to meet new standards. Second, any averaging provisions, if finalized, that would provide flexibility in meeting the Class I and Class II standards would not be useful until the 2006 model year, when some exchange of emission credits between the three motorcycle classes may be allowed (see the request for comment on averaging flexibilities for Classes I and II in section C.2 below). Nevertheless, we request comment on the 2006 implementation date, and whether it should be earlier for the current Class I and II motorcycles, given that all 2002 motorcycles in these classes are already certified at emission levels that would meet the proposed standards. For example, we could implement standards for the over 50cc motorcycles in 2004 and for those under 50cc in 2006.

We recognize, as discussed in detail below, that the U.S. is a small market for scooters and mopeds with engine displacements of under 50cc, and that many of the factors that are currently driving technology development are actions by the governments in the major world markets for these types of two-wheelers. A U.S. attempt to drive technology to achieve emission limits more stringent or sooner than those applicable in the largest scooter markets (South Asia, Europe) might result in some manufacturers choosing to withdraw from the U.S. market, rather than develop specific technologies to address U.S. requirements. (This appeared to occur in the mid-to late-1980's when new California standards,

[39] See comments on the ANPRM from Harley-Davidson and the Motorcycle Industry Council, available in the public docket for review (Docket A–2000–01; document II–D–48).

[40] Based on analysis of motorcycle emissions certification data.

combined with fairly active advertising by Honda, drove the European manufacturers from the U.S. market.) For the Class I motorcycles under 50cc, we therefore request comment on the cost and technology that would be associated with standards within a range of 1.0 to 2.0 grams per kilometer HC (or HC+$NO_X$). We believe that, in view of the standards that apply or will soon apply in many of the major scooter markets around the world (see Table V.A–6), that a standard in this range is similar to standards in other countries and would allow the use of similar technologies for U.S. standards. Standards in this range would be intended to allow the U.S. to be more certain that we would receive the same scooters being marketed in the rest of major scooter markets.

TABLE V.A–6.—SUMMARY OF CURRENT AND FUTURE WORLDWIDE EMISSION STANDARDS FOR MOTORCYCLES LESS THAN 50CC DISPLACEMENT

| Country | HC | CO | $NO_X$ | HC+$NO_X$ | Test cycle | Notes |
|---|---|---|---|---|---|---|
| European Union | ..... | 6.0 | ..... | 3.0 | ECE R47 | Current (''Euro1''). |
| | ..... | 1.0 | ..... | 1.2 | ECE R47 | 2002 (''Euro 2''). |
| Switzerland | 0.5 | 0.5 | 0.1 | ..... | ECE R47 | Current. |
| India | ..... | 2.0 | ..... | 2.0 | India Drive (IDC) | Current. |
| | ..... | 1.3 | ..... | 1.3 | India Drive (IDC) | 2003 Proposed. |
| | ..... | 1.0 | ..... | 1.0 | India Drive (IDC) | 2005 Proposed. |
| China | ..... | 6.0 | ..... | 3.0 | ECE R47 | Current. |
| | ..... | 1.0 | ..... | 1.2 | ECE R47 | 2005. |
| Japan | 5.26 | 14.4 | 0.14 | ..... | ISO 6460 | Current 2-stroke. |
| | 2.93 | 20.0 | 0.51 | ..... | ISO 6460 | Current 4-stroke. |
| Korea | 4.0 | 8.0 | 0.1 | ..... | ECE R47 | Current. |
| Singapore | 5.0 | 12.0 | ..... | ..... | FTP | Current. |
| Taiwan | ..... | 3.5 | 2.0 | ..... | ECE R47 | Current. |
| | ..... | 7.0 | ..... | 1.0 | ECE R47 | 2003 2-stroke. |
| | ..... | 7.0 | ..... | 2.0 | ECE R47 | 2003 4-stroke. |
| Thailand | 3.0 | 4.5 | ..... | ..... | ECE R40 | Current. |

b. Class III Motorcycles. We are proposing to harmonize the federal Class III motorcycle standards with the exhaust emission standards of the recently finalized California program. Specifically, we propose to adopt the Tier 1 standard of 1.4 g/km HC+$NO_X$ starting in the 2006 model year, and the Tier 2 standard of 0.8 g/km starting in the 2010 model year. Because both HC and $NO_X$ are ozone precursors, this new standard would better reduce ozone than an HC-only standard. Implementation on a nationwide basis would therefore take place starting two model years after implementation of identical exhaust emission standards in California, ensuring that manufacturers have adequate lead time to plan for these new standards. As described below in further detail, these standards can be met on a corporate-average basis.

As noted earlier, California ARB plans a technology progress review in 2006 to evaluate manufacturers' progress in meeting the Tier 2 standards. We plan to participate in that review and work with California ARB, intending to make any appropriate adjustments to the standards or implementation schedule if warranted. For example, if California ARB determines in the review process that the standards are achievable, but in 2010 rather than 2008, we could follow with a rulemaking that would consider appropriate adjustment to the federal requirements.

2. Could I Average, Bank, or Trade Emission Credits?

To provide flexibility in meeting the standards, we are proposing to adopt an emission-credit program comparable to the existing California ARB regulations, and requesting comment on some additional flexibility relative to California ARB's program that could be included in our proposed program. There is currently no federal emission-credit program for highway motorcycles. As proposed, the program allows manufacturers to meet the standards on a fleet-average basis (*i.e.,* an averaging program).

Under the emission-credit program, manufacturers would be able to balance the certified HC+$NO_X$ emissions of their Class III motorcycles so that the sales-weighted HC+$NO_X$ emissions level meets the applicable standard. This means that some engine families may have HC+$NO_X$ emissions below the standards, while others have HC+$NO_X$ emissions higher than the standards. For enforcement purposes, manufacturers are required to specify a certification limit, or ''Family Emission Limit'' for each engine family. For example, one of a manufacturer's Class III engine families could be certified at 1.7 g/km HC+$NO_X$; this would be allowable under the California regulations if the sales-weighted average of all the manufacturer's engine families met the applicable 1.4 or 0.8 g/km HC+$NO_X$ standard.

As discussed below, EPA is proposing early credits provisions where credits may be banked prior to the beginning of the program. In several other emissions control programs, EPA allows manufacturers to bank credits after the start of the program for future use, or trade them to another manufacturer. In general, EPA has been supportive of these additional flexibilities and sees the potential for added value here as a means to reduce cost and provide additional compliance flexibility as needed * * * California's current program, however, does not contain banking (except for early banking) and trading provisions and manufacturers have not shown an interest in such provisions. Harmonization with California has been the overarching concern. Banking and trading provisions

that are out-of-step with the California program may have little use because manufacturers plan on carrying over their California products nationwide. In addition, such provisions complicate the certification and compliance protocols because EPA must set up systems for tracking credits and these systems must be established even if the use of the credit provisions is unlikely.

Because EPA believes banking and trading provisions would complicate the program, EPA is requesting comment on them rather than proposing them. EPA requests comment on an approach where manufacturers would establish $HC+NO_X$ family emissions limits (FELs) that are either below the standard, for generating credits, or above the standard, for using credits. These FELs, in effect, become the standard for the individual family. This would be similar in nature to the program for heavy-duty engines (see 40 CFR 86.004–15), but without transient conversion factors. Those commenting in support of credit banking and trading are encouraged to also provide detailed comments on any related provisions which would need to be considered in establishing the program for generating and using credits such as credit life, discounts (if any), cross displacement class trading issues, etc.

To maintain equity, California ARB adopted a cap on Family Emission Limits of 2.5 g/km HC for all individual engine families under the existing emission-credit program (*i.e.,* for Class III motorcycles). Because the 2.5 g/km HC-only standard was in effect in California before the emission-credit program was adopted, the 2.5 g/km cap continues to prevent manufacturers from selling motorcycles with emissions higher than the previous standard. Based on this reasoning, we are proposing a similar cap. However, because the current federal standard is 5.0 g/km, we are proposing an emissions cap on individual engine families of 5.0 g/km $HC+NO_X$. This will provide the added benefit of enabling manufacturers to retain some of the federally certified engine families that might otherwise have had some difficulty meeting the somewhat lower cap specified by California. Manufacturers producing these higher-emitting models would need to offset these emissions with other models certified below the standard.

To provide additional flexibility for manufacturers, we are requesting comment on the possible benefits of incorporating Class I and Class II motorcycles into the averaging program described above. This could be done in various ways. One option would be to define the proposed Class I and Class II HC-only standard of 1.0 g/km as an averaging standard, either within each class or for Class I and Class II combined. However, we believe this option would be of limited use, given the small number of engine families in these motorcycle classes. A second option would be to develop a credit program similar to that in place for the California Low-Emission Vehicle Program. Under this type of program, for example, credits accumulated by Class III motorcycles could be used to offset ''debits'' accumulated in one or both of the other classes. Credits would be accumulated by having a sales-weighted fleet-average value of the class below the applicable standard, while debits would result from having a class fleet-average value above the standard. A third option would be to allow the certification of Class I and II motorcycles to the Class III ''averaging set.'' In other words, under this option the combined sales-weighted fleet average of Class I, II, and III motorcycles would, at the manufacturer's option, be certified to the Tier 1 and Tier 2 fleet average $HC+NO_X$ standards. We request comment on the value of provisions of this nature, and on the advantages and disadvantages of each of these basic approaches. We also request comment on whether there are any adaptations of this averaging program that would improve the flexibility for small volume manufacturers.

To encourage early compliance, we are also proposing incentives in the emission-credit program similar to those in place in California, with timing adjusted due to the differing federal implementation schedule. We believe such incentives will encourage manufacturers to introduce Tier 2 motorcycles nationwide earlier than required by this proposal. In addition, we believe some manufacturers can reduce emissions even further than required by the Tier 2 standard; we would like to encourage the early introduction of these very low-emission vehicles. This proposal would provide incentives for early compliance by assigning specific multiplier factors based on how early a manufacturer produces a Tier 2 motorcycle and a motorcycle certified at 0.4 g/km $HC+NO_X$; these multipliers are shown in Table V.C–1.

Because we expect the Tier 2 technologies to become more widespread as 2010 approaches, the multipliers decrease linearly in value from 2006 until 2010, when the early compliance incentive would no longer have any value (*i.e.,* the multiplier has a value of 1.0) and the program would terminate. As shown in Table V.C–1, each unit of early Tier 2 motorcycles (those certified at 0.8 g/km $HC+NO_X$) would count as Y motorcycles at 0.8 g/km $HC+NO_X$ for purposes of corporate averaging in 2010, where Y is 1.5 for those motorcycles sold during model years (MY) 2003 through 2006, 1.375 for those sold in MY 2007, 1.250 for those sold in MY 2008, and 1.125 for those sold in MY 2009. A similar set of multipliers is shown in Table V.C–1 for pre-MY 2010 motorcycles certified even lower at 0.4 g/km $HC+NO_X$.

TABLE V.C–1.—MULTIPLIERS TO ENCOURAGE EARLY COMPLIANCE WITH THE PROPOSED TIER 2 STANDARD AND BEYOND

| Model year sold | Multiplier (Y) for use in MY 2010 corporate averaging* | |
|---|---|---|
| | Early tier 2 | Certified at 0.4 g/km $HC+NO_X$ |
| 2003 through 2006 | 1.5 | 3.0 |
| 2007 | 1.375 | 2.5 |
| 2008 | 1.250 | 2.0 |
| 2009 | 1.125 | 1.5 |

*Early Tier 2 motorcycles and motorcycles certified to 0.4 g/km are counted cumulatively toward the MY 2010 corporate average.

In 2010 and later model years the program would become a basic averaging program, where each manufacturer would have to meet the applicable $HC+NO_X$ standard on a fleet-average basis. See the proposed regulations at § 86.449.

3. Is EPA Proposing Blue Sky Standards for These Engines?

We are not proposing Blue Sky Standards for motorcycles at this time. Under the proposed averaging program there is an incentive to produce very clean motorcycles early, but it is of limited duration. However, several possible approaches could include a Blue Sky program, such as the ones discussed for marine evaporative emissions earlier in this document. For example, a Blue Sky standard could be set at the 0.4 g/km $HC+NO_X$ level used under the proposed averaging program. We request comment on whether a Blue Sky program is desirable for motorcycles, and what standards would be appropriate for such a program.

4. Do These Standards Apply to Alternative-Fueled Engines?

The proposed emission standards would apply to all motorcycles, regardless of fuel. Although the federal numerical emission standards have not

been updated in more than twenty years, the regulations were revised twice in the 1990's to apply the standards to certain alternative-fueled motorcycles. In 1990 the emission standards became applicable to methanol-fueled motorcycles (see 54 FR 14539, Apr. 11, 1989), and in 1997 the standards became applicable to natural gas-fueled and liquified petroleum gas-fueled motorcycles (see 59 FR 48512, Sept. 21, 1994).

We propose to apply the emission standards for highway motorcycles, regardless of fuel. This would have the effect of including any motorcycles that operate on diesel fuel. We do not believe the provisions in this proposal create any unique issues for motorcycles powered by alternative fuels. However, we request comment on whether there are unique aspects to motorcycles fueled with these alternative fuels (if there are any such motorcycles) that would make the proposed standards particularly challenging or infeasible.

5. Should Highway and Off-Highway Regulations Be Integrated?

We recognize that many motorcycle manufacturers produce both on- and off-highway motorcycles and are interested in receiving comment on integrating the two sets of requirements into a single part of the regulations. Currently, EPA regulations for highway motorcycles are in 40 CFR part 86, while the proposed regulations for recreational vehicles and engines are in 40 CFR part 1051. Given that the proposed requirements for off-highway motorcycles and ATVs would duplicate many of the requirements that apply to highway motorcycles (such as test procedures and certification protocol), it may be appropriate to integrate the highway motorcycle requirements with the recreational vehicle requirements in part 1051. This may help manufacturers with both on- and off-highway products by eliminating differing or inconsistent paperwork or testing requirements for the different products. We request comment on the value of centralizing the requirements in this way.

6. Is EPA Proposing Production Line Testing Requirements for Highway Motorcycles?

Production line testing requirements have never been required for highway motorcycles, but we are seeking comment on them as part of this proposal. However, we recognize that production-line testing may serve as a valuable tool to ensure that newly assembled engines control emissions at least as well as the prototype models used for certification. We believe testing highway motorcycles from the production line would add little additional burden and could easily be incorporated into the existing production-line quality checks that most manufacturers routinely perform. In fact, some nonroad engine manufacturers use emission measurements as part of their standard quality-control protocol at the assembly line to ensure proper engine functioning. Also, we would waive testing requirements for manufacturers with consistently good emission results. We request comment on extending to highway motorcycles the production-line testing requirements recently proposed for nonroad engines and vehicles (66 FR 51098). If such requirements were extended to highway motorcycles, we request comment on the impact of such requirements on smaller manufacturers and whether such requirements should apply to small manufacturers (*i.e.,* those with less than 3,000 annual unit sales). In the absence of production line testing we are not likely to allow post-certification changes to be made to the Family Emission Limits (FELs) applicable to a given engine family under the emissions averaging program.

7. What Test Fuel Is Specified for Emission Testing of Motorcycles?

The specifications for gasoline to be used by the EPA and by manufacturers for emission testing can be found in 40 CFR 86.513–94. These regulations also specify that the fuel used for vehicle service accumulation shall be ''representative of commercial fuels and engine lubricants which will be generally available through retail outlets.'' During the last twenty years of regulation of motorcycle emissions, the fuel specifications for motorcycle testing have been essentially identical to those for automotive testing. However, on February 10, 2000, EPA issued a final rule entitled ''Tier 2 Motor Vehicle Emissions Standards and Gasoline Sulfur Control Requirements'' (65 FR 6697, Feb. 10, 2000). In addition to finalizing a single set of emission standards that will apply to all passenger cars, light trucks, and larger passenger vehicles (*e.g.,* large SUVs), the rule requires the introduction of low-sulfur gasoline nationwide. To provide consistency with the fuels that will be in the marketplace, the rule amended the test fuel specifications, effective starting in 2004 when the new standards will take effect. The principal change that was made was a reduction in the allowable levels of sulfur in the test fuel, from a maximum of 0.10 percent by weight to a range of 0.0015 to 0.008 percent by weight.

Given that low-sulfur fuel will be the existing fuel in the marketplace when our proposed program would take effect (and therefore required for service accumulation), we propose to amend the motorcycle test fuel to reflect the true nature of the fuels available in the marketplace. Doing so would remove the possibility that a test could be conducted with an unrealistically high level of sulfur in the fuel.

8. Highway Motorcycle Evaporative Emissions

In addition to California's exhaust emission standards, California ARB has also established evaporative emission standards for highway motorcycles. These standards took effect with the 1983 model year for Class I and II motorcycles, and the 1984 model year for Class III motorcycles. An initial evaporative emission standard that applied for two model years was set at 6.0 grams of hydrocarbons per test. Following two model years at this level, the standard was reduced to a more stringent 2.0 grams of hydrocarbons per test for all motorcycle classes. This is the currently applicable standard, and it was not changed during California's recent revisions to their motorcycle exhaust emission standards.

We believe that it is not necessary at this time to propose adopting broad evaporative emission standards such as California's. The fuel tanks are generally small, resulting in diurnal and refueling emissions that we expect to be proportionately low. The use rates of motorcycles is likewise low, and we expect that hot soak emissions will be low as well. California has unique air quality concerns that may prompt the State to pursue and select emissions controls that we may find unnecessary for a national program. However, our investigation into the hydrocarbon emissions related to permeation of fuel tanks and fuel hoses with respect to marine applications has raised a new emissions concern that has a broad reach across many different vehicle types. Permeation of fuel tanks and hoses is one of four components of a vehicle's evaporative emissions. The other three primary evaporative components are: hot soak emissions, which occur when fuel evaporates from hot engine surfaces; diurnal emissions, which occur when fuel in tanks and hoses heats up in response to increases in ambient temperature; and refueling emissions, which occur when fuel vapors are displaced from the tank during refueling. As described in section III, the permeation emissions

from boats outweigh other evaporative emissions significantly; in fact, permeation from tanks and hoses results in more emissions than the other three types of evaporative emissions combined. Given this, we are assessing other vehicle types, including highway motorcycles, off-road motorcycles, and all-terrain vehicles, that may use fuel tanks or hoses with less-than-optimal control of permeation emissions. The fact that the fuel tanks in these types of vehicles are generally small does not significantly affect the importance of these emissions; it is the fact that permeation is occurring every hour of every day when there is fuel in the tank that results in the significance of emissions related to permeation.

Section III.H of this preamble, as well as the Draft Regulatory Support Document, detail some of the technological strategies that may be employed to reduce fuel permeation. The application of several of these technologies to highway motorcycles appears to be relatively straightforward, with little cost and essentially no adverse performance or aesthetic impacts. These technologies, which are already available and which appear to be relatively inexpensive, could reduce permeation of tanks and hoses by 95 percent or more. In addition, the control technology may pay for itself in many instances due to positive fuel consumption impacts.

We request comment on finalizing standards that would require low permeability fuel tanks on highway motorcycles, starting with the 2006 model year. We would presume that the metal fuel tanks that equip most highway motorcycles would already meet the low permeability requirement, and thus, there would be no need for any fuel tank design or material changes on the vast majority of highway motorcycles. However, many if not all of the dual-sport motorcycles are equipped with plastic fuel tanks, as are some motorcycles in the sport or super-sport categories. These motorcycles, under the type of regulation that we are requesting comment on, would have to employ metal tanks or plastic fuel tanks using one of the barrier technologies (*e.g.,* a fluorination or sulfonation treatment) described in section III.H to meet the standards. We expect that any standards finalized would be similar in design to those proposed regarding fuel tank permeation for marine engines, as discussed earlier in this preamble.

Retail sales data from Dealernews for the 2001 calendar year indicates that sales of motorcycles in the sport category amounted to just over 20 percent of total highway motorcycle sales, and dual-sport motorcycles were a much smaller 4 percent of the total. We may then conservatively estimate that approximately 25 percent of current motorcycles now have plastic tanks that would need upgrading. This is a conservative estimate for two reasons: (1) Some of these motorcycles are probably using metal tanks; and (2) it is highly likely that some of the existing plastic tanks have already been upgraded with a barrier treatment in order to meet the California evaporative emission requirements. We are interested in collecting more information regarding the degree to which plastic fuel tanks are used on highway motorcycles, and, to the extent they are, what if any measures have been taken by manufacturers to reduce permeation emissions.

Highway motorcycle fuel tanks range in capacity from just over one gallon on some small scooters to about 7.5 gallons on some large touring and sport touring motorcycles. Most of the sport and super-sport motorcycles appear to have fuel tanks that fall generally in the range of 4 to 6 gallons, while dual-sport motorcycles may be slightly smaller on average, perhaps typically in the 3 to 5 gallon range. If we select 5 gallons as a conservative estimate of the average size of the fuel tanks for those types of motorcycles most likely to have to employ one of the fuel tank barrier technologies, the additional cost per tank (assuming fluorination treatment) is estimated to be about $3.25 (see section 5.2.1 of the Draft Regulatory Support Document). We estimate that shipping, handling, and overhead costs would be an additional $0.85, resulting in a total average cost of about $4.10. Therefore, the average industry-wide price increase that would be associated with a requirement of this nature would be about $1.00.

We also request comment on promulgating standards that would require the use of low permeability fuel hoses on all highway motorcycles, starting in the 2006 model year. Like low permeation fuel tanks, it is very likely that some manufacturers have already addressed permeation from the fuel hoses on some of their product line due to the California evaporative emission requirements. However, we will conservatively estimate that no current motorcycles are equipped with fuel hoses that significantly reduce or eliminate permeation. The cost of a fuel line with low permeation properties is estimated to be about $1.30 per foot (see section 5.2.1 of the Draft Regulatory Support Document). Highway motorcycles are estimated to have about one to two feet of fuel line on average; thus, using the average cost and a fuel line length of 18 inches, we estimate an average industry-wide price increase associated with a low permeation fuel line requirement to be about $2.00 per motorcycle. We therefore estimate that the total increased cost per motorcycle that would result from requiring low permeation fuel tanks and fuel hoses would be about $3.00. We are interested in collecting more information regarding fuel hoses currently used on highway motorcycles, in particular regarding the typical length, the material, and the permeation properties.

We request comment on the form these standards would take (*e.g.,* whether there should be absolute numerical limits or percentage reduction requirements, if we determined they were appropriate.) We also request comment on implementing requirements such as those described above by allowing the manufacturer to submit a statement at the time of certification that the fuel tanks and hoses used on their products meet standards, specified materials, or construction requirements based on testing results. For example, a manufacturer using plastic fuel tanks could state that the engine family at issue is equipped with a fuel tank with a low permeability barrier treatment such as fluorination. Fuel hoses could be certified as being manufactured in compliance with certain accepted SAE specifications. These certification statements could be done on an engine family basis, or possibly a blanket statement could cover a manufacturer's entire product line. EPA expects that 95 percent reductions over uncontrolled emission levels for permeation are achievable for plastic fuel tanks. These reductions imply a tank permeability standard of about 0.024 g/gal/day for fuel tanks. For fuel hoses, we would consider the proposed standards for marine hoses of 5 grams per square meter per day. We request comment on these and other options that would enable regulation and enforcement of low permeability requirements.

As was discussed earlier regarding marine evaporative emissions, California ARB and EPA have conducted permeation testing with regard to evaporative emissions from HDPE plastic tanks. There are 8 data points for tanks of 3.9 to 7.5 gallons capacity. The permeation rates varied from 0.2 to1.0 grams per gallon per day with an average value of 0.75 g/gal/day. This data was based on tests with an average temperature of about 29°C. As discussed in Chapter 4 of the draft RSD, temperature has a first order effect on the rate of permeation. Roughly,

permeation doubles with every 10°C increase in temperature. For the 5 gallon tank discussed above, at 23°C, the average emission rate is about 0.50 g/gal/day or 2.5 g/day.

For the purposes of this analysis we assumed a fuel hose with an inside diameter of about 1cm (⅜ inch) and a permeation rate of 550 grams per square meter per day at 23°C. This permeation rate is based on the SAE J30 requirement for R7 fuel hose, the type of hose found on a small sample of motorcycles we examined. For the 18 inch hose mentioned above this yields an emission rate of 7.5 g/day.

Combining the average emission rates determined for the fuel tanks and fuel hoses above and adjusting for the 25 percent of tanks that would be affected by permeation standards yields a daily average emission rate of 8.1 g/day (7.5 g/day + (0.25 x 2.5 g/day)). The total combined tank and hose emission rate for those motorcycles that we estimate will require fuel tank treatments (25 percent of motorcycles) is 9.9 g/day (7.5 g/day + 2.5 g/day).

Table V.C–2 presents national totals for permeation emissions from motorcycles. These permeation estimates are based on the emission rates discussed above and population, turnover, and temperature projections discussed in Chapter 6 of the draft RSD.

TABLE V.C–2.—PROJECTED MOTORCYCLE PERMEATION HYDROCARBON EMISSIONS

[short tons]

| Calendar year | Baseline | Control | Reduction |
|---|---|---|---|
| 2005 ..... | 14,600 | 14,600 | 0 |
| 2010 ..... | 16,900 | 10,800 | 6,100 |
| 2015 ..... | 19,200 | 6,010 | 13,200 |
| 2020 ..... | 21,500 | 1,950 | 19,600 |
| 2030 ..... | 26,200 | 317 | 25,900 |

The average lifetime of a typical motorcycle is estimated to be about 12.5 years. Permeation control techniques can reduce emissions by 95 percent for tanks and more than 99 percent for hoses. Multiplying this efficiency and these emission rates by 12.5 years and discounting at 7 percent yields lifetime per motorcycle emission reductions of 0.0013 tons for the fuel tank, 0.017 tons for the fuel hose, and 0.019 tons on average overall. In turn, using the cost estimates above, these emission reductions yield HC cost per ton values of $794 for the 5 gallon tank, $112 for the fuel hose, and $160 for the average overall.

Because evaporative emissions are composed of otherwise useable fuel that is lost to the atmosphere, measures that reduce evaporative emissions can result in potentially significant fuel savings. For a motorcycle with a 5 gallon fuel tank, we estimate that the low permeability measures discussed in this section could save 9.6 gallons over the 12.5 year average operating lifetime, which translates to a discounted lifetime savings of $6.75 at an average fuel price of $1.10 per gallon. Combining this savings with an estimated cost per motorcycle of $3.00 results in a discounted lifetime savings per motorcycle of $3.75. The cost per ton of the evaporative emission reductions described above is $160; however, if the fuel savings are included, the estimated cost per ton is actually -$203. This means that the fuel savings are larger than the cost of using low permeation technology.

*D. Special Compliance Provisions*

While the highway motorcycle market is dominated by large companies, there are over 30 small businesses manufacturing these products. They are active in both the federal and California markets. California has been much more active than EPA in setting new requirements for highway motorcycles, and indeed, the California requirements have driven the technology demands and timing for highway motorcycle emission controls. We have developed our special compliance provisions partly in response to the technology, timing, and scope of the requirements that apply to the small businesses in California's program. The provisions discussed below would reduce the economic burden on small businesses, allowing harmonization with California requirements in a phased, but timely manner.

We propose that the flexibilities described below will be available for small entities with highway motorcycle annual sales of fewer than 3,000 units per model year (combined Class I, II, and III motorcycles) and fewer than 500 employees. These provisions are appropriate because of the significant research and development resources may be necessary to meet the proposed emission standards. These provisions would reduce the burden while ensuring the vast majority of the program is implemented to ensure timely emission reductions. We also understand that many small highway motorcycle manufacturers market ''classic'' and ''custom'' motorcycles, often with a ''retro'' appearance, that tends to make the addition of new technologies a uniquely resource-intensive prospect.

1. Delay of Proposed Standards

We propose to delay compliance with the Tier 1 standard of 1.4 g/km HC+$NO_X$ until the 2008 model year for small-volume manufacturers. We are proposing a Tier 1 standard beginning in the 2006 model year for highway motorcycles. Small manufacturers are required to meet the Tier 1 standard in 2008 in California. Given that the California requirements apply in 2008 for small businesses, we seek comment on whether additional time is needed for small businesses to comply with the federal program.

The current California regulations do not require small manufacturers to comply with the Tier 2 standard of 0.8 g/km HC+$NO_X$. The California Air Resources Board found that the Tier 2 standard represents a significant technological challenge and is a potentially infeasible limit for these small manufacturers. We share the California ARB's concern regarding this issue. As noted above, many of these manufacturers market a specialty product with a ''retro'' simplicity that may not easily lend itself to the addition of advanced technologies like catalysts. However, the ARB has acknowledged that, in the course of their progress review planned for 2006, they will revisit their small-manufacturer provisions. Therefore, we plan to participate with the ARB in the 2006 progress review as these provisions are revisited, and delay making decisions on the applicability to small businesses of Tier 2 or other revisions to the federal regulations that are appropriate following the review.

2. Broader Engine Families

Small businesses have met EPA certification requirements since 1978. Nonetheless, certifying motorcycles to revised emission standards has cost and lead time implications. Relaxing the criteria for what constitutes an engine or vehicle family could potentially allow small businesses to put all of their models into one vehicle or engine family (or more) for certification purposes. Manufacturers would then certify their engines using the ''worst case'' configuration within the family. This is currently allowed under the existing regulations for small-volume highway motorcycle manufacturers. We propose that these provisions remain in place.

3. Exemption From Production Line Testing

There is currently no mandatory production line testing requirement for highway motorcycles. The current

regulations allow us to request production vehicles from any certifying manufacturer for testing. We are proposing no changes to these existing provisions at this time.

4. Averaging, Banking, and Trading

An emission-credit program allows a manufacturer to produce and sell engines and vehicles that exceed the applicable emission standards, as long as the excess emissions are offset by the production of engines and vehicles emitting at levels below the standards. The sales-weighted average of a manufacturer's total production for a given model year must meet the standards. An emission-credit program typically also allows a manufacturer to bank credits for use in future model years, as well as buy credits from, or sell credits to, other manufacturers. Emission-credit programs are generally made available to all manufacturers, though special provisions for small businesses could be created to increase flexibility. We therefore propose an emission-credit program for highway motorcycles similar to that discussed above in V.C.2. for all motorcycle manufacturers.

For the reasons described in section V.C.2., we are not proposing post implementation emissions credits banking and trading provisions, but are requesting comment on them. This is not consistent with the Panel's recommendations for small entities. We request comment on the usefulness of banking and trading for small entities. For additional information on this subject, commenters may review a report prepared for the Small Business Administration on credits programs, ''Emissions Trading for Small Business'', for ideas on how such programs could be useful for small entities.[41]

5. Hardship Provisions

We are proposing two types of provisions to address unusual hardship circumstances for motorcycle manufacturers. The first type of hardship program would allow small businesses to petition EPA for additional lead time (*e.g.*, up to 3 years) to comply with the standards. A small manufacturer would have to make the case that it has taken all possible business, technical, and economic steps to comply but the burden of compliance costs would have a significant impact on the company's solvency. A manufacturer would be required to provide a compliance plan detailing when and how it would achieve compliance with the standards. Hardship relief could include requirements for interim emission reductions and/or purchase and use of emission credits. The length of the hardship relief decided during review of the hardship application would be up to one year, with the potential to extend the relief as needed. The second hardship program would allow companies to apply for hardship relief if circumstances outside their control cause the failure to comply (*i.e.*, supply contract broken by parts supplier) and if the failure to sell the subject engines would have a major impact on the company's solvency. See the proposed regulatory text in 40 CFR 1068.240 and 1068.241 for additional details.

In light of the California requirements, which do not include hardship provisions, we request comment on this alternative.

6. Reduced Certification Data Submittal and Testing Requirements

Current regulations allow significant flexibility for certification by manufacturers projecting sales below 10,000 units of combined Class I, II, and III motorcycles. For example, a qualifying manufacturer must submit an application for certification with a statement that their vehicles have been tested and, on the basis of the tests, conform to the applicable emission standards. The manufacturer retains adequate emission test data, for example, but need not submit it. Qualifying manufacturers also need not complete the detailed durability testing required in the regulations. We are proposing no changes to these existing provisions.

7. Nonconformance Penalties

Clean Air Act section 206(g) (42 U.S.C. 7525(g)), allows EPA to issue a certificate of conformity for heavy-duty engines or for highway motorcycles that exceed an applicable section 202(a) emissions standard, but do not exceed an upper limit associated with that standard, if the manufacturer pays a nonconformance penalty established by rulemaking. Congress adopted section 206(g) in the Clean Air Act Amendments of 1977 as a response to perceived problems with technology-forcing heavy-duty engine emissions standards. If strict standards were maintained, then some manufacturers, ''technological laggards,'' might be unable to comply initially and would be forced out of the marketplace. Nonconformance penalties were intended to remedy this potential problem. The laggards would have a temporary alternative that would permit them to sell their engines or vehicles by payment of a penalty. There are three criteria for determining the eligibility of emission standards for nonconformance penalties in any given model year. First, the emission standard in question must become more difficult to meet, either by becoming more stringent itself or by its interaction with another emission standard that has become more stringent. Second, substantial work must be required to meet the emission standard. We consider ''substantial work'' to mean the application of technology not previously used in that vehicle or engine class/ subclass, or a significant modification of existing technology, to bring that vehicle/engine into compliance. We do not consider minor modifications or calibration changes to be classified as substantial work. Third, it must be likely that a company will become a technological laggard. A technological laggard is defined as a manufacturer who cannot meet a particular emission standard due to technological (not economic) difficulties and who, in the absence of nonconformance penalties, might be forced from the marketplace.

Nonconformance penalties have been offered on occasion as a compliance option for several heavy-duty engine emission standards, but they have never been offered for highway motorcycles. However, as noted above, the Clean Air Act provides us with the authority to provide nonconformance penalties for highway motorcycles if they can be justified. While we do not currently believe that the three criteria established by rulemaking could be satisfied with respect to the Tier 1 standard (the ''substantial work'' criterion may not be applicable), there is a greater possibility that the criteria could be satisfied with respect to the Tier 2 standard. We request comment on whether the three criteria noted above could apply to the Tier 1 or Tier 2 standard, and if so, whether nonconformance penalties should be considered as an option. Typically, however, it is impossible at the time of a rulemaking to make the finding that a technological laggard has emerged with respect to a standard taking effect well into the future. For example, the proposed program would provide eight years of lead time to meet the Tier 2 standard, and making a judgment in this rulemaking regarding the existence of a technological laggard is impossible. It would be likely, for example, that we revisit this issue in the context of California ARB's 2006 progress review, or even later. However,

[41] ''Emissions Trading for Small Businesses'', Final Report, Jack Faucett Associates, March 2002, *http://www.sba.gov/advo/research/rs216tot.pdf* (Docket A–2000–01; document IV–A–26).

we request comment nevertheless on whether nonconformance penalties would be a desirable option, should conditions develop that warrant them. We also request comment on, given the availability of the hardship provisions described above, whether non-conformance penalties would potentially be needed.

*E. Technological Feasibility of the Standards*

1. Class I and Class II Motorcycles Between 50 and 180cc

As noted above, we are proposing to adopt the current California standards for Class I and Class II motorcycles. These standards have been in place in California since 1982. The question of whether or not these standards are technically feasible has been answered in the affirmative, since 21 of the 22 EPA-certified 2001 model year motorcycle engine families in these classes are already certified to these standards, and all 24 of the 2002 model year engine families meet these standards. These 24 engine families are all powered by four-stroke engines, with a variety of emission controls applied, including basic engine modifications on almost all engine families, secondary air injection on three engine families, and a two-way oxidation catalyst on one engine family.

In past model years, but not in the 2002 model year, an engine family that does not meet the California standards had certified to the existing federal standards and not sold in California. It was a 100cc dual-sport motorcycle powered by a two-stroke engine, with an HC certification level of 3.9 g/km. This motorcycle no longer appears to be available as of the 2002 model year. Adopting the California standards for these motorcycle classes could preclude this motorcycle or others like it from being certified and sold federally, unless the federal program includes additional flexibility relative to the California program. As discussed above, we are proposing that the HC standard for Class I and Class II motorcycles be an averaging standard, in a departure from California's treatment of these motorcycle classes. This in itself could be of limited use given the low number of Class I and Class II engine families, but, as discussed in Section V.C.2 above, we are also proposing to allow credits accumulated by certifying Class III engine families to a level lower than the standard to be used to offset Class I or Class II engine families certified to levels above the fleet-average standard.[42]

2. Class I Motorcycles Under 50cc

As we have described earlier we are proposing to apply the current California standard for Class I motorcycles to motorcycles with displacements of less than 50cc (e.g., most motor scooters). These motorcycles are currently not subject to regulation by the U.S. EPA or by the State of California. They are, however, subject to emission standards in Europe and much of the rest of the world. Historically these motorcycles have been powered by 2-stroke engines, but a trend appears to be developing that would result in most of these being replaced by 4-stroke engines or possibly by advanced technology 2-stroke engines, in some cases with catalysts.

The 4-stroke engine is capable of meeting our proposed standards. Class I motorcycles above 50cc are already meeting it, most of them employing nothing more than a 4-stroke engine. For example, the existing Class I scooters certify at levels ranging from 0.4 to 0.8 grams per kilometer HC. All of these achieve the standards with 4-stroke engine designs, and only one incorporates additional technology (a catalyst). These engines range from 80 to 151cc in displacement, indicating that a smaller engine should encounter few problems meeting the proposed standards.

In order to meet more stringent standards being implemented worldwide, manufacturers are developing and implementing a variety of options. Honda, perhaps the largest seller of scooters in the U.S., has entirely eliminated 2-stroke engines from their scooter product lines as of the 2002 model year. They continue to offer a 50cc model, but with a 4-stroke engine. Both of Aprilia's 49cc scooters available in the U.S. have incorporated electronic direct injection technology, which, in the case of one model, enables it to meet the ''Euro-2'' standards of 1.2 grams per kilometer HC and 0.3 grams per kilometer $NO_X$, without use of a catalytic converter.[43] Piaggio, while currently selling a 49cc basic 2-stroke scooter in the U.S., expects to begin production of a direct injection version in 2002, and a 4-stroke 50cc scooter is also in development. Numerous 49cc models marketed by Piaggio in Europe are available either as a 4-stroke or a 2-stroke with a catalyst. Piaggio, also an engine manufacturer and seller, is already offering a 50cc 4-stroke engine to its customers for incorporation into scooters.

The U.S. represents a very small portion of the market for small motorcycles and scooters. There are few, if any, manufacturers that develop a small-displacement motorcycle exclusively for the U.S. market; the domestic sales volumes do not appear large enough at this time to support an industry of this kind. The Italian company Piaggio (maker of the Vespa scooters), for example, sold about as many scooters worldwide in 2000 (about 480,000) as the entire volume of highway motorcycles of all sizes sold in the U.S. in that year. U.S. sales of Vespas in 2000 amounted to about 4800. The largest scooter markets today are in South Asia and Europe, where millions are sold annually. In Taiwan alone almost 800,000 motorcycles were sold domestically. More than one third of these were powered by 2-stroke engines. Two- and three-wheelers constitute a large portion of the transportation sector in Asia, and in some urban areas these vehicles—many of them powered by 2-stroke engines—can approach 75 percent of the vehicle population. According to a World Bank report, two-stroke gasoline engine vehicles are estimated to account for about 60 percent of the total vehicle fleet in South Asia.[44]

Many nations are now realizing that the popularity of these vehicles and the high density of these vehicles in urban areas are contributing to severe air quality problems. As a consequence, some of the larger small motorcycle markets in Asia and India are now placing these vehicles under fairly strict regulation. It is clear that actions in these nations will move the emission control technology on small motorcycles, including those under 50cc, in a positive direction. For example, according to the World Bank report, as of 2000 catalytic converters are installed in all new two-stroke engine motorcycles in India, and 2003 standards in Taiwan will effectively ban new two-strokes with emission

[42] The manufacturer taht had certified this two-stroke for highway use has typically certified 4–5 other Class I or II engine families; therefore, a basic averaging program could enable them to continue to market their two-stroke dual-sport. However, other manufacturers may not have adequate additional engine families in these classes, making a basic average standard less useful to them.

[43] Aprilia webstie, *http://www.apriliausa.com/ridezone/ing/models/scarabeo50dt/moto.htm.* Available in the public docket for review.

[44] Improving Urban Air Quality in South Asia by Reducing Emissions from Two-Stroke Engine Vehicles. Masami Kojima, Carter Brandon, and Jitendra Shah. December 2000. Prepared for the World Bank. Available in the public docket for review (Docket A–2000–01; document II–D–191), or on the internet at: *http://www.worldbank.org/html/fpd/esmpa/publication/airquality.html.*

standards so stringent that only a four-stroke engine is capable of meeting them.

Given the emerging international picture regarding emission standards for scooters, we believe that scooter manufacturers will be producing scooters of less than 50cc displacement that meet our proposed standards well in advance of the 2006 model year, the first year we propose to subject this category of motorcycle to U.S. emission standards. We would expect that small entities that import scooters into the U.S. from the larger scooter markets would be able to import complying vehicles. We request comment on this assessment.

There are other numerous factors in the international arena that may affect the product offerings in the less than 50cc market segment. For example, the European Union recently changed the requirements regarding insurance and helmet use for under 50cc scooters and mopeds. Previously, the insurance discounts and lack of helmet requirements in Europe provided two relatively strong incentives to purchasers to consider a 49cc scooter. Recently, however, the provisions were changed such that helmets are now required and the insurance costs are comparable to larger motorcycles. The result was a drop of about 30% in European sales of 49cc scooters in 2001 due to customers perceiving little benefit from a 49cc scooter relative to a larger displacement engine.

3. Class III motorcycles

a. Tier 1 standards. In the short term, the proposed Tier 1 $HC+NO_X$ standard of 1.4 g/km $HC+NO_X$ reflects the goal of achieving emission reductions that could be met with reasonably available control technologies, primarily involving engine modifications rather than catalytic converters. As noted earlier, we are proposing that this standard be effective for the 2006 model year. Based on current certification data, a number of existing engine families already comply with this standard or would need relatively simple modifications to comply. In other cases, the manufacturers will need to use control technologies that are available but are not yet used on their particular vehicles (*e.g.,* electronic fuel injection to replace carburetors, changes to cam lobes/timing, etc.). For the most part, manufacturers will not need to use advanced technologies such as close-coupled, closed-loop three way catalysts.

While manufacturers will use various means to meet the Tier 1 standard, there are four basic types of existing, non-catalyst-based, emission-control systems available to manufacturers. The most important of these is the use of secondary pulse-air injection. Other engine modifications and systems include more precise fuel control, better fuel atomization and delivery, and reduced engine-out emission levels from engine changes. The combinations of low-emission technologies ultimately chosen by motorcycle manufacturers are dependent on the engine-out emission levels of the vehicle, the effectiveness of the prior emission-control system, and individual manufacturer preferences.

Secondary pulse-air injection, as demonstrated on current motorcycles, is applied using a passive system (i.e., no air pump involved) that takes advantage of the flow of gases (''pulse'') in the exhaust pipes to draw in fresh air that further combusts unburned hydrocarbons in the exhaust. Engine modifications include a variety of techniques designed to improve fuel delivery or atomization; promote ''swirl'' (horizontal currents) and ''tumble'' (vertical currents); maintain tight control on air-to-fuel (A/F) ratios; stabilize combustion (especially in lean A/F mixtures); optimize valve timing; and retard ignition timing.

Secondary pulse air injection involves the introduction of fresh air into the exhaust pipe immediately after the gases exist the engine. The extra air causes further combustion to occur, thereby controlling more of the hydrocarbons that escape the combustion chamber. This type of system is relatively inexpensive and uncomplicated because it does not require an air pump; air is drawn into the exhaust through a one-way reed valve due to the pulses of negative pressure inside the exhaust pipe. Secondary pulse-air injection is one of the most effective non-catalytic emission-control technologies; compared to engines without the system, reductions of 10 to 40 percent for HC are possible with pulse-air injection. Sixty-five of the 151 2001 model year Class III engine families certified for sale in the U.S employ secondary pulse-air injection to help meet the current California standards. We anticipate that most of the remaining engine families will use this technique to help meet the Tier 1 and Tier 2 standards.

Improving fuel delivery and atomization primarily involves the replacement of carburetors, currently used on most motorcycles, with more precise fuel injection systems. There are several types of fuel injection systems and components manufacturers can choose. The most likely type of fuel injection manufacturers will choose to help meet the Tier 1 standard is sequential multi-point fuel injection (SFI).

Unlike conventional multi-point fuel injection systems that deliver fuel continuously or to paired injectors at the same time, sequential fuel injection can deliver fuel precisely when needed by each cylinder. With less than optimum fuel injection timing, fuel puddling and intake-manifold wall wetting can occur, both of which hinder complete combustion. Use of sequential-fuel-injection systems help especially in reducing cold start emissions when fuel puddling and wall wetting are more likely to occur and emissions are highest.

Motorcycle manufacturers are already beginning to use sequential fuel injection (SFI). Of the 152 Class III motorcycle engine families certified for sale this year, 36 employ SFI systems. We anticipate increased applications of this or similar fuel injection systems to achieve the more precise fuel delivery needed to help meet the Tier 1 and Tier 2 standards.

In addition to the techniques mentioned above, various engine modifications can be made to improve emission levels. Emission performance can be improved, for example, by reducing crevice volumes in the combustion chamber. Unburned fuel can be trapped momentarily in crevice volumes before being subsequently released. Since trapped and re-released fuel can increase engine-out emissions, the elimination of crevice volumes would be beneficial to emission performance. To reduce crevice volumes, manufacturers can evaluate the feasibility of designing engines with pistons that have reduced, top ''land heights'' (the distance between the top of the piston and the first ring).

Lubrication oil which leaks into the combustion chamber also has a detrimental effect on emission performance since the heavier hydrocarbons in oil do not oxidize as readily as those in gasoline and some components in lubricating oil may tend to foul the catalyst and reduce its effectiveness. Also, oil in the combustion chamber may trap HC and later release the HC unburned. To reduce oil consumption, manufacturers can tighten the tolerances and improve the surface finish on cylinders and pistons, piston ring design and materials, and exhaust valve stem seals to prevent excessive leakage of lubricating oil into the combustion chamber.

Increasing valve overlap is another engine modification that can help reduce emissions. This technique helps

reduce $NO_X$ generation in the combustion chamber by essentially providing passive exhaust gas recirculation (EGR). When the engine is undergoing its pumping cycle, small amounts of combusted gases flow past the intake valve at the start of the intake cycle. This creates what is essentially a passive EGR flow, which is then either drawn back into the cylinder or into another cylinder through the intake manifold during the intake stroke. These combusted gases, when combined with the fresh air/fuel mixture in the cylinder, help reduce peak combustion temperatures and $NO_X$ levels. This technique can be effected by making changes to cam timing and intake manifold design to optimize $NO_X$ reduction while minimizing impacts to HC emissions.

Secondary pulse-air injection and engine modifications already play important parts in reducing emission levels; we expect increased uses of these techniques to help meet the Tier 1 standard. Direct evidence of the extent these technologies can help manufacturers meet the Tier 1 standard can be found in EPA's highway motorcycle certification database. This database is comprised of publicly-available certification emission levels as well as some confidential data reported by the manufacturers pursuant to existing motorcycle emission certification requirements.

We do not expect any of these possible changes to adversely affect performance. Indeed, the transition to some of these technologies (*e.g.,* advanced fuel injection) would be expected to improve performance, fuel economy, and reliability. A direct comparison of several motorcycle models in the EPA certification database between the ''California'' model (where one is offered; it is the exception rather than the rule that a manufacturer offers a separate engine system for California) and the model sold in the rest of the U.S. reveals no change in the performance characteristics in the database (*e.g.,* rated horsepower, torque). We request comment on the impact these anticipated changes might have on performance-related factors.

b. Tier 2 standards. In the long term, the proposed Tier 2 $HC+NO_X$ standard of 0.8 g/km would ensure that manufacturers will continue to develop and improve emission control technologies. We are proposing the Tier 2 standard to be effective by the 2010 model year. We believe this standard is technologically feasible, though it will present some challenges for manufacturers. Several manufacturers are, however, already using some of the technologies that will be needed to meet this standard. In addition, our proposed implementation time frame gives manufacturers two years of experience in meeting this standard in California before having to meet it on a nationwide basis. At least one manufacturer already uses closed-loop, three-way catalysts on several of its product lines. One manufacturer has already certified a large touring motorcycle to the Tier 2 standards for sale in California. Depending on assumptions regarding $NO_X$ levels, other manufacturers have products currently in the market with emission levels close to the Tier 2 standards using two-way catalysts, fuel injection, secondary pulse-air injection, and other engine modifications. The current average HC certification level for Class III motorcycles is just under 1.0 g/km, with a number of motorcycles from a variety of manufacturers at levels of 0.5 g/km or lower. We expect that the proposed eight years of lead time prior to meeting these standards on a nationwide basis would allow manufacturers to optimize these and other technologies to meet the Tier 2 standard.

To meet the proposed Tier 2 standard for $HC+NO_X$, manufacturers would likely use more advanced engine modifications and secondary air injection. Specifically, we believe manufacturers would use computer-controlled secondary pulse-air injection (i.e., the injection valve would be connected to a computer-controlled solenoid). In addition to these systems, manufacturers would probably need to use catalytic converters on some motorcycles to meet the proposed Tier 2 standards. There are two types of catalytic converters currently in use: two-way catalysts (which control only HC and CO) and three-way catalysts (which control HC, CO, and $NO_X$). Under the proposed Tier 2 standard, manufacturers would need to minimize levels of both HC and $NO_X$. Therefore, to the extent catalysts are used, manufacturers would likely use a three-way catalyst in addition to engine modifications and computer-controlled, secondary pulse-air injection.

As discussed previously, improving fuel control and delivery provides emission benefits by helping to reduce engine-out emissions and minimizing the exhaust variability which the catalytic converter experiences. One method for improving fuel control is to provide enhanced feedback to the computer-controlled fuel injection system through the use of heated oxygen sensors. Heated oxygen sensors (HO2S) are located in the exhaust manifold to monitor the amount of oxygen in the exhaust stream and provide feedback to the electronic control module (ECM). These sensors allow the fuel control system to maintain a tighter band around the stoichiometric A/F ratio than conventional oxygen sensors (O2S). In this way, HO2S assist vehicles in achieving precise control of the A/F ratio and thereby enhance the overall emissions performance of the engine. At least one manufacturer is currently using this technology on several 2001 engine families.

In order to further improve fuel control, some motorcycles with electronic controls may utilize software algorithms to perform individual cylinder fuel control. While dual oxygen sensor systems are capable of maintaining A/F ratios within a narrow range, some manufacturers may desire even more precise control to meet their performance needs. On typical applications, fuel control is modified whenever the O2S determines that the combined A/F of all cylinders in the engine or engine bank is ''too far'' from stoichiometric. The needed fuel modifications (*i.e.,* inject more or less fuel) are then applied to all cylinders simultaneously. Although this fuel control method will maintain the ''bulk'' A/F for the entire engine or engine bank around stoichiometric, it would not be capable of correcting for individual cylinder A/F deviations that can result from differences in manufacturing tolerances, wear of injectors, or other factors.

With individual cylinder fuel control, A/F variation among cylinders will be diminished, thereby further improving the effectiveness of the emission controls. By modeling the behavior of the exhaust gases in the exhaust manifold and using software algorithms to predict individual cylinder A/F, a feedback fuel control system for individual cylinders can be developed. Except for the replacement of the conventional front O2S with an HO2S sensor and a more powerful engine control computer, no additional hardware is needed in order to achieve individual cylinder fuel control. Software changes and the use of mathematical models of exhaust gas mixing behavior are required to perform this operation.

In order to maintain good driveability, responsive performance, and optimum emission control, fluctuations of the A/F must remain small under all driving conditions including transient operation. Virtually all current fuel systems in automobiles incorporate an adaptive fuel control system that automatically adjusts the system for component wear, varying environmental

conditions, varying fuel composition, etc., to more closely maintain proper fuel control under various operating conditions. For some current fuel control systems, this adaptation process affects only steady-state operating conditions (i.e., constant or slowly changing throttle conditions). However, most vehicles are now being introduced with adaptation during ''transient'' conditions (*e.g.,* rapidly changing throttle, purging of the evaporative system).

Accurate fuel control during transient driving conditions has traditionally been difficult because of the inaccuracies in predicting the air and fuel flow under rapidly changing throttle conditions. Because of air and fuel dynamics (fuel evaporation in the intake manifold and air flow behavior) and the time delay between the air flow measurement and the injection of the calculated fuel mass, temporarily lean A/F ratios can occur during transient driving conditions that can cause engine hesitation, poor driveability and primarily an increase in $NO_X$ emissions. However, by utilizing fuel and air mass modeling, vehicles with adaptive transient fuel control are more capable of maintaining accurate, precise fuel control under all operating conditions. Virtually all cars will incorporate adaptive transient fuel control software; motorcycles with computer controlled fuel injection can also benefit from this technique at a relatively low cost.

Three-way catalytic converters traditionally utilize rhodium and platinum as the catalytic material to control the emissions of all three major pollutants (hydrocarbons (HC), CO, $NO_X$). Although this type of catalyst is very effective at converting exhaust pollutants, rhodium, which is primarily used to convert $NO_X$, tends to thermally deteriorate at temperatures significantly lower than platinum. Recent advances in palladium and tri-metal (*i.e.,* palladium-platinum-rhodium) catalyst technology, however, have improved both the light-off performance (light-off is defined as the catalyst bed temperature where pollutant conversion reaches 50-percent efficiency) and high temperature durability over previous catalysts. In addition, other refinements to catalyst technology, such as higher cell density substrates and adding a second layer of catalyst washcoat to the substrate (dual-layered washcoats), have further improved catalyst performance from just a few years ago.

Typical cell densities for conventional catalysts used in motorcycles are less than 300 cells per square inch (cpsi). To meet the Tier 2 standard, we expect manufacturers to use catalysts with cell densities of 300 to 400 cpsi. If catalyst volume is maintained at the same level (we assume volumes of up to 60 percent of engine displacement), using a higher density catalyst effectively increases the amount of surface area available for reacting with pollutants. Catalyst manufacturers have been able to increase cell density by using thinner walls between each cell without increasing thermal mass (and detrimentally affecting catalyst light-off) or sacrificing durability and performance.

In addition to increasing catalyst volume and cell density, we believe that increased catalyst loading and improved catalyst washcoats will help manufacturers meet the Tier 2 standard. In general, increased precious metal loading (up to a certain point) will reduce exhaust emissions because it increases the opportunities for pollutants to be converted to harmless constituents. The extent to which precious metal loading is increased will be dependent on the precious metals used and other catalyst design parameters. We believe recent developments in palladium/rhodium catalysts are very promising since rhodium is very efficient at converting $NO_X$, and catalyst suppliers have been investigating methods to increase the amount of rhodium in catalysts for improved $NO_X$ conversion.

Double layer technologies allow optimization of each individual precious metal used in the washcoat. This technology can provide reduction of undesired metal-metal or metal-base oxide interactions while allowing desirable interactions. Industry studies have shown that durability and pollutant conversion efficiencies are enhanced with double layer washcoats. These recent improvements in catalysts can help manufacturers meet the Tier 2 standard at reduced cost relative to older three-way catalysts.

New washcoat formulations are now thermally stable up to 1050 °C. This is a significant improvement from conventional washcoats, which are stable only up to about 900 °C. With the improvements in light-off capability, catalysts may not need to be placed as close to the engine as previously thought. However, if placement closer to the engine is required for better emission performance, improved catalysts based on the enhancements described above would be more capable of surviving the higher temperature environment without deteriorating. The improved resistance to thermal degradation will allow closer placement to the engines where feasible, thereby providing more heat to the catalyst and allowing them to become effective quickly.

It is well established that a warmed-up catalyst is very effective at converting exhaust pollutants. Recent tests on advanced catalyst systems in automobiles have shown that over 90 percent of emissions during the Federal Test Procedure (FTP) are now emitted during the first two minutes of testing after engine start up. Similarly, the highest emissions from a motorcycle occur shortly after start up. Although improvements in catalyst technology have helped reduce catalyst light-off times, there are several methods to provide additional heat to the catalyst. Retarding the ignition spark timing and computer-controlled, secondary air injection have been shown to increase the heat provided to the catalyst, thereby improving its cold-start effectiveness.

In addition to using computer-controlled secondary air injection and retarded spark timing to increase the heat provided to the catalyst, some vehicles may employ warm-up, pre-catalysts to reduce the size of their main catalytic converters. Palladium-only warm-up catalysts (also known as ''pipe catalysts'' or ''Hot Tubes'') using ceramic or metallic substrates may be added to further decrease warm-up times and improve emission performance. Although metallic substrates are usually more expensive than ceramic substrates, some manufacturers and suppliers believe metallic substrates may require less precious metal loading than ceramic substrates due to the reduced light-off times they provide.

Improving insulation of the exhaust system is another method of furnishing heat to the catalyst. Similar to close-coupled catalysts, the principle behind insulating the exhaust system is to conserve the heat generated in the engine for aiding catalyst warm-up. Through the use of laminated thin-wall exhaust pipes, less heat will be lost in the exhaust system, enabling quicker catalyst light-off. As an added benefit, the use of insulated exhaust pipes will also reduce exhaust noise. Increasing numbers of manufacturers are expected to utilize air-gap exhaust manifolds (*i.e.,* manifolds with metal inner and outer walls and an insulating layer of air sandwiched between them) for further heat conservation.

Besides the hardware modifications described above, motorcycle manufacturers may borrow from other current automobile techniques. These include using engine calibration changes such as a brief period of substantial ignition retard, increased

cold idling speed, and leaner air-fuel mixtures to quickly provide heat to a catalyst after cold-starts. Only software modifications are required for an engine which already uses a computer to control the fuel delivery and other engine systems. For these engines, calibration modifications provide manufacturers with an inexpensive method to quickly achieve light-off of catalytic converters. When combined with pre-catalysts, computer-controlled secondary air injection, and the other heat conservation techniques described above, engine calibration techniques may be very effective at providing the required heat to the catalyst for achieving the Tier 2 standard. These techniques are currently in use on most low emission vehicle (LEV) automobiles and may have applications in on-road motorcycles.

The nature of motorcycling makes riders particularly aware of the many safety issues that confront them. Many riders that submitted comments to us following the publication of the ANPRM in December of 2000 questioned whether catalytic converters could be implemented on motorcycles without increasing the risk of harm to the rider and/or passenger. The primary concern is regarding the close proximity of the riders to hot exhaust pipes and the catalytic converter. Protecting the rider from the excessive heat is a concern for both riders and manufacturers. The current use of catalytic converters on a number of motorcycles (accounting for tens of thousands of motorcycles in the current U.S. fleet and over 15 million worldwide) already indicates that these issues are not insurmountable on a variety of motorcycle styles and engine sizes. Countries that have successfully implemented catalyst-based emission control programs for motorcycles (some of which have many years of experience) do not report any safety issues associated with the use of catalytic converters on motorcycles under real-world conditions.[45] A number of approaches to shielding the rider from the heat of the catalytic converter are possible, such as exterior pipe covers, shielded foot rests, and similar components. Some manufacturers have found that placing the converter on the underside of the engine can keep it adequately distant from the rider. Others may use double-pipe systems that reduce overall heat loss while remaining cooler on the exterior. Based on the significant lead time proposed that would be allowed for meeting these standards, as well as on the two years of prior experience in California before meeting the requirements federally, we believe that these issues can be satisfactorily resolved for the proportion of motorcycles for which catalytic converters would likely be used to meet the proposed standards.

We do not expect any of these possible changes to adversely affect performance. Indeed, the transition to some of these technologies (*e.g.,* advanced fuel injection) would be expected to improve performance, fuel economy, and reliability. A direct comparison of several motorcycle models in the EPA certification database between the ''California'' model (where one is offered; it is the exception rather than the rule that a manufacturer offers a separate engine system for California) and the model sold in the rest of the U.S. reveals no change in the performance characteristics in the database (*e.g.,* rated horsepower, torque). We request comment on the impact these anticipated changes might have on performance-related factors.

## VI. Projected Impacts

This section summarizes the projected impacts of the proposed emission standards. The anticipated environmental benefits are compared with the projected cost of the program for an assessment of the cost per ton of reducing emissions for this proposal.

### *A. Environmental Impact*

Diurnal evaporative emission factors from marine vessels were developed using established equations for determining evaporative emission factors as a function of ambient conditions and fuel tank size. Permeation emissions were developed based on known material permeation rates as a function of surface area and temperature. Other inputs for these calculations were taken from the latest version of our NONROAD model. Emission estimates for highway motorcycles were developed using information on the emission levels of current motorcycles and updated information on motorcycle use provided by the motorcycle industry. A more detailed description of the methodology used for projecting inventories and projections for additional years can be found in the Chapter 6 of the Draft Regulatory Support Document. We request comment on all aspects of the emission inventory analysis, including the usage rates and other inputs used in the analysis.

Tables V.A–1 and V.A–2 contain the projected emission inventories for the years 2010 and 2020, respectively, from the engines and vehicles subject to this proposal. The inventories are presented for the base case which assumes no change from current conditions (*i.e.,* without the proposed standards taking effect) and assuming the proposed standards take effect. The inventories for 2010 and 2020 include the effect of growth. The percent reductions based on a comparison of estimated emission inventories with and without the proposed emission standards are also presented.

TABLE VI.A–1.—2010 PROJECTED EMISSIONS INVENTORIES

[Thousand short tons]

| Category | $NO_X$ | | | HC* | | |
|---|---|---|---|---|---|---|
| | Base case | With proposed standards | Percent reduction | Base case | With proposed standards | Percent reduction |
| Marine SI Evap | 0 | 0 | 0 | 106 | 91 | 14 |
| Highway motorcycles | 11 | 10 | 9 | 46 | 41 | 11 |
| Total | 11 | 10 | 9 | 152 | 132 | 13 |

*Evaporative HC for marine SI; exhaust HC for highway motorcycles.

[45] See written testimony of the Manufacturers of Emission Controls Association on the Proposed Rulemaking on Control of Emissions from Nonroad Large Spark-Ignited Engines and Recreational Engines. Available in the public docket for review (Docket A–2000–01; document IV–D–213).

TABLE VI.A–2.—2020 PROJECTED EMISSIONS INVENTORIES

[Thousand short tons]

| Category | $NO_X$ | | | HC* | | |
|---|---|---|---|---|---|---|
| | Base case | With proposed standards | Percent reductions | Base case | With proposed standards | Percent reduction |
| Marine SI Evap | 0 | 0 | 0 | 114 | 50 | 56 |
| Highway motorcycles | 14 | 7 | 50 | 58 | 29 | 50 |
| Total | 14 | 7 | 50 | 172 | 79 | 53 |

*Evaporative HC for marine SI; exhaust HC for highway motorcycles.

As described in Section II, there will also be environmental benefits associated with reduced haze in many sensitive areas.

Finally, anticipated reductions in hydrocarbon emissions will correspond with reduced emissions of the toxic air emissions referenced in Section II. In 2020, the projected reduction in hydrocarbon emissions should result in an equivalent percent reduction in air toxic emissions.

*B. Economic Impact*

In assessing the economic impact of setting emission standards, we have made a best estimate of the technologies and their associated costs to meet the proposed standards. In making our estimates we have relied on our own technology assessment, which includes information supplied by individual manufacturers and our own in-house testing. Estimated costs include variable costs (for hardware and assembly time) and fixed costs (for research and development, retooling, and certification). We projected that manufacturers will recover the fixed costs over the first five years of production and used an amortization rate of 7 percent in our analysis. The analysis also considers total operating costs, including maintenance and fuel consumption. Cost estimates based on the projected technologies represent an expected change in the cost of engines as they begin to comply with new emission standards. All costs are presented in 2001 dollars. Full details of our cost analysis can be found in Chapter 5 of the Draft Regulatory Support Document. We request comment on this cost information.

Cost estimates based on the current projected costs for our estimated technology packages represent an expected incremental cost of vehicles in the near term. For the longer term, we have identified factors that would cause cost impacts to decrease over time. First, as noted above, we project that manufacturers will spread their fixed costs over the first five years of production. After the fifth year of production, we project that the fixed costs would be retired and the per unit costs would be reduced as a result.

For highway motorcycles above 50cc, the analysis also incorporates the expectation that manufacturers and suppliers will apply ongoing research and manufacturing innovation to making emission controls more effective and less costly over time. Research in the costs of manufacturing has consistently shown that as manufacturers gain experience in production and use, they are able to apply innovations to simplify machining and assembly operations, use lower cost materials, and reduce the number or complexity of component parts.[46] (see the Draft Regulatory Support Document for additional information). The cost analysis generally incorporates this learning effect by decreasing estimated variable costs by 20 percent starting in the third year of production and an additional 20 percent starting in the sixth year of production. Long-term impacts on costs are expected to decrease as manufacturers fully amortize their fixed costs and learn to optimize their designs and production processes to meet the standards more efficiently. The learning curve has not been applied to the marine evaporative controls or the motorcycles under 50cc because we expect manufacturers to use technologies that will be well established prior to the start of the program. We request comment on the methodology used to incorporate the learning curve into the analysis.

Evaporative emission controls for boats with marine SI engines have an average projected cost of about $36 per boat. While manufacturers may choose from a wide variety of technologies to meet emission standards, we base these cost estimates on all boats using limited flow orifices for diurnal emission control, fluorination for fuel tank permeation control and low permeability barrier for fuel hose permeation control. Under the proposed emission-credit program, manufacturers would have the option of offering different technologies to meet emission standards. Where there is a current demand for more sophisticated fuel-tank technology, we would expect a greater cost impact than from the lower-cost, high-production models. Emissions are reduced by preventing evaporation of fuel, so these controls translate directly into a fuel savings, which we have estimated to be about $27 per boat (net present value at the point of sale). Therefore, we get an average cost of $9 per boat when the fuel savings are considered.

We project average costs of $26 per Class III highway motorcycle to meet the Tier 1 standard and $35 to meet the Tier 2 standards. We anticipate the manufacturers will meet the proposed emission standards with several technology changes, including electronic fuel injection, catalysts, pulse-air systems, and other general improvements to engines. For motorcycles with engines of less than 50cc, we project average costs of $44 per motorcycle to meet the proposed standards. We anticipate the manufacturers of these small motorcycles (mostly scooters) will meet the proposed emission standards by transitioning any remaining two-stroke engines to four-strokes. The costs are based on the conversion to 4-stroke because we believe this to be the most likely technology path for the majority of scooters. Manufacturers could also choose to employ advanced technology two-stroke (*e.g.,* direct injection and/or catalysts) designs. The process of developing clean technologies is very much underway already as a result of regulatory actions in Europe and the rest of world where the primary markets for

[46] For further information on learning curves, see previous final rules for Tier 2 highway vehicles (65 FR 6698, February 10, 2000), marine diesel engines (64 FR 73300, December 29, 1999), nonroad diesel engines (63 FR 56968, October 23, 1998), and highway diesel engines (62 FR 54694, October 21, 1997).

small motorcycles exist. Chapter 4 of the Draft Regulatory Support Document describes these technologies further. Because several models are already available with the anticipated long-term emission-control technologies, we believe that manufacturers and consumers will be able to bear the added cost associated with the new emission standards.

The above analysis presents unit cost estimates for each engine type. These costs represent the total set of costs the engine manufacturers will bear to comply with emission standards. With current and projected estimates of engine and equipment sales, we translate these costs into projected direct costs to the nation for the new emission standards in any year. A summary of the annualized costs to manufacturers by equipment type is presented in Table VI.B–1. (The annualized costs are determined over the first twenty-years that the proposed standards would be effective.) The annual cost savings for marine vessels and highway motorcycles (<50cc only) are due to reduced fuel costs. The total fleetwide fuel savings start slowly, then increase as greater numbers of compliant vessels or motorcycles (<50cc only) enter the fleet. Table VI.B–1 presents a summary of the annualized reduced operating costs as well.

TABLE VI.B–1.—ESTIMATED ANNUAL COST TO MANUFACTURERS AND ANNUAL FUEL SAVINGS DUE TO THE PROPOSED STANDARDS

[Millions/year]

| Category | Annualized cost to manufacturers | Annual fuel savings |
|---|---|---|
| Marine SI Evap | $27.5 | $15.6 |
| Highway Motorcycles | 18.8 | 0.2 |
| Aggregate* | 42.0 | 13.3 |

*Because of the different proposed implementation dates for the two classes, the aggregate is based on a 22 year (rather than 20 year) annualized cost. Therefore, the aggregate is not equal to the sum of the costs for the two engine types.

*C. Cost per Ton of Emissions Reduced*

We calculated the cost per ton of emission reductions for the proposed standards. For these calculations, we attributed the entire cost of the proposed program to the control of ozone precursor emissions (HC or $NO_X$ or both). Table VI.C–1 presents the discounted cost-per-ton estimates for this proposal. Reduced operating costs offsets a portion of the increased cost of producing the cleaner marine vessels and highway motorcycles (<50cc only).

TABLE VI.C–1.—ESTIMATED COST-PER-TON OF THE PROPOSED EMISSION STANDARDS

| Category | Effective date | Discounted reductions per engine (short tons) | Pollutants | Discounted cost per ton | |
|---|---|---|---|---|---|
| | | | | Without fuel savings | With fuel savings |
| Marine SI: | | | | | |
| Diurnal | 2008 | 0.01 | Evaporative HC | $745 | $382 |
| Tank permeation | | 0.02 | | 523 | 160 |
| Hose permeation | | 0.04 | | 367 | 4 |
| Aggregate | | 0.07 | | 478 | 115 |
| Highway motorcycles >50cc | 2006 | 0.03 | Exhaust HC+$NO_X$ | 970 | 970 |
| Highway motorcycles >50cc | 2010 | 0.03 | Exhaust HC+$NO_X$ | 1,230 | 1,230 |
| Highway motorcycles >50cc | 2006 | 0.02 | Exhaust HC | 2,130 | 1,750 |

Because the primary purpose of cost-effectiveness is to compare our program to alternative programs, we made a comparison between the cost per ton values presented in this chapter and the cost-effectiveness of other programs. Table VI.C–2 summarizes the cost effectiveness of several recent EPA actions for controlled emissions from mobile sources. Additional discussion of these comparisons is contained in the Regulatory Impact Analysis.

TABLE VI.C–2—COST-EFFECTIVENESS OF PREVIOUSLY IMPLEMENTED MOBILE SOURCE PROGRAMS

[Costs adjusted to 2001 dollars]

| Program | $/ton |
|---|---|
| Tier 2 vehicle/gasoline sulfur | 1,437–2,423 |
| 2007 Highway HD diesel | 1,563–2,002 |
| 2004 Highway HD diesel | 227–444 |
| Off-highway diesel engine | 456–724 |

TABLE VI.C–2—COST-EFFECTIVENESS OF PREVIOUSLY IMPLEMENTED MOBILE SOURCE PROGRAMS—Continued

[Costs adjusted to 2001 dollars]

| Program | $/ton |
|---|---|
| Tier 1 vehicle | 2,202–2,993 |
| NLEV | 2,069 |
| Marine SI engines | 1,255–1,979 |
| On-board diagnostics | 2,480 |
| Marine CI engines | 26–189 |

*D. Additional Benefits*

For the marine evaporative emission standards, we expect there will be a fuel savings as manufacturers redesign their vessels to comply with the proposed standards. This savings is the result of preventing fuel from evaporating into the atmosphere. Overall, the fuel savings associated with the anticipated changes in technology are estimated to be about 31 million gallons per year once the program is fully phased in.

For the motorcycle emission standards, we expect there will be a fuel savings as manufacturers redesign their engines to comply with the proposed standards. This savings is the result of converting motorcycles <50cc from 2-stroke designs to more fuel efficient 4-stroke designs. Overall, the fuel savings associated with the anticipated changes in technology are estimated to be about 0.3 million gallons per year once the program is fully phased in.

The controls in this rule are a highly cost-effective means of obtaining reductions in HC and $NO_X$ emissions. A related subject concerns the value of the health and welfare benefits these reductions might produce. While we have not conducted a formal benefit-cost analysis for this rule, we believe the benefits of this rule clearly will greatly outweigh any cost.

Ozone causes a range of health problems related to breathing, including chest pain, coughing, and shortness of breath Exposure to PM (including secondary PM formed in the atmosphere from $NO_X$ and NMHC emissions) is associated with premature death, increased emergency room visits, and increased respiratory symptoms and disease Children, the elderly, and individuals with pre-existing respiratory conditions are most at risk regarding both ozone and PM. In addition, ozone, $NO_X$, and PM adversely affect the environment in various ways, including crop damage, acid rain, and visibility impairment.

In two recent mobile-source control rules, for light-duty vehicles (the Tier 2/Gasoline Sulfur rule) and for highway heavy-duty engines and diesel fuel, we conducted a full analysis of the expected benefits once the rules were fully implemented. These rules, which primarily reduced $NO_X$ and NMHC emissions, were seen to yield health and welfare benefits far exceeding the costs. Besides reducing premature mortality, there were large projected reductions in chronic bronchitis cases, hospital admissions for respiratory and cardiovascular causes, asthma attacks and other respiratory symptoms, and a variety of other effects.

Given the similarities in pollutants being controlled, we would expect this rule to produce substantial benefits compared to its cost.

## VII. Public Participation

This rule was proposed under the authority of section 307(d) of the Clean Air Act. We request comment on all aspects of this proposal. This section describes how you can participate in this process.

### *A. How Do I Submit Comments?*

We are opening a formal comment period by publishing this document. We will accept comments for the period indicated under **DATES** above. If you have an interest in the program described in this document, we encourage you to comment on any aspect of this rulemaking. We request comment on various topics throughout this proposal.

We attempted to incorporate all the comments received in response to the Advance Notice of Proposed Rulemaking, though not all comments are addressed directly in this document. Anyone who has submitted comments on the Advance Notice, or any previous publications related to this proposal, and feels that those comments have not been adequately addressed is encouraged to resubmit comments as appropriate.

Your comments will be most useful if you include appropriate and detailed supporting rationale, data, and analysis. If you disagree with parts of the proposed program, we encourage you to suggest and analyze alternate approaches to meeting the air quality goals described in this proposal. You should send all comments, except those containing proprietary information, to our Air Docket (see **ADDRESSES**) before the end of the comment period.

If you submit proprietary information for our consideration, you should clearly separate it from other comments by labeling it ''Confidential Business Information.'' You should also send it directly to the contact person listed under **FOR FURTHER INFORMATION CONTACT** instead of the public docket. This will help ensure that no one inadvertently places proprietary information in the docket. If you want us to use your confidential information as part of the basis for the final rule, you should send a nonconfidential version of the document summarizing the key data or information. We will disclose information covered by a claim of confidentiality only through the application of procedures described in 40 CFR part 2. If you don't identify information as confidential when we receive it, we may make it available to the public without notifying you.

### *B. Will There Be a Public Hearing?*

We will hold a public hearing for issues related to highway motorcycles on July 16 in Dulles, VA. We will hold a public hearing for issues related to marine vessels on July 18 in Ann Arbor, MI. The hearings will start at 9:30 a.m. and continue until testimony is complete. See **ADDRESSES** above for location and phone information.

If you would like to present testimony at a public hearing, we ask that you notify the contact person listed above at least ten days before the hearing. You should estimate the time you need for your presentation and identify any needed audio/visual equipment. We suggest that you bring copies of your statement or other material for the EPA panel and the audience. It would also be helpful if you send us a copy of your statement or other materials before the hearing.

We will make a tentative schedule for the order of testimony based on the notification we receive. This schedule will be available on the morning of each hearing. In addition, we will reserve a block of time for anyone else in the audience who wants to give testimony.

We will conduct the hearing informally, and technical rules of evidence won't apply. We will arrange for a written transcript of the hearing and keep the official record of the hearing open for 30 days to allow you to submit supplementary information. You may make arrangements for copies of the transcript directly with the court reporter.

## VII. Administrative Requirements

### *A. Administrative Designation and Regulatory Analysis (Executive Order 12866)*

Under Executive Order 12866 (58 FR 51735, October 4, 1993), the Agency must determine whether the regulatory action is ''significant'' and therefore subject to review by the Office of Management and Budget (OMB) and the requirements of this Executive Order. The Executive Order defines a ''significant regulatory action'' as any regulatory action that is likely to result in a rule that may:

- 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;
- Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;
- Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs, or the rights and obligations of recipients thereof; or
- Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

A Draft Regulatory Support Document has been prepared and is available in the docket for this rulemaking and at the internet address listed under **ADDRESSES** above. Pursuant to the terms of Executive Order 12866, OMB has notified EPA that it considers this a ''significant regulatory action'' within the meaning of the Executive Order. EPA has submitted this action to OMB for review. Changes made in response to OMB suggestions or recommendations will be documented in the public record.

### *B. Regulatory Flexibility Act*

1. Overview

The RFA generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute unless the agency

certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions.

For purposes of assessing the impacts of this action on small entities, small entity is defined as: (1) A small business that meet the definition for business based on SBA size standards; (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. The following table provides an overview of the primary SBA small business categories potentially affected by this regulation.

TABLE VIII.B–1.—PRIMARY SBA SMALL BUSINESS CATEGORIES POTENTIALLY AFFECTED BY THIS PROPOSED REGULATION

| Industry | NAICS [1] codes | Defined by SBA as a small business If: [2] |
|---|---|---|
| Motorcycles and motorcycle parts manufacturers | 336991 | <500 employees. |
| Independent Commercial Importers of Vehicles and parts | 421110 | <100 employees. |
| Boat Building and Repairing | 336612 | < 500 employees. |
| Fuel Tank Manufacturers | 336211 | <1000 employees. |

[1] North American Industry Classification System.

[2] According to SBA's regulations (13 CFR part 121), businesses with no more than the listed number of employees or dollars in annual receipts are considered ''small entities'' for purposes of a regulatory flexibility analysis.

2. Background

In accordance with Section 603 of the RFA, EPA prepared an initial regulatory flexibility analysis (IRFA) that examines the impact of the proposed rule on small entities along with regulatory alternatives that could reduce that impact. In preparing this IRFA, we looked at both the effect of this proposal and the October 5, 2001 proposal for other nonroad categories (66 FR 51098). The IRFA is available for review in the docket and is summarized below.

The process of establishing standards for nonroad engines began in 1991 with a study to determine whether emissions of carbon monoxide (CO), oxides of nitrogen ($NO_X$), and volatile organic compounds (VOCs) from new and existing nonroad engines, equipment, and vehicles are significant contributors to ozone and CO concentrations in more than one area that has failed to attain the national ambient air quality standards for ozone and CO.[47] In 1994, EPA finalized its finding that nonroad engines as a whole ''are significant contributors to ozone or carbon monoxide concentrations'' in more than one ozone or carbon monoxide nonattainment area.[48]

Upon this finding, the Clean Air Act (CAA or the Act) requires EPA to establish standards for all classes or categories of new nonroad engines that cause or contribute to air quality nonattainment in more than one ozone or carbon monoxide (CO) nonattainment area. Since the finding in 1994, EPA has been engaged in the process of establishing programs to control emissions from nonroad engines used in many different applications. Nonroad categories already regulated include:

- Land-based compression ignition (CI) engines (*e.g.,* farm and construction equipment),
- Small land-based spark-ignition (SI) engines (*e.g.,* lawn and garden equipment, string trimmers),
- Marine engines (outboards, personal watercraft, CI commercial, CI engines <37kW), and
- Locomotive engines.

On December 7, 2000, EPA issued an Advance Notice of Proposed Rulemaking (ANPRM) for the control of emissions from nonroad large SI engines, recreational vehicles (marine and land-based), and highway motorcycles. As discussed in the ANPRM, the proposal under development will be a continuation of the process of establishing standards for nonroad engines and vehicles, as required by CAA section 213(a)(3). If, as expected, standards for these engines and vehicles are established, essentially all new nonroad engines will be required to meet emissions control requirements.

This proposal is the second part of an effort to control emissions from nonroad engines that are currently unregulated and for updating Federal emissions standards for highway motorcycles. The first part of this effort was a proposal published on October 5, 2001 for emission control from large spark-ignition engines such as those used in forklifts and airport tugs; recreational vehicles using spark-ignition engines such as off-highway motorcycles, all-terrain vehicles, and snowmobiles; and recreational marine diesel engines.

EPA found that the nonroad engines described above cause or contribute to air quality nonattainment in more than one ozone or carbon monoxide (CO) nonattainment area.[49] CAA section 213 (a)(3) requires EPA to establish standards that achieve the greatest degree of emissions reductions achievable taking cost and other factors into account. EPA plans to propose emissions standards and related programs consistent with the requirements of the Act.

In addition to proposing standards for the nonroad vehicles and engines noted above, this proposal reviews EPA requirements for highway motorcycles. The emissions standards for highway motorcycles were established twenty-three years ago. These standards allow motorcycles to emit about 100 times as much per mile as new cars and light trucks. California recently adopted new emissions standards for highway motorcycles, and new standards and testing cycles are being considered internationally. There may be opportunities to reduce emissions in a cost-effective way.

The program under consideration will cover engines and vehicles that vary in design and use, and many readers may only be interested in one or two of the applications. There are various ways EPA could group the engines and present information. For purposes of the proposed rule EPA has chosen to group engines by common applications (*e.g,* recreational land-based engines, marine

[47] ''Nonroad Engine and Vehicle Emission Study—Report and Appendices,'' EPA–21A–201, November 1991 (available in Air docket A–91–24). It is also available through the National Technical Information Service, referenced as document PB 92–126960.

[48] 59 FR 31306 (July 17, 1994).

[49] See Final Finding, ''Control of Emissions from New Nonroad Spark-Ignition Engines Rated above 19 Kilowatts and New Land-Based Recreational Spark-Ignition Engines'' for EPA's finding for Large SI engines and recreational vehicles (65 FR 76790, December 7, 2000). EPA's findings for marine engines are contained in 61 FR 52088 (October 4, 1996) for gasoline engines and 64 FR 73299 (December 29, 1999) for diesel engines.

engines, large spark ignition engines used in commercial applications).

3. Summary of Regulated Small Entities

The small entities directly regulated by this proposed rule are the following:

a. Highway Motorcycles. Of the numerous manufacturers supplying the U.S. market for highway motorcycles, Honda, Harley Davidson, Yamaha, Kawasaki, Suzuki, and BMW are the largest, accounting for 95 percent or more of the total U.S. sales. All of these companies except Harley-Davidson and BMW also manufacture off-road motorcycles and ATVs for the U.S. market. Harley-Davidson is the only company manufacturing highway motorcycles exclusively in the U.S. for the U.S. market.

Since highway motorcycles have had to meet emission standards for the last twenty years, EPA has good information on the number of companies that manufacture or market highway motorcycles for the U.S. market in each model year. In addition to the big six manufacturers noted above, EPA finds as many as several dozen more companies that have operated in the U.S. market in the last couple of model years. Most of these are U.S. companies that are either manufacturing or importing motorcycles, although a few are U.S. affiliates of larger companies in Europe or Asia. Some of the U.S. manufacturers employ only a few people and produce only a handful of custom motorcycles per year, while others may employ several hundred and produce up to several thousand motorcycles per year.

The proposed emission standards impose no new development or certification costs for any company producing compliant engines in California. If fact, implementing the California standards with a two-year delay also allows manufacturers to streamline their production to further reduce the cost of compliance. The estimated hardware costs are less than one percent of the cost of producing a highway motorcycle, so none of these companies should have a compliance burden greater than one percent of revenues. We expect that a small number of companies affected by EPA emission standards will not already be certifying products in California. For these companies, the modest effort associated with applying established technology will add compliance costs representing between 1 and 3 percent of revenues. The flexible approach we are proposing to limit testing, reporting, and recordkeeping burden prevent excessive costs for all these companies.

b. Marine Vessels. Marine vessels include the boat, engine, and fuel system. The evaporative emission controls discussed above may affect the boat builders and/or the fuel tank manufacturers. Exhaust emission controls including NTE requirements, as addressed in the August 29, 1999 SBAR Panel Report, would affect the engine manufacturers and may affect boat builders.

EPA has less precise information about recreational boat builders than is available about engine manufacturers. EPA has utilized several sources, including trade associations and Internet sites when identifying entities that build and/or sell recreational boats. EPA has also worked with an independent contractor to assist in the characterization of this segment of the industry. Finally, EPA has obtained a list of nearly 1,700 boat builders known to the U.S. Coast Guard to produce boats using engines for propulsion. At least 1,200 of these companies install engines that use gasoline fueled engines and would therefore be subject to the evaporative emission control program discussed above. More than 90% of the companies identified so far would be considered small businesses as defined by SBA. EPA continues to develop a more complete picture of this segment of the industry and will provide additional information as it becomes available.

Based on information supplied by a variety of recreational boat builders, fuel tanks for boats using SI marine engines are usually purchased from fuel tank manufacturers. However, some boat builders construct their own fuel tanks. The boat builder provides the specifications to the fuel tank manufacturer who helps match the fuel tank for a particular application. It is the boat builder's responsibility to install the fuel tank and connections into their vessel design. For vessels designed to be used with small outboard engines, the boat builder may not install a fuel tank; therefore, the end user would use a portable fuel tank with a connection to the engine.

EPA has determined that total sales of tanks for gasoline marine applications is approximately 550,000 units per year. The market is broken into manufacturers that produce plastic tanks and manufacturers that produce aluminum tanks. EPA has determined that there are at least seven companies that make plastic fuel tanks with total sales of approximately 440,000 units per year. EPA has determined that there at least four companies that make aluminum fuel tanks with total sales of approximately 110,000 units per year. All but one of these plastic and aluminum fuel tank manufacturers is a small business as defined under SBA.

EPA has determined that there are at least 16 companies that manufacture CI diesel engines for recreational vessels. Nearly 75 percent of diesel engines sales for recreational vessels in 2000 can be attributed to three large companies. Six of the 16 identified companies are considered small businesses as defined by SBA. Based on sales estimates for 2000, these six companies represent approximately 4 percent of recreational marine diesel engine sales. The remaining companies each comprise between two and seven percent of sales for 2000.

EPA has determined that there are at least 24 companies that manufacture SD/I gasoline engines (including airboats and jet boats) for recreational vessels. Seventeen of the identified companies are considered small businesses as defined by SBA. These 17 companies represent approximately 6 percent of recreational gasoline marine engines sales for 2000. Approximately 70–80 percent of gasoline SD/I engines manufactured in 2000 can be attributed to one company. The next largest company is responsible for about 10–20 percent of 2000 sales.

For any boat builders that would certify to the proposed requirements, the costs of compliance would be much less than one percent of their revenues. Incremental costs of fuel tanks are dwarfed by the capital and variable costs associated with manufacturing power boats. Of the six known small businesses producing plastic fuel tanks for gasoline-powered marine vessels, these companies would have costs approaching 10 percent of revenues. While this is a large percentage, it comes predominantly from increasing variable costs to upgrade the fuel tanks. Capital expenses to upgrade to compliant products are relatively small. Also, to the extent that tank manufacturers certify their products, they will be increasing the value of their product for their customers, who would otherwise need to assume certification responsibilities. As a result, we believe that these companies will be able to largely recover their compliance costs over time. The net cost absorbed by tank manufacturers will be much less than one percent.

For this proposal as a whole, there are hundreds of small businesses that will have total compliance costs less than 1 percent of their annual revenues. We estimate that three companies will have compliance costs between 1 and 3 percent of revenues and six companies

will have compliance costs exceeding 3 percent of revenues.

4. Potential Reporting, Recordkeeping, and Compliance

For any emission control program, EPA must have assurances that the regulated engines will meet the standards. Historically, EPA programs have included provisions placing manufacturers responsible for providing these assurances. The program that EPA is considering for manufacturers subject to this proposal may include testing, reporting, and record keeping requirements. Testing requirements for some manufacturers may include certification (including deterioration testing), and production line testing. Reporting requirements would likely include test data and technical data on the engines including defect reporting. Manufacturers would likely have to keep records of this information.

5. Related Federal Rules

The Panel is aware of several other current Federal rules that relate to the proposed rule under development. During the Panel's outreach meeting, SERs specifically pointed to Consumer Product Safety Commission (CPSC) regulations covering ATVs, and noted that they may be relevant to crafting an appropriate definition for a competition exclusion in this category. The Panel recommends that EPA continue to consult with the CPSC in developing a proposed and final rule in order to better understand the scope of the Commission's regulations as they may relate to the competition exclusion.

Other SERs, representing manufacturers of marine engines, noted that the U.S. Coast Guard regulates vessel tanks, most notably tank pressure and anti-siphoning requirements for carburetted engines. Tank manufacturers would have to take these requirements into account in designing evaporative control systems. The Panel recommends that EPA continue to work with the Coast Guard to evaluate the safety implications of any proposed evaporative emissions standards and to avoid interference with Coast Guard safety regulations.

The Panel is also aware of other Federal rules that relate to the categories that EPA would address with the proposed rule, but are not likely to affect policy considerations in the rule development process. For example, there are now EPA noise standards covering off-road motorcycles; however, EPA expects that most emission control devices are likely to reduce, rather than increase, noise, and that therefore the noise standards are not likely to be important in developing a proposed rule.

OTAQ is currently developing a proposal that would revise the rule assigning fees to be paid by parties required to certify engines in return for continuing Government oversight and testing. Among other options, EPA could propose to extend the fee structure to several classes of non-road engines for which requirements are being established for the first time under the Recreation Rule. The Panel understands that EPA will carefully examine the potential impacts of the Fees Rule on small businesses. The Panel also notes that EPA's Office of Air Quality, Planning, and Standards (OAQPS) is preparing a Maximum Achievable Control Technology (MACT) standard for Engine Testing Facilities, which is a related matter.

6. Significant Panel Findings

The Panel considered a wide range of options and regulatory alternatives for providing small businesses with flexibility in complying with the proposed emissions standards and related requirements. As part of the process, the Panel requested and received comment on several ideas for flexibility that were suggested by SERs and Panel members. The major options recommended by the Panel are summarized below. The complete set of recommendations can be found in Section 9 of the Panel's full Report.

The panel recommendations for motorcycles described below were developed for the exhaust emission standards. Potential controls for permeation emissions from motorcycles were not part of the panel process, because review of the need for such controls resulted from comments received on the related recreational vehicles proposal and further investigation by EPA following the end of the panel process. However, EPA believes that the potential permeation emission controls on motorcycles would not, if promulgated, have a significant effect on the burdens of this rule on regulated entities, or on small entities in particular, due to the relatively low cost and the availability of materials and treatment support by outside vendors. Low permeation fuel hoses are available from vendors today, and we would expect that surface treatment for tanks would be applied through an outside company. We request comment on the need for flexibilities for the potential permeation standards, if they are adopted. If the comments or other information the Agency receives indicate that flexibilities similar to (or the same as) those for the motorcycle exhaust standards are appropriate for the motorcycle permeation standards, then we will adopt such flexibilities as part of our final rule if we adopt such permeation standards.

Many of the flexible approaches recommended by the Panel can be applied to either marine vessels or highway motorcycles. These approaches are listed below:

1. Additional lead time for compliance.
2. Hardship provisions.
3. Certification flexibility.
4. Broadly defined product certification families.
5. Averaging, banking, and trading.

Based on consultations with SERs, the Panel believes that the first two provisions listed above are likely to provide the greatest flexibility for many small entities. These provisions are likely to be most valuable because they either provide more time for compliance (*e.g.,* additional lead time and hardship provisions). The remaining three approaches have the potential to reduce near-term and even long-term costs once a small entity has a product it is preparing to certify. These are important in that the reducing costs of testing several emission families and/or developing deterioration factors. Small businesses could also meet an emission standard on average or generate credits for producing engines which emit at levels below the standard; these credits could then be sold to other manufacturers for compliance or banked for use in future model years.

During the consultation process, it became evident that, in a few situations, it could be helpful to small entities if unique provisions were available. Two such provisions are described below.

a. Marine Vessel Tanks. Most of this sector involves small fuel tank manufacturers and small boat builders. The Panel recommends that the program be structured with longer lead times and an early credit generation program to enable the fuel tank manufacturers to implement controls on tanks on a schedule consistent with their normal turnover of fuel tank molds. Also, the panel recommends that the program allow small businesses have the option of certifying to the evaporative emission performance standards based on fuel tank design characteristics designed to reduce emissions.

b. Highway Motorcycles. The California Air Resources Board (CARB) has found that California's Tier 2 standard is potentially infeasible for small manufacturers. Therefore, the Panel recommends that EPA delay making decisions on the applicability to small businesses of Tier 2 or other such

revisions to the federal regulations until California's 2006 review is complete.

7. Summary of SBREFA Process and Panel Outreach

As required by section 609(b) of the RFA, as amended by SBREFA, EPA also conducted outreach to small entities and convened a Small Business Advocacy Review Panel to obtain advice and recommendations of representatives of the small entities that potentially would be subject to the rule's requirements.

On May 3, 2001, EPA's Small Business Advocacy Chairperson convened this Panel under Section 609(b) of the Regulatory Flexibility Act (RFA) as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA). In addition to the Chair, the Panel consisted of the Director of the Assessment and Standards Division (ASD) within EPA's Office of Transportation and Air Quality, the Chief Counsel for Advocacy of the Small Business Administration, and the Deputy Administrator of the Office of Information and Regulatory Affairs within the Office of Management and Budget. As part of the SBAR process, the Panel met with small entity representatives (SERs) to discuss the potential emission standards and, in addition to the oral comments from SERs, the Panel solicited written input. In the months preceding the Panel process, EPA conducted outreach with small entities from each of the five sectors as described above. On May 18, 2001, the Panel distributed an outreach package to the SERs. On May 30 and 31, 2001, the Panel met with SERs to hear their comments on preliminary alternatives for regulatory flexibility and related information. The Panel also received written comments from the SERs in response to the discussions at this meeting and the outreach materials. The Panel asked SERs to evaluate how they would be affected under a variety of regulatory approaches, and to provide advice and recommendations regarding early ideas for alternatives that would provide flexibility to address their compliance burden.

SERs representing companies in each of the sectors addressed by the Panel raised concerns about the potential costs of complying with the rules under development. For the most part, their concerns were focused on two issues: (1) The difficulty (and added cost) that they would face in complying with certification requirements associated with the standards EPA is developing, and (2) the cost of meeting the standards themselves. SERs observed that these costs would include the opportunity cost of deploying resources for research and development, expenditures for tooling/retooling, and the added cost of new engine designs or other parts that would need to be added to equipment in order to meet EPA emission standards. In addition, in each category, the SERs noted that small manufacturers (and in the case of one category, small importers) have fewer resources and are therefore less well equipped to undertake these new activities and expenditures. Furthermore, because their product lines tend to be smaller, any additional fixed costs must be recovered over a smaller number of units. Thus, absent any provisions to address these issues, new emission standards are likely to impose much more significant adverse effects on small entities than on their larger competitors.

The Panel discussed each of the issues raised in the outreach meetings and in written comments by the SERs. The Panel agreed that EPA should consider the issues raised by the SERs and that it would be appropriate for EPA to propose and/or request comment on various alternative approaches to address these concerns. The Panel's key discussions centered around the need for and most appropriate types of regulatory compliance alternatives for small businesses. The Panel considered a variety of provisions to reduce the burden of complying with new emission standards and related requirements. Some of these provisions would apply to all companies (*e.g.,* averaging, banking, and trading), while others would be targeted at the unique circumstances faced by small businesses. A complete discussion of the regulatory alternatives recommended by the Panel can be found in the Final Panel Report. Copies of the Final Report can be found in the docket for this rulemaking or at *http://www.epa.gov/sbrefa.* Summaries of the Panel's recommended alternatives for each of the sectors subject to this action can be found in the respective sections of the preamble.

As required by section 609(b) of the RFA, as amended by SBREFA, EPA also conducted outreach to small entities and convened a Small Business Advocacy Review Panel to obtain advice and recommendations of representatives of the small entities that potentially would be subject to the rule's requirements. EPA's Small Business Advocacy Chairperson convened this on May 3, 2001. In addition to the Chair, the Panel consisted of the Director of the Assessment and Standards Division (ASD) within EPA's Office of Transportation and Air Quality, the Chief Counsel for Advocacy of the Small Business Administration, and the Deputy Administrator of the Office of Information and Regulatory Affairs within the Office of Management and Budget.

The proposal being developed includes marine sterndrive and inboard (SD/I) engines and boats powered by SI marine engines. In addition, EPA also intends to update EPA requirements for highway motorcycles. Finally, the proposal being developed included evaporative emission control requirements for gasoline fuel tanks and systems used on marine vessels.

The Panel met with Small Entity Representatives (SERs) to discuss the potential emissions standards and, in addition to the oral comments from SERs, the Panel solicited written input. In the months preceding the Panel process, EPA conducted outreach with small entities from each of the five sectors as described above. On May 18, 2001, the Panel distributed an outreach package to the SERs. On May 30 and 31, 2001, the Panel met with SERs to hear their comments on preliminary options for regulatory flexibility and related information. The Panel also received written comments from the SERs in response to the discussions at this meeting and the outreach materials. The Panel asked SERs to evaluate how they would be affected under a variety of regulatory approaches, and to provide advice and recommendations regarding early ideas to provide flexibility. See Section 8 of the Panel Report for a complete discussion of SER comments, and Appendices A and B for summaries of SER oral comments and SER written comments.

Consistent with the RFA/SBREFA requirements, the Panel evaluated the assembled materials and small-entity comments on issues related to the elements of the IRFA. A copy of the Panel report is included in the docket for this proposed rule. The following are Panel recommendations adopted by the Agency. Please note *all* Panel recommendations were adopted for this proposal.

a. Related Federal Rules. The Panel recommends that EPA continue to consult with the CPSC in developing a proposed and final rule in order to better understand the scope of the Commission's regulations as they may relate to the competition exclusion. In addition, the Panel recommends that EPA continue to work with the Coast Guard to evaluate the safety implications of any proposed evaporative emissions standards and to avoid interference with Coast Guard safety regulations.

b. Regulatory Flexibility Alternatives. The Panel recommends that EPA consider and seek comments on a wide range of alternatives, including the flexibility options described below.

(i) Marine Vessels.

(*A*) Smooth Transition to Proposed Standards.

The Panel recommends that EPA propose an approach that would implement any evaporative standards five years after a regulation for marine engines takes effect. The Panel also recommends that EPA seek comment on this five year period and on whether there are small entities whose product line is dominated by tanks that turn over at a time rate slower time than five years.

(*B*) Design-Based Certification.

The Panel recommends that EPA propose to grant small businesses the option of certifying to the evaporative emission performance requirements based on fuel tank design characteristics that reduce emissions. The Panel also recommends that EPA seek comment on and consider proposing an approach that would allow manufacturers to use this averaging approach with designs other than those listed in the final rule.

(*C*) ABT of Emission Credits with Design-Based Certification.

The Panel recommends that EPA allow manufacturers using design-based certification to generate credits. The Panel also recommends that EPA provide adequately detailed design specifications and associated emission levels for several technology options that could be used to certify.

(*D*) Broadly Defined Product Certification Families.

The Panel recommends that EPA take comment on the need for broadly defined emission families and how these families should be defined.

(*E*) Hardship Provisions.

The Panel recommends that EPA propose two types of hardship programs for marine engine manufacturers, boat builders and fuel tank manufacturers: (1) Allow small businesses to petition EPA for additional lead time to comply with the standards; and (2) allow small businesses to apply for hardship relief if circumstances outside their control cause the failure to comply (*i.e.* supply contract broken by parts supplier) and if the failure to sell the subject fuel tanks or boats would have a major impact on the company's solvency. The Panel also recommends that EPA work with small manufacturers to develop these criteria and how they would be used.

(ii) Highway Motorcycles.

The Panel recommends that EPA include the flexibilities described below for small entities with highway motorcycle annual sales of less than 3,000 units per model year (combined Class I, II, and III motorcycles) and fewer than 500 employees.

(*A*) Delay of Proposed Standards.

The Panel recommends that EPA propose to delay compliance with the Tier 1 standard of 1.4 g/km $HC+NO_X$ until the 2008 model year for small volume manufacturers. The Panel also recommends that EPA seek comment on whether additional time is needed for small businesses to comply with the Federal program. The Panel recommends that EPA participate with CARB in the 2006 progress review as these provisions are revisited, and delay making decisions on the applicability to small businesses of Tier 2 or other revisions to the federal regulations that are appropriate following the review. The Panel also recommends that any potential Tier 2 requirements for small manufacturer motorcycles consider potential test procedure changes arising from the ongoing World Motorcycle Test Cycle work described in the Panel Report.

(*B*) Broader Engine Families.

The Panel recommends that EPA keep the current existing regulations for small volume highway motorcycle manufacturers.

(*C*) Exemption from Production Line Testing.

The Panel recommends that EPA keep the current provisions for no mandatory production line testing requirement for highway motorcycles and allow the EPA to request production vehicles from any certifying manufacturer for testing.

(*D*) Averaging, Banking, and Trading (ABT).

The Panel recommends that EPA propose an ABT program for highway motorcycles.

(*E*) Hardship Provisions.

The Panel recommends that EPA propose two types of hardship programs for highway motorcycles: (1) Allow small businesses to petition EPA for additional lead time to comply with the standards; and (2) allow small businesses to apply for hardship relief if circumstances outside their control cause the failure to comply (*i.e.* supply contract broken by parts supplier) and if failure to sell the subject engines or vehicles would have a major impact on the company's solvency. The Panel also recommends that EPA request comment on the California requirements, which do not include hardship provisions.

(*F*) Reduced Certification Data Submittal and Testing Requirements.

The Panel recommends that EPA keep current EPA regulations allow significant flexibility for certification by manufacturers who project fewer than 10,000 unit sales of combined Class I, II, and III motorcycles.

We invite comments on all aspects of the proposal and its impacts on small entities.

*C. Paperwork Reduction Act*

The information collection requirements in this proposed rule have been submitted for approval to the Office of Management and Budget (OMB) under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* Information Collection Requests (ICR No. 1897.03 for marine vessels and 0783.43 for highway motorcycles) have been prepared by EPA, and a copy may be obtained from Susan Auby, Collection Strategies Division; U.S. Environmental Protection Agency (2822); 1200 Pennsylvania Ave., NW., Washington, DC 20460, by e-mail at *auby.susan@epamail.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 being collected is to be used by EPA to ensure that new marine vessels and fuel systems and new highway motorcycles comply with applicable emissions standards through certification requirements and various subsequent compliance provisions.

For marine vessels, the annual public reporting and recordkeeping burden for this collection of information is estimated to average 6 hours per response, with collection required annually. The estimated number of respondents is 810. The total annual cost for the first 3 years of the program is estimated to be $230,438 year and includes no annualized capital costs, $14,000 in operating and maintenance costs, at a total of 4,838 hours per year.

For highway motorcycles, the annual public reporting and recordkeeping burden for this collection of information is estimated to average 228 hours per response, with collection required annually. The estimated number of respondents is 73. The total annual cost for the first 3 years of the program is estimated to be $3,430,908 per year and includes no annualized capital costs, $2,728,000 in operating and maintenance costs, at a total of 16,647 hours per year.

Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, 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; adjusting the

existing ways to comply with any previously applicable instructions and requirements; train personnel to be able 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 regulations are displayed in 40 CFR part 9 and 48 CFR chapter 15.

Comments are requested on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques. Send comments on the ICR to the Director, Collection Strategies Division; U.S. Environmental Protection Agency (2822); 1200 Pennsylvania Ave., NW., Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th St., NW., Washington, DC 20503, marked ''Attention: Desk Officer for EPA.'' Include the ICR number in any correspondence. Since OMB is required to make a decision concerning the ICR between 30 and 60 days after August 14, 2002, a comment to OMB is best ensured of having its full effect if OMB receives it by September 13, 2002. The final rule will respond to any OMB or public comments on the information collection requirements contained in this proposal.

*D. Intergovernmental Relations*

1. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Pub. L. 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 one 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 of why that alternative was not adopted.

Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including tribal governments, it must have developed under section 203 of the UMRA a small government agency plan. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements.

This rule contains no Federal mandates for state, local, or tribal governments as defined by the provisions of Title II of the UMRA. The rule imposes no enforceable duties on any of these governmental entities. Nothing in the rule would significantly or uniquely affect small governments.

EPA has determined that this rule contains federal mandates that may result in expenditures of less than $100 million to the private sector in any single year. EPA believes that the proposal represents the least costly, most cost-effective approach to achieve the air quality goals of the rule. The costs and benefits associated with the proposal are discussed in Section VI and in the Draft Regulatory Support Document.

2. 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 6, 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.'' ''Policies that have tribal implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and the Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.''

This proposed rule does not have tribal implications. It will not have substantial direct effects on tribal governments, 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, as specified in Executive Order 13175. This rule contains no federal mandates for tribal governments. Thus, Executive Order 13175 does not apply to this rule. However, in the spirit of Executive Order 13175, and consistent with EPA policy to promote communications between EPA and tribal governments, we specifically solicit additional comment on this proposed rule from tribal officials.

*E. National Technology Transfer and Advancement Act*

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (''NTTAA''), Public Law 104–113, § 12(d) (15 U.S.C. 272 note) directs EPA to use voluntary consensus standards in its regulatory activities unless doing so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.,* materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards.

This proposed rule involves technical standards. The following paragraphs describe how we specify testing procedures for engines subject to this proposal.

We are proposing to test highway motorcycles with the Federal Test Procedure, a chassis-based transient test. There is no voluntary consensus standard that would adequately address engine or vehicle operation for suitable emission measurement.

For marine vessels, we are proposing to use an evaporative emission test procedure based on the highway Federal Test Procedure. There is no voluntary consensus standard for testing evaporative emission from marine vessels. In addition, we are proposing the option of using design-based certification.

*F. Protection of Children (Executive Order 13045)*

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, Section 5–501 of the Order directs the Agency to 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.

This proposed rule is not subject to the Executive Order because it does not involve decisions on environmental health or safety risks that may disproportionately affect children.

The effects of ozone and PM on children's health were addressed in detail in EPA's rulemaking to establish the NAAQS for these pollutants, and EPA is not revisiting those issues here. EPA believes, however, that the emission reductions from the strategies proposed in this rulemaking will further reduce air toxics and the related adverse impacts on children's health.

*G. Federalism (Executive Order 13132)*

Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.''

Under Section 6 of Executive Order 13132, EPA may not issue a regulation that has federalism implications, that imposes substantial direct compliance costs, and that is not required by statute, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by State and local governments, or EPA consults with State and local officials early in the process of developing the proposed regulation. EPA also may not issue a regulation that has federalism implications and that preempts State law, unless the Agency consults with State and local officials early in the process of developing the proposed regulation.

Section 4 of the Executive Order contains additional requirements for rules that preempt State or local law, even if those rules do not have federalism implications (*i.e.,* the rules 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). Those requirements include providing all affected State and local officials notice and an opportunity for appropriate participation in the development of the regulation. If the preemption is not based on express or implied statutory authority, EPA also must consult, to the extent practicable, with appropriate State and local officials regarding the conflict between State law and Federally protected interests within the agency's area of regulatory responsibility.

This proposed 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.

Although Section 6 of Executive Order 13132 does not apply to this rule, EPA did consult with representatives of various State and local governments in developing this rule. EPA has also consulted representatives from STAPPA/ALAPCO, which represents state and local air pollution officials.

In the spirit of Executive Order 13132, and consistent with EPA policy to promote communications between EPA and State and local governments, EPA specifically solicits comment on this proposed rule from State and local officials.

*H. Energy Effects (Executive Order 13211)*

This rule is not a ''significant energy action'' as defined in Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355 (May 22, 2001)) because it is not likely to have a significant adverse effect on the supply, distribution or use of energy. The proposed standards have for their aim the reduction of emission from certain nonroad engines, and have no effect on fuel formulation, distribution, or use. Generally, the proposed program leads to reduced fuel usage due to the reduction of wasted fuel through evaporation.

*I. Plain Language*

This document follows the guidelines of the June 1, 1998 Executive Memorandum on Plain Language in Government Writing. To read the text of the regulations, it is also important to understand the organization of the Code of Federal Regulations (CFR). The CFR uses the following organizational names and conventions.

Title 40—Protection of the Environment
Chapter I—Environmental Protection Agency
Subchapter C—Air Programs. This contains parts 50 to 99, where the Office of Air and Radiation has usually placed emission standards for motor vehicle and nonroad engines.
Subchapter U—Air Programs Supplement. This contains parts 1000 to 1299, where we intend to place regulations for air programs in future rulemakings.
Part 1045—Control of Emissions from Marine Spark-ignition Engines and Vessels
Part 1068—General Compliance Provisions for Engine Programs. Provisions of this part apply to everyone.

Each part in the CFR has several subparts, sections, and paragraphs. The following illustration shows how these fit together.

Part 1045
Subpart A
Section 1045.1
(a)
(b)
(1)
(2)
(i)
(ii)
(A)
(B)

A cross reference to § 1045.1(b) in this illustration would refer to the parent paragraph (b) and all its subordinate paragraphs. A reference to ''§ 1045.1(b) introductory text'' would refer only to the single, parent paragraph (b).

**List of Subjects**

*40 CFR Part 86*

Environmental protection, Administrative practice and procedure, Confidential business information, Labeling, Motor vehicle pollution, Reporting and recordkeeping requirements

*40 CFR Part 90*

Environmental protection, Administrative practice and procedure, Air pollution control, Confidential business information, Imports, Labeling, Reporting and recordkeeping requirements, Research, Warranties

*40 CFR Part 1045*

Environmental protection, Administrative practice and procedure,

Air pollution control, Confidential business information, Imports, Labeling, Penalties, Reporting and recordkeeping requirements, Research, Warranties

*40 CFR Part 1051*

Environmental protection, Administrative practice and procedure, Air pollution control, Confidential business information, Imports, Labeling, Penalties, Reporting and recordkeeping requirements, Warranties.

*40 CFR Part 1068*

Environmental protection, Administrative practice and procedure, Confidential business information, Imports, Motor vehicle pollution, Reporting and recordkeeping requirements, Warranties.

Dated: July 25, 2002.

**Christine Todd Whitman,**

*Administrator.*

For the reasons set out in the preamble, title 40, chapter I of the Code of Federal Regulations is proposed to be amended as set forth below:

## PART 86—CONTROL OF EMISSIONS FROM NEW AND IN-USE HIGHWAY VEHICLES AND ENGINES

1. The authority citation for part 86 continues to read as follows:

**Authority:** 42 U.S.C. 7401–7521(l) and 7521(m)–7671q.

## Subpart E—[Amended]

2. A new § 86.401–2006 is added to subpart E to read as follows:

### § 86.401–2006 General applicability.

This subpart applies to 1978 and later model year, new, gasoline-fueled motorcycles built after December 31, 1977, and to 1990 and later model year, new methanol-fueled motorcycles built after December 31, 1989, and to 1997 and later model year, new natural gas-fueled and liquefied petroleum gas-fueled motorcycles built after December 31, 1996, and to 2006 and later model year new motorcycles, regardless of fuel.

3. Section 86.402–78(a) is amended by adding a definition for ''Motor vehicle'' in alphabetical order to read as follows:

### § 86.402–78 Definitions.

(a) * * *

*Motor vehicle* has the meaning we give in 40 CFR 85.1703.

* * * * *

4. A new § 86.410–2006 is added to subpart E to read as follows:

### § 86.410–2006 Emission standards for 2006 and later model year motorcycles.

(a)(1) Exhaust emissions from Class I and Class II motorcycles shall not exceed the standards listed in the following table:

TABLE E.—2006.1 CLASS I AND II MOTORCYCLE EMISSION STANDARDS

| Model year | Emission standards (g/km) | |
|---|---|---|
| | HC | CO |
| 2006 and later ..... | 1.0 | 12.0 |

(2) Exhaust emissions from Class III motorcycles shall not exceed the standards listed in the following table:

TABLE E.—2006.2 CLASS III MOTORCYCLE EMISSION STANDARDS

| Tier | Model year | Emission standards (g/km) | |
|---|---|---|---|
| | | $HC+NO_X$ | CO |
| 1 ..... | 2006–2009 | 1.4 | 12.0 |
| 2 ..... | 2010 and later. | 0.8 | 12.0 |

(b) The standards set forth in paragraphs (a) (1) and (2) of this section refer to the exhaust emitted over the driving schedule as set forth in subpart F and measured and calculated in accordance with those procedures.

(c) Compliance with the $HC+NO_X$ standards set forth in paragraph (a)(2) of this section may be demonstrated using the averaging provisions of § 86.449.

(d) No crankcase emissions shall be discharged into the ambient atmosphere from any new motorcycle subject to this subpart.

(e) Manufacturers with fewer than 500 employees and producing fewer than 3000 motorcycles per year are considered small-volume manufacturers for the purposes of this section. The following provisions apply for these small-volume manufacturers:

(1) Small-volume manufacturers are not required to comply with the Tier 1 standards until model year 2008.

(2) Small-volume manufacturers are not required to comply with the Tier 2 standards.

5. A new § 86.419–2006 is added to subpart E to read as follows:

### § 86.419–2006 Engine displacement, motorcycle classes.

(a)(1) Engine displacement shall be calculated using nominal engine values and rounded to the nearest whole cubic centimeter, in accordance with ASTM E 29–67 (incorporated by reference in § 86.1).

(2) For rotary engines, displacement means the maximum volume of a combustion chamber between two rotor tip seals, minus the minimum volume of the combustion chamber between those two rotor tip seals, times three times the number of rotors, according to the following formula:

cc = (max. chamber volume − min. chamber volume) × 3 × no. of rotors

(b) Motorcycles will be divided into classes based on engine displacement.

(1) Class I—0 to 169 cc (0 to 10.4 cu. in.).

(2) Class II—170 to 279 cc (10.4 to 17.1 cu. in.).

(3) Class III—280 cc and over (17.1 cu. in. and over).

(c) At the manufacturer's option, a vehicle described in an application for certification may be placed in a higher class (larger displacement). All procedures for the higher class must then be complied with, compliance withemission standards will be determined on the basis of engine displacement.

6. A new § 86.445–2006 is added to subpart E to read as follows:

### § 86.445–2006 What temporary provisions address hardship due to unusual circumstances?

(a) After considering the circumstances, we may permit you to introduce into commerce highway motorcycles that do not comply with emission standards if all the following conditions and requirements apply:

(1) Unusual circumstances that are clearly outside your control and that could not have been avoided with reasonable discretion prevent you from meeting requirements from this chapter.

(2) You exercised prudent planning and were not able to avoid the violation; you have taken all reasonable steps to minimize the extent of the nonconformity.

(3) Not having the exemption will jeopardize the solvency of your company.

(4) No other allowances are available under the regulations to avoid the impending violation.

(b) To apply for an exemption, you must send the Designated Officer a written request as soon as possible before you are in violation. In your request, show that you meet all the conditions and requirements in paragraph (a) of this section.

(c) Include in your request a plan showing how you will meet all the applicable requirements as quickly as possible.

(d) You must give us other relevant information if we ask for it.

(e) We may include reasonable additional conditions on an approval granted under this section, including provisions to recover or otherwise address the lost environmental benefit or

paying fees to offset any economic gain resulting from the exemption. For example, we may require that you meet standards less stringent than those that currently apply.

7. A new § 86.446–2006 is added to subpart E to read as follows:

**§ 86.446–2006 What are the provisions for extending compliance deadlines for small-volume manufacturers under hardship?**

(a) After considering the circumstances, we may extend the compliance deadline for you to meet new or revised emission standards, as long as you meet all the conditions and requirements in this section.

(b) To be eligible for this exemption, you must qualify as a small-volume manufacturer under § 86.410–2006(e).

(c) To apply for an extension, you must send the Designated Officer a written request. In your request, show that all the following conditionsand requirements apply:

(1) You have taken all possible business, technical, and economic steps to comply.

(i) In the case of importers, show that you are unable to find a manufacturer capable of supplying complying products.

(ii) For all other manufacturers, show that the burden of compliance costs prevents you from meeting the requirements of this chapter.

(2) Not having the exemption will jeopardize the solvency of your company.

(3) No other allowances are available under the regulations to avoidthe impending violation.

(d) In describing the steps you have taken to comply under paragraph (c)(1) of this section, include at least the following information:

(1) Describe your business plan, showing the range of projects active or under consideration.

(2) Describe your current and projected financial standing, with and without the burden of complying with regulations.

(3) Describe your efforts to raise capital to comply with regulations.

(4) Identify the engineering and technical steps you have taken or planto take to comply with regulations.

(5) Identify the level of compliance you can achieve. For example, you may be able to produce engines that meet a somewhat less stringent emission standard than the regulations require.

(e) Include in your request a plan showing how you will meet all the applicable requirements as quickly as possible.

(f) You must give us other relevant information if we ask for it.

(g) An authorized representative of your company must sign the request andinclude the statement: ''All the information in this request is true andaccurate, to the best of my knowledge.''

(h) Send your request for this extension at least nine months before new standards apply. Do not send your request before the regulations in question apply to other manufacturers.

(i) We may include reasonable requirements on an approval granted underthis section, including provisions to recover or otherwise address the lostenvironmental benefit. For example, we may require that you meet a less stringent emission standard or buy and use available emission credits.

(j) We will approve extensions of up to one year. We may review and revisean extension as reasonable under the circumstances.

8. A new § 86.447–2006 is added to subpart E to read as follows:

**§ 86.447–2006 What are the provisions for exempting motorcycles under 50 cc from the requirements of this part if they use engines you certify under other programs?**

(a) This section applies to you if you manufacture engines under 50 cc for installation in a highway motorcycle. See § 86.448–2006 if you are not the engine manufacturer.

(b) The only requirements or prohibitions from this part that apply to a motorcycle that is exempt under this section are in this section and § 86.448–2006.

(c) If you meet all the following criteria regarding your new engine, itis exempt under this section:

(1) You must produce it under a valid certificate of conformity for one of the following types of engines or vehicles:

(i) Class II engines under 40 CFR part 90.

(ii) Recreational vehicles under 40 CFR part 1051.

(2) You must not make any changes to the certified engine that we could reasonably expect to increase its exhaust emissions. For example, if you make any of the following changes to one of these engines, you do not qualify for this exemption:

(i) Change any fuel system parameters from the certified configuration.

(ii) Change any other emission-related components.

(iii) Modify or design the engine cooling system so that temperatures or heat rejection rates are outside the original engine's specified ranges.

(3) You must make sure the engine has the emission label we require under 40 CFR part 90 or part 1051.

(4) You must make sure that fewer than 50 percent of the engine model'stotal sales, from all companies, are used in highway motorcycles.

(d) If you produce only the engine, give motorcycle manufacturers anynecessary instructions regarding what they may or may not change under paragraph (c)(2) of this section.

(e) If you produce both the engine and motorcycle under this exemption, you must do all of the following to keep the exemption valid:

(1) Make sure the original emission label is intact.

(2) Add a permanent supplemental label to the engine in a position where it will remain clearly visible after installation in the vehicle. In your engine's emission label, do the following:

(i) Include the heading: ''Highway Motorcycle Emission ControlInformation''.

(ii) Include your full corporate name and trademark.

(iii) State: ''THIS ENGINE WAS ADAPTED FOR HIGHWAY USE WITHOUT AFFECTING ITS EMISSION CONTROLS.''.

(iv) State the date you finished installation (month and year).

(3) Send the Designated Officer a signed letter by the end of each calendar year (or less often if we tell you) with all the following information:

(i) Identify your full corporate name, address, and telephone number.

(ii) List the models you expect to produce under this exemption in the coming year.

(iii) State: ''We produce each listed model as a highway motorcycle without making any changes that could increase its certified emission levels, as described in 40 CFR 86.447.''.

(f) If your vehicles do not meet the criteria listed in paragraph (c) of this section, they will be subject to the standards and prohibitions of this part. Producing these vehicles without a valid exemption or certificate of conformity would violate the prohibitions in Clean Air Act section 203 (42 U.S.C. 7522).

(g) If we request it, you must send us emission test data on the duty cycle for Class I motorcycles. You may include the data in your application for certification or in your letter requesting the exemption.

(h) Vehicles exempted under this section are subject to all the requirements affecting engines and vehicles under 40 CFR part 90 or part 1051, as applicable. The requirements and restrictions of 40 CFR part 90 or 1051 apply to anyone manufacturing these engines, anyone manufacturing vehicles that use these engines, and all other persons in the same manner as if

these engines were used in a nonroad application.

9. A new § 86.448–2006 is added to subpart E to read as follows:

**§ 86.448–2006 What are the provisions for producing motorcycles under 50 cc with engines already certified under other programs?**

(a) You may produce a highway motorcycle under 50 cc using a nonroad engine if you meet three criteria:

(1) The engine or vehicle is certified to 40 CFR part 90 or part 1051.

(2) The engine is not adjusted outside the manufacturer's specifications, as described in § 86.447–2006(c)(2) and (d).

(3) The engine or vehicle is not modified in any way that may affect its emission control.

(b) This section does not apply if you manufacture the engine yourself; see § 86.447–2006.

10. A new § 86.449 is added to subpart E to read as follows:

**§ 86.449 Averaging provisions.**

(a) Compliance with the $HC+NO_X$ standards set forth in § 86.410–2006(a)(2) may be demonstrated using the averaging provisions of this section. To do this you must show that your average emission levels are at or below the applicable standards in § 86.410–2006. Family emission limits (FELs) may not exceed 5.0 g/km.

(b) Do not include any exported vehicles in the certification averaging program. Include only motorcycles certified under this subpart.

(c) To use the averaging program, do the following things:

(1) Certify each vehicle to a family emission limit.

(2) Calculate a preliminary average emission level according to paragraph (d) of this section using projected production volumes for your application for certification.

(3) After the end of your model year, calculate a final average emission level according to paragraph (d) of this section for each type of recreational vehicle or engine you manufacture or import. Use actual production volumes.

(d) Calculate your average emission level for each type of recreational vehicle or engine for each model year according to the following equation and round it to the nearest tenth of a g/km. Use consistent units throughout the calculation.

(1) Calculate the average emission level as:

$$\text{Emission level} = \left[\sum_i (\text{FEL})_i \times (\text{UL})_i \times (\text{Production})_i\right] \Big/ \left[\sum_i (\text{Production})_i \times (\text{UL})_i\right]$$

Where:

$FEL_i$ = The FEL to which the engine family is certified.

$UL_i$ = The useful life of the engine family.

$Production_i$ = The number of vehicles in the engine family.

(2) Use production projections for initial certification, and actual production volumes to determine compliance at the end of the model year.

(e)(1) Maintain and keep five types of properly organized and indexed records for each group and for each emission family:

(i) Model year and EPA emission family.

(ii) FEL.

(iii) Useful life.

(iv) Projected production volume for the model year.

(v) Actual production volume for the model year.

(2) Keep paper records of this information for three years from the due date for the end-of-year report. You may use any additional storage formats or media if you like.

(3) Follow paragraphs (f) through (i) of this section to send us the information you must keep.

(4) We may ask you to keep or send other information necessary to implement this subpart.

(f) Include the following information in your applications for certification:

(1) A statement that, to the best of your belief, you will not have a negative credit balance for any type of recreational vehicle or engine when all credits are calculated. This means that if you believe that your average emission level will be above the standard (*i.e.*, that you will have a deficit for the model year), you must have banked credits pursuant to paragraph (j) of this section to offset the deficit.

(2) Detailed calculations of projected emission credits (zero, positive, or negative) based on production projections. If you project a credit deficit, state the source of credits needed to offset the credit deficit.

(g) At the end of each model year, send an end-of-year report.

(1) Make sure your report includes three things:

(i) Calculate in detail your average emission level and any emission credits based on actual production volumes.

(ii) If your average emission level is above the allowable average standard, state the source of credits needed to offset the credit deficit.

(2) Base your production volumes on the point of first retail sale. This point is called the final product-purchase location.

(3) Send end-of-year reports to the Designated Officer within 120 days of the end of the model year. If you send reports later, you are violating the Clean Air Act.

(4) If you generate credits for banking pursuant to paragraph (j) of this section and you do not send your end-of-year reports within 120 days after the end of the model year, you may not use or trade the credits until we receive and review your reports. You may not use projected credits pending our review.

(5) You may correct errors discovered in your end-of-year report, including errors in calculating credits according to the following table:

| If. . . | And if. . . | Then we . . . |
|---|---|---|
| (i) Our review discovers an error in your end-of-year report that increases your credit balance. | the discovery occurs within 180 days of receipt. | restore the credits for your use. |
| (ii) You discover an error in your report that increases your credit balance. | the discovery occurs within 180 days of receipt. | restore the credits for your use. |

| If. . . | And if. . . | Then we . . . |
|---|---|---|
| (iii) We or you discover an error in your report that increases your credit balance. | the discovery occurs more than 180 days after receipt. | do not restore the credits for your use. |
| (iv) We discover an error in your report that reduces your credit balance. | at any time after receipt ..... | reduce your credit balance. |

(h) Include in each report a statement certifying the accuracy and authenticity of its contents.

(i) We may void a certificate of conformity for any emission family if you do not keep the records this section requires or give us the information when we ask for it.

(j) You may include motorcycles that you certify with $HC+NO_X$ emissions below 0.8 g/km in the following optional early banking program:

(1) To include a motorcycle in the early banking program, assign it an emission rate of 0.8 g/km when calculating your average emission level for compliance with the Tier 1 standards.

(2)(i) Calculate bankable credits from the following equation:

Bonus credit = Y x [ (0.8 g/km—Certfied emission level) ]x [(Production volume of engine family) x (Useful life) ]

(ii) The value of Y is defined by the model year and emission level, as shown in the following table:

| Model year | Multiplier (Y) for use in MY 2010 or later corporate averaging | |
|---|---|---|
| | If your certified emission level is less than 0.8 g/km, but greater than 0.4 g/km, then Y = . . . | If your certified emission level is less than 0.4 g/km, then Y = . . . |
| 2003 through 2006 ..... | 1.5 | 3.0 |
| 2007 ..... | 1.375 | 2.5 |
| 2008 ..... | 1.250 | 2.0 |
| 2009 ..... | 1.125 | 1.5 |

(3) Credits banked under this paragraph (j) may be used for compliance with any 2010 or later model year standards as follows:

(i) If your average emission level is above the average standard, calculate your credit deficit according to the following equation, rounding to the nearest tenth of a gram:

Deficit = (Emission Level − Average Standard) x (Total Annual Production)

(ii) Credits deficits may be offset using banked credits.

## Subpart F—[Amended]

11. A new § 86.513–2004 is added to subpart F to read as follows:

### § 86.513–2004 Fuel and engine lubricant specifications.

Section 86.513–2004 includes text that specifies requirements that differ from § 86.513–94. Where a paragraph in § 86.513–94 is identical and applicable to § 86.513–2004, this may be indicated by specifying the corresponding paragraph and the statement ''[Reserved]. For guidance see § 86.513–94.'' Where a corresponding paragraph of § 86.513–94 is not applicable, this is indicated by the statement ''[Reserved].''

(a) *Gasoline.* (1) Gasoline having the following specifications will be used by the Administrator in exhaust emission testing of gasoline-fueled motorcycles. Gasoline having the following specifications or substantially equivalent specifications approved by the Administrator, shall be used by the manufacturer for emission testing except that the octane specifications do not apply.

TABLE 1 OF § 86.513–2004.—GASOLINE TEST FUEL SPECIFICATIONS

| Item | Procedure | Value |
|---|---|---|
| Distillation Range: | | |
| 1. Initial boiling point, °C ..... | ASTM D 86–97 ..... | 23.9—35.0.[1] |
| 2. 10% point, °C ..... | ASTM D 86–97 ..... | 48.9—57.2 |
| 3. 50% point, °C ..... | ASTM D 86–97 ..... | 93.3—110.0. |
| 4. 90% point, °C ..... | ASTM D 86–97 ..... | 148.9—162.8. |
| 5. End point, °C ..... | ASTM D 86–97 ..... | 212.8. |
| Hydrocarbon composition: | | |
| 1. Olefins, volume % ..... | ASTM D 1319–98 ..... | 10 maximum. |
| 2. Aromatics, volume % ..... | ASTM D 1319–98 ..... | 35 minimum. |
| 3. Saturates ..... | ASTM D 1319–98 ..... | Remainder. |
| Lead (organic), g/liter ..... | ASTM D 3237 ..... | 0.013 maximum. |
| Phosphorous, g/liter ..... | ASTM D 3231 ..... | 0.005 maximum. |
| Sulfur, weight % ..... | ASTM D 1266 ..... | 0.08 maximum. |
| Volatility (Reid Vapor Pressure), kPa ..... | ASTM D 3231 ..... | 55.2 to 63.4.[1] |

[1] For testing at altitudes above 1 219 m, the specified volatility range is 52 to 55 kPa and the specified initial boiling point range is 23.9° to 40.6° C.

(2) Unleaded gasoline and engine lubricants representative of commercial fuels and engine lubricants which will be generally available though retail outlets shall be used in service accumulation.

(3) The octane rating of the gasoline used shall be no higher than 4.0. Research octane numbers above the minimum recommended by the manufacturer.

(4) The Reid Vapor Pressure of the gasoline used shall be characteristic of commercial gasoline fuel during the season in which the service accumulation takes place.

(b) through (d) [Reserved]. For guidance see § 86.513–94.

12. Section 86.544–90 is amended by revising the text preceding the formula to read as follows:

**§ 86.544–90 Calculations; exhaust emissions.**

The final reported text results, with oxides of nitrogen being optional for model years prior to 2006 and required for 2006 and later model years, shall be computed by use of the following formula (The results of all emission tests shall be rounded, in accordance with ASTM E29–90 (incorporated by reference in § 86.1), to the number of places to the right of the decimal point indicated by expressing the applicable standard to three significant figures.):

* * * * *

## Subpart I__[Amended]

13. Section 86.884–14 is amended by revising the equation in paragraph (a) to read as follows:

**§ 86.884–14 Calculations.**

(a) * * *

* * * * *

$$N_s = 100 \times \left(1 - \left(1 - N_m/100\right)^{L_s/L_m}\right)$$

## PART 90—CONTROL OF EMISSIONS FROM NONROAD SPARK-IGNITION ENGINES

14. The authority for part 90 continues to read as follows:

**Authority:** 42 U.S.C. 7521, 7522, 7523, 7524, 7525, 7541, 7542, 7543, 7547, 7549, 7550, and 7601(a).

## Subpart A—[Amended]

15. Section 90.1 as proposed at 66 FR 51181 is amended by adding a new paragraph (f) to read as follows:

**§ 90.1 Applicability.**

* * * * *

(f) This part also applies to engines under 50 cc used in highway motorcycles if the manufacturer uses the provisions of 40 CFR 86.447–2006 to meet the emission standards in this part instead of the requirements of 40 CFR part 86. Compliance with the provisions of this part is a required condition of that exemption.

**Subchapter U—Air Pollution Controls**

16. Part 1045 is added to subchapter U as proposed at 66 FR 51189 to read as follows:

## PART 1045—CONTROL OF EMISSIONS FROM SPARK-IGNITION MARINE VESSELS

**Subpart A—Determining How to Follow This Part**

Sec.



**Subpart B—Emission Standards and Related Requirements**



**Subpart C—Certifying Emission Families**



**Subpart D—[Reserved]**

**Subpart E—Testing In-use Engines**



**Subpart F—Test Procedures**



**Subpart G—Compliance Provisions**



**Subpart H—Averaging, Banking, and Trading for Certification**



**Subpart I—Definitions and Other Reference Information**



**Authority:** 42 U.S.C. 7401–7671(q).

## Subpart A—Determining How To Follow This Part

**§ 1045.1 Does this part apply to me?**

(a) This part applies to you if you manufacture or import new spark-ignition marine vessels (defined in § 1045.801) or part of a fuel system for such vessels (defined in § 1045.801), unless we exclude the vessels under § 1045.5. You should read § 1045.145 to determine whether we require all manufacturers to meet a specific requirement.

(b) See 40 CFR part 90 to meet exhaust-emission requirements for spark-ignition marine engines. Note that 40 CFR part 90 does not apply to all spark-ignition marine engines.

(c) Note in subpart G of this part that 40 CFR part 1068 applies to everyone, including anyone who manufactures, owns, operates, or repairs any of the vessels this part covers.

(d) You need not follow this part for vessels produced before the 2008 model year, unless you certify voluntarily. See § 1045.105, § 1045.145, and the definition of model year in § 1045.801

for more information about the timing of new requirements.

(e) See §§ 1045.801 and 1045.805 for definitions and acronyms that apply to this part.

(f) For now, ignore references to engines, which will apply when we establish exhaust emission standards in this part for spark-ignition marine engines.

#### § 1045.5 Are any of my vessels excluded from the requirements of this part?

(a) The requirements of this part do not apply to either of two types of marine vessels:

(1) *Hobby vessels.*

(2) Vessels fueled with diesel fuel, LPG, natural gas, or other fuel that is not a volatile liquid fuel.

(b) See part 1068, subpart C, of this chapter for exemptions of specific vessels.

(c) We may require you to label a vessel if this section excludes it and other requirements in this chapter do not apply (for example, hobby vessels).

(d) Send the Designated Officer a written request with supporting documentation if you want us to determine whether this part covers or excludes certain vessels. Excluding engines from this part's requirements does not affect other requirements that may apply to them.

#### § 1045.10 What main steps must I take to comply with this part?

(a) Every new vessel subject to the standards in this part must be covered by a certificate of conformity before it is sold, offered for sale, introduced into commerce, distributed or delivered for introduction into commerce, or imported into the United States. For evaporative emissions, either the vessel manufacturer or the fuel system manufacturer must apply for a certificate of conformity for each new model year.

(b) To get a certificate of conformity and comply with its terms, you must do three things:

(1) Show that each vessel will meet one of the individual emission standards and other requirements in subpart B of this part. You may also need to meet a corporate-average emission standard (see § 1045.105).

(2) Apply for certification (see subpart C of this part).

(3) Follow our instructions throughout this part.

(c) Subpart F of this part and 40 CFR part 86 describe the procedures you must follow to test your vessels. Subpart F of this part and § 1045.20 describe cases for which you may test the fuel system alone instead of testing the entire vessel.

(d) Subpart G of this part and 40 CFR part 1068 of this chapter describe requirements and prohibitions that apply to manufacturers, owners, operators, repairers, and all others associated with spark-ignition marine vessels.

#### § 1045.15 Do any other regulation parts affect me?

(a) Part 86 of this chapter describes how to measure evaporative emissions. Subpart F of this part describes how to apply part 86 of this chapter to show you meet this part's emission standards.

(b) Part 1068 of this chapter describes general provisions, including these seven areas:

(1) Prohibited acts and penalties for manufacturers and others.

(2) Rebuilding and other aftermarket changes.

(3) Exemptions for certain vessels.

(4) Importing vessels.

(5) Selective enforcement audits of your production.

(6) Defect reporting and recall.

(7) Procedures for public hearing.

(c) Other parts of this chapter affect you if referenced in this part.

#### § 1045.20 Can I certify just the fuel system instead of the entire vessel?

(a) You may certify only the fuel system if you manufacture part or all of the system for a vessel. Vessels using certified fuel systems do not need to be certified separately.

(b) If you certify a fuel system, you must do two things:

(1) Use good engineering judgment to ensure the engine will comply with emission standards after it is installed in a vessel.

(2) Comply with § 1045.130.

(c) Do not use the provisions of this section to circumvent emission standards or other requirements of this part.

## Subpart B—Emission Standards and Related Requirements

#### § 1045.105 What evaporative emission standards must my vessels meet?

Beginning January 1, 2008, each new vessel and new portable fuel tank must be certified to the emission standards of paragraphs (a) and (b) of this section (except as allowed by paragraph (c) of this section). Vessel manufacturers may certify vessels directly or use fuel systems certified by fuel-system manufacturers.

(a) *Diurnal Emissions.* Diurnal emissions from your vessel may not exceed 1.1 grams per gallon per day as measured according to the diurnal evaporative test procedures in subpart F of this part. You may use the averaging provisions in Subpart H of this part to show you meet the standards of this paragraph (a). Emission standards described in this paragraph apply to marine vessels with installed fuel tanks; they do not apply to portable fuel tanks, which are addressed in paragraph (c) of this section.

(b) *Permeation emissions.* Permeation emissions may not exceed the following standards:

(1) Permeation emissions from your vessel's fuel tank(s) may not exceed 0.08 grams per gallon per day as measured according to the tank permeation test procedures in subpart F of this part.

(2) Permeation emissions from your vessel's fuel lines may not exceed 5 grams per square-meter per day as measured according to the fuel line permeation test procedures in subpart F of this part. Use the inside diameter of the hose to determine the surface area of the hose.

(c) You may certify portable fuel tanks to the diurnal emission standards in paragraph (a) of this section by meeting the following design criteria:

(1) The tank may include no more than two vents, which must be readily sealable for pressures up 3 psig.

(2) All vents and the fuel-line connection to the engine must seal automatically when disconnected.

(d) You may certify vessels and fuel systems using the control technologies shown in the following tables ''by design.'' This means the design of these technologies certifies them to the standards specified in paragraph (a) of this section:

TABLE 1 OF § 1045.105.—DIURNAL LEVELS FOR DESIGN CERTIFICATION

| If the diurnal control technology is . . . | Then you may design-certify with a diurnal emission level of . . . |
|---|---|
| 1. Open-vented fuel tank | 1.5 g/gal/test. |
| 2. A sealed fuel tank with a pressure-relief valve that would open at a pressure of 0.5 psi | 1.3 g/gal/test. |
| 3. A sealed insulated fuel tank (R-value of 15 or better) with a limited flow orifice with a maximum cross-sectional area defined by the following equation: Area in $mm^2$ = 0.04 × fuel tank capacity in gallons (Example: A 20 gallon tank with an orifice no more than 1.0 mm in diameter.) | 1.3 g/gal/test. |
| 4. A sealed fuel tank with a pressure-relief valve that would open at a pressure of 1.0 psi | 1.1 g/gal/test. |
| 5. A sealed fuel tank with a pressure-relief valve that would open at a pressure of 1.5 psi | 0.9 g/gal/test. |
| 6. A sealed fuel tank with a pressure-relief valve that would open at a pressure of 2.0 psi | 0.7 g/gal/test. |
| 7. A sealed fuel tank with a pressure-relief valve that would open at a pressure of 0.5 psi, and with a volume-compensating bag made from a low-permeability material[1] with a bag volume equal to at least 25 percent of the volume of the fuel tank. | 0.5 g/gal/test. |
| 8. A sealed bladder fuel tank made from a low-permeability | 0.1 g/gal/test. |

[1] Permeability of 5 $g/m^2$/day or less.

TABLE 2 OF § 1045.105.—TANK PERMEATION LEVELS FOR DESIGN CERTIFICATION

| If the tank permeability control technology is . . . | Then you may design-certify with a tank emission level of . . . |
|---|---|
| 1. A metal fuel tank with no non-metal gaskets or with gaskets made from a low-permeability material[1] | 0.08 g/gal/test-day. |
| 2. A metal fuel tank with non-metal gaskets with an exposed surface area of 1000 $mm^2$ or less | 0.08 g/gal/test-day. |

[1] Permeability of 10 $g/m^2$/day or less.

TABLE 3 OF § 1045.105.—FUEL AND VENT-LINE PERMEATION LEVELS FOR DESIGN CERTIFICATION

| If the fuel-line and vent-line permeability control technology is . . . | Then you may design-certify with a fuel line permeation emission level of . . . |
|---|---|
| Hose meeting SAE 2260 Category 1 permeation level[1] | 5 $g/m^2$/test-day. |

[1] Hose must also meet U.S. Coast Guard Regulations.

(e) We may establish additional design certification options based on test data.

**§ 1045.115 What other requirements must my vessels meet?**

(a) through (d) [Reserved]

(e) *Prohibited controls.* You may not do either of the following things:

(1) You may not design engines or vessels with an emission-control system that emits any noxious or toxic substance that the engine would not emit during operation in the absence of such a system, except as specifically permitted by regulation.

(2) You may not design engines or vessels with an emission-control system that is unsafe. For example, emission controls must comply with all applicable U.S. Coast Guard regulations.

(f) *Defeat devices.* You may not equip your vessels with a defeat device. A defeat device is an auxiliary emission-control device or other control feature that degrades emission controls under conditions you may reasonably expect the vessel to encounter during normal operation and use.

(g) *Evaporative technology.* Make sure (by testing or engineering

analysis) that technologies used to meet evaporative emission standards keep working for at least 30 days while the boat or engine is not used. Design them to last for the full *useful life.* The useful life for evaporative controls is ten years.

(h) *Fuel-tank location.* The test procedures in subpart F of this part do not represent the experience of a vessel with the fuel tank exposed to direct sunlight (sun exposure can cause much greater fuel-temperature swings, which would increase evaporative emissions). If you design your vessel this way, you must show that you meet emission standards by measuring emissions with a test that incorporates the effect of the sun's radiant heat. Note: This requirement does not apply to portable fuel tanks.

**§ 1045.120 What warranty requirements apply to me?**

(a) You must warrant to the ultimate buyer that the new vessel meets two conditions:

(1) You have designed, built, and equipped it to meet the requirements of this part.

(2) It is free from defects in materials and workmanship that may keep it from meeting these requirements.

(b) Your emission-related warranty for evaporative controls must be valid for at least 50 percent of the useful life in years. You may offer a warranty more generous than we require. This warranty may not be shorter than any published or negotiated warranty you offer for the vessel or any of its components.

**§ 1045.125 What maintenance instructions must I give to buyers?**

Give the ultimate buyer of each new vessel written instructions for properly maintaining and using the vessel, including the emission-control system.

**§ 1045.130 What installation instructions must I give to vessel manufacturers?**

(a) If you sell a certified fuel system for someone else to install in a spark-ignition marine vessel, give the buyer of the fuel system written instructions for installing it consistent with the requirements of this part. Make sure these instructions have the following information:

(1) Include the heading: ''Emission-related installation instructions.''

(2) State: ''Failing to follow these instructions when installing a certified fuel system in a spark-ignition marine vessel violates federal law (40 CFR 1068.105(b)), subject to fines or other penalties as described in the Clean Air Act.''.

(3) Describe any other instructions to make sure the installed fuel system will operate according to design specifications in your application for certification.

(4) State: ''If you obscure the fuel system's emission label, you must attach a duplicate label to your vessel, as described in 40 CFR 1068.105.''.

(b) You do not need installation instructions for fuel systems you install in your own vessel.

**§ 1045.135 How must I label and identify the vessels and fuel systems I produce?**

(a) [Reserved]

(b) At the time of manufacture, add a permanent label identifying each tank. To meet labeling requirements, do three things:

(1) Attach the label in one piece so it is not removable without being destroyed or defaced.

(2) Design and produce it to be durable and readable for the vessel's entire life.

(3) Write it in block letters in English.

(c) On your fuel tank label, do ten things:

(1) Include the heading ''EMISSION CONTROL INFORMATION.''

(2) Include your full corporate name and trademark.

(3) State: ''THIS VESSEL IS CERTIFIED TO OPERATE ON [specify operating fuel or fuels].''.

(4) State the date of manufacture [DAY (optional), MONTH, and YEAR].

(5) State: ''THIS VESSEL MEETS U.S. ENVIRONMENTAL PROTECTION AGENCY REGULATIONS FOR [MODEL YEAR] VESSELS].''.

(6) Include EPA's standardized designation for the emission family.

(7) Include the model number (or part number) of the fuel tank.

(8) Include the part number(s) of the fuel lines.

(9) Include the fuel tank capacity in U.S. gallons.

(10) Describe other information on proper maintenance and use.

(11) Identify any other emission standards to which you have certified the vessel.

(d) You may combine the EPA emission control label with the label required by the U.S. Coast Guard. If you are unable to meet the exact labeling requirements described in paragraph (c) of this section for your combined label, you may ask us to modify the requirements consistent with the intent of this section.

(e) Some vessels may not have enough space for a label with all the required information. In this case, we may allow you to omit some of the information required if you print it in the owner's manual instead.

(f) If you are unable to meet these labeling requirements, you may ask us to modify them consistent with the intent of this section.

(g) If you obscure the fuel-tank label while installing the tank in the vessel, you must place a duplicate label on the vessel. If someone else installs the fuel tank in a vessel, give them duplicate labels if they ask for them (see 40 CFR 1068.105).

(h) Non-metallic fuel lines must be labeled with the name of the fuel line manufacturer and with a permeability classification.

**§ 1045.140 What interim provisions apply only for a limited time?**

From 2004 to 2007, if you certify to an FEL below the average standard in § 1045.105(a), you may generate early credits. Calculate credits according to § 1045.720(b) by replacing ''Average Standard'' with 1.1 g/gallon and ''Emission Level'' with the FEL to which the emission family is certified.

**§ 1045.145 What provisions apply to non-certifying manufacturers?**

(a) *General requirements.* The following general requirements apply to non-certifying manufacturers:

(1) Every manufacturer is responsible for compliance with the requirements of this part that apply to manufacturers. However, if one manufacturer complies with a requirement, then we will consider all manufacturers to have complied with that specific requirement.

(2) Where more than one entity meets the definition of manufacturer for a particular vessel and any one of the manufacturers obtains a certificate of conformity covering the whole vessel, the requirements of subparts C and H of this part and subparts E and F of part 1068 of this chapter apply to the manufacturer that holds the certificate of conformity. Other manufacturers must meet the requirements of subparts C and H of this part and subparts E and F of part 1068 of this chapter only if we say so. In this case, we will allow a reasonable time to meet the requirements that apply.

(b) *Requirements for permeability treatment.* If you treat fuel tanks or fuel lines to reduce permeability but do not hold the certificate, you must keep records of the treatment process for three years after the treatment occurs. You must make these records available to us if we request them.

(c) *Requirements for fuel system or emission control components.* If you manufacture a fuel system component or an emission control component or fuel lines used to reduce permeability but do not hold the certificate, we may require you to keep records of your manufacturing process for three years after the component is manufactured. You must make these records available to us if we request them.

(d) *Requirements for emission test data.* If a certifying manufacturer uses your emission test data to certify, we may require you to give us a signed statement verifying that your tests were conducted using the test procedures in this part.

## Subpart C—Certifying Emission Families

**§ 1045.201 What are the general requirements for submitting a certification application?**

(a) Send us an application for a certificate of conformity for each emission family. Each application is valid for only one model year.

(b) The application must not include false or incomplete statements or information (see § 1045.250). We may choose to ask you to send us less information than we specify in this subpart, but this would not change your recordkeeping requirements.

(c) Use good engineering judgment for all decisions related to your application (see § 1068.005 of this chapter).

(d) An authorized representative of your company must approve and sign the application.

**§ 1045.205 How must I prepare my application?**

In your application, you must do all the following things:

(a) Describe the emission family's specifications and other basic

parameters of the design. List the types of fuel you intend to use to certify the emission family (for example, gasoline or methanol).

(b) Explain how the emission-control system operates. Describe in detail all the system's components, auxiliary emission-control devices, and all fuel-system components you will install on any production or test system. Explain how you determined that the emission-control system comply with the requirements of § 1045.115, including why any auxiliary emission-control devices are not defeat devices (see § 1045.115(f)). Do not include detailed calibrations for components unless we ask for them.

(c) Describe the vessels, engines, tanks, and/or hoses you selected for testing and the reasons for selecting them.

(d) Describe any special or alternate test procedures you used (see § 1045.501).

(e) [Reserved]

(f) List the specifications of the test fuel to show that it falls within the required ranges we specify in 40 CFR part 1065, subpart C.

(g) Identify the emission family's useful life.

(h) Propose maintenance and use instructions for the ultimate buyer (see § 1045.125).

(i) Propose emission-related installation instructions if you sell fuel systems for someone else to install in a vessel (see § 1045.130).

(j) Propose an emission-control label.

(k) Present emission data for HC to show you meet the emission standards we specify in § 1045.105.

(l) Report all test results, including those from invalid tests or from any nonstandard tests.

(m) [Reserved]

(n) Describe all adjustable operating parameters.

(o) If you conducted testing, state that you conducted your emission tests according to the specified procedures and test parameters using the fuels described in the application to show you meet the requirements of this part.

(p) If you did not conduct testing, state how your emission family meets the requirements for design certification.

(q) State unconditionally that all the vessels in the emission family comply with the requirements of this part, other referenced parts, and the Clean Air Act (42 U.S.C. 7401 *et seq.*).

(r) Include estimates of vessel (or fuel system) production.

(s) Add other information to help us evaluate your application if we ask for it.

**§ 1045.215 What happens after I complete my application?**

(a) If any of the information in your application changes after you submit it, amend it as described in § 1045.225.

(b) We may decide that we cannot approve your application unless you revise it.

(1) If you inappropriately use the provisions of § 1045.230(c) or (d) to define a broader or narrower emission family, we will require you to redefine your emission family.

(2) If your proposed label is inconsistent with § 1045.135, we will require you to change it (and tell you how, if possible).

(3) If you require or recommend maintenance and use instructions inconsistent with § 1045.125, we will require you to change them.

(4) If we find any other problem with your application, we will tell you how to correct it.

(c) If we determine your application is complete and shows you meet all the requirements, we will issue a certificate of conformity for your emission family for that model year. If we deny the application, we will explain why in writing. You may then ask us to hold a hearing to reconsider our decision (see § 1045.820).

**§ 1045.225 How do I amend my application to include a new or modified product?**

(a) You must amend your application for certification before you take either of the following actions:

(1) Add a vessel, engine, or fuel system to a certificate of conformity.

(2) Make a design change for a certified emission family that may affect emissions or an emission-related part over the lifetime of the vessel, engine, or fuel system.

(b) Send the Designated Officer a request to amend the application for certification for an emission family. In your request, do all of the following:

(1) Describe the model or configuration you are adding or changing.

(2) Include engineering evaluations or reasons why the original testing is or is not still appropriate.

(3) If the original testing for the emission family is not appropriate to show compliance for the new or modified vessel, include new test data showing that the new or modified product meets the requirements of this part.

(c) You may start producing the new or modified product anytime after you send us your request.

(d) You must give us test data within 30 days if we ask for more testing, or stop production if you are not able do this.

(e) If we determine that the certificate of conformity would not cover your new or modified product, we will send you a written explanation of our decision. In this case, you may no longer produce these vessels, engines, or fuel systems, though you may ask for a hearing for us to reconsider our decision (see § 1045.820).

**§ 1045.230 How do I select emission families?**

(a) Divide your product line into groups of vessels (or fuel systems) that you expect to have similar emission characteristics. These groups are call emission families. (b) You need a separate emission family for each model year.

**§ 1045.235 How does testing fit with my application for a certificate of conformity?**

This section describes how to do testing in your effort to apply for a certificate of conformity.

(a) Test your vessels using the procedures and equipment specified in subpart F of this part.

(1) For evaporative testing, you may test the fuel system without the vessel.

(2) For exhaust testing, test the engine without the vessel.

(b) Select from each emission family a test vessel for each fuel type with a configuration you believe is most likely to exceed an applicable standard (e.g., the diurnal evaporative standard). Using good engineering judgment, consider the emission levels of all regulated constituents over the full useful life of the vessel.

(c) You may submit emission data for equivalent emission families from previous years instead of doing new tests, but only if the data shows that the test vessel would meet all the requirements for the latest models. We may require you to do new emission testing if we believe the latest models could be substantially different from the previously tested vessel.

(d) We may choose to measure emissions from any of your test vessels.

(1) If we do this, you must provide the test vessel at the location we select. We may decide to do the testing at your plant or any other facility. If we choose to do the testing at your plant, you must schedule it as soon as possible and make available the instruments and equipment we need. This provision does not apply for evaporative emission testing for manufacturers that use the design certification provisions for all of the products under § 1045.105(d).

(2) If we measure emissions on one of your test vessels, the results of that testing become the official data for the vessel. Unless we later invalidate this

data, we may decide not to consider your data in determining if your emission family meets the emission standards.

(e) We may allow you to certify vessels using existing data from vessels with similarly-designed fuel systems that you did not manufacture. In those cases, you are not required to emission-test your vessels or fuel systems.

(f) For fuel tanks that are design-certified based on permeability treatments for plastic fuel tanks, you do not need to test each emission family. However, you must use good engineering judgment to determine permeation rates for the tanks. Good engineering judgment requires that at least one fuel tank be tested for each set of treatment conditions. For example, if you treat tanks made from the same material using the identical tretament process, but that are in different emission families, then you would only need to test one tank.

#### § 1045.240 How do I determine if my emission family complies with emission standards?

(a) Your emission family complies with the applicable numerical emission standards in § 1045.105 if all emission-data vessels representing that family have test results showing emission levels at or below all applicable standards, provided you also comply with the average emission standard for your total production.

(b) Your emission family does not comply if any emission-data vessel representing that family has test results showing emission levels above the applicable standards from § 1045.105.

(c) If your average emission level is above an applicable standard, then all of emission families with emission levels above the average standard are noncompliant.

#### § 1045.245 What records must I keep and make available to EPA?

(a) Organize and maintain the following records to keep them readily available; we may review these records at any time:

(1) A copy of all applications and any summary information you sent us.

(2) Any of the information we specify in § 1045.205 that you did not include in your application.

(3) A detailed history of each emission-data vessel. In each history, describe the test vessel's construction, including its origin and buildup, steps you took to ensure that it represents production vessels, any components you built specially for it, and all emission-related components.

(b) Keep data from routine emission tests for one year after we issue the associated certificate of conformity. Keep all other information specified in paragraph (a) of this section for eight years after we issue your certificate.

(c) Store these records in any format and on any media, as long as you can promptly send us organized, written records in English if we ask for them.

(d) Send us copies of any vessel maintenance instructions or explanations if we ask for them.

#### § 1045.250 When may EPA deny, revoke, or void my certificate of conformity?

(a) We may deny your application for certification if your emission-data vessels fail to comply with emission standards or other requirements. Our decision may be based on any information available to us. If we deny your application, we will explain why in writing.

(b) In addition, we may deny your application or revoke your certificate if you do any of the following:

(1) Refuse to comply with any testing or reporting requirements.

(2) Submit false or incomplete information (paragraph (d) of this section applies if this is fraudulent).

(3) Render inaccurate any test data.

(4) Deny us from completing authorized activities despite our presenting a warrant or court order (see § 1068.020 of this chapter).

(5) Produce vessels for importation into the United States at a location where local law prohibits us from carrying out authorized activities.

(c) We may void your certificate if you do not keep the records we require or do not give us information when we ask for it.

(d) We may void your certificate if we find that you committed fraud to get it. This means intentionally submitting false or incomplete information.

(e) If we deny your application or revoke or void your certificate, you may ask for a hearing (see § 1045.820). Any such hearing will be limited to substantial and factual issues.

## Subpart D—[Reserved]

## Subpart E—Testing In-use Engines

#### § 1045.401 What provisions apply for in-use testing of vessels?

We may conduct in-use testing of any vessel (or part of a vessel) subject to the standards of this part. If we determine that a substantial number of vessels do not comply with the regulations of this part, we may order the manufacturer to conduct a recall as specified in 40 CFR part 1068.

## Subpart F—Test Procedures

#### § 1045.501 What equipment and general procedures must I use to test my vessels?

(a) *Diurnal testing.* Use the equipment specified in 40 CFR part 86 subpart B (*i.e.,* the procedures used to measure diurnal evaporative emissions for gasoline-fueled highway vehicles). Use the procedures specified in § 1045.505 to measure diurnal emissions.

(1) These provisions require placing your vessel or fuel system within a sealed, temperature-controlled enclosure called a SHED (Sealed Housing for Evaporative Determination).

(2) You must include a fan to maintain a minimum wind speed of 5 miles per hour across the tank.

(b) *Permeation testing.* Use the following equipment and procedures for measuring permeation emissions:

(1) For fuel tank permeation, see § 1045.506.

(2) For fuel line permeation, see SAE J1527 (incorporated by reference in § 1045.810). Alternatively, you may use the equipment and procedures specified in SAE J1737 (incorporated by reference in § 1045.810), except that all tests must be conducted at 23°C ± 2°C.

(c) *Special or alternate procedures.* You may use special or alternate procedures, as described in § 1065.010 of this chapter.

#### § 1045.505 How do I test for diurnal evaporative emissions?

Measure evaporative emissions by placing the preconditioned vessel or fuel system within a sealed, temperature-controlled SHED and recording the concentration of fuel vapors within the SHED as the temperature cycles between 22.2°C and 35.6°C.

(a) *Preconditioning and test preparation.* To prepare your vessel or fuel system, follow these seven steps:

(1) To precondition the tank, fill it to its nominal capacity and allow it to soak at 30°C ± 5°C for one month. Note: You may omit this step; however, if you omit this step, you may not correct measured emissions for permeation that occurs during the test.

(2) Determine the tank's fuel capacity in gallons as configured in the vessel (using at least three significant figures).

(3) Fill the fuel tank with the test fuel to its capacity. If you fill the tank within the SHED, do not spill any fuel.

(4) Allow the tank and its contents to equilibrate to 22.2°C ± 1°C within the SHED.

(5) Connect a fuel siphon to the tank outlet and drain 60 percent of the fuel. You may vent the tank before draining it. Do not spill any fuel.

(6) Close the SHED and set the temperature control to 22.2° F. Allow the SHED to equilibrate for two hours.

(7) If the fuel tank vent will have an attached vent hose when installed in the vessel, attach a vent hose representative of the shortest length of vent hose that will be used when the tank is installed in the vessel. You may attach the hose at any time before you start the test run (§ 1045.505(b)).

(b) *Test run.* To measure emissions from your vessel or fuel system, follow these six steps:

(1) Ensure that the measured temperature within the SHED is 22.2 ± 0.2°C.

(2) Ventilate the SHED.

(3) Seal the SHED and record the hydrocarbon concentration within the SHED. This is the zero-hour value.

(4) Begin the temperature cycle in Table 1 of § 1045.505. Run the temperature cycle three times.

(5) Record the hydrocarbon concentration at the end of each temperature cycle.

(6) Use the calculation procedures of 40 CFR 86.143–96 to calculate the mass emissions for each of the three 24-hour temperature cycles. The highest of the these three is the official test result. If you precondition the tank as specified in § 1045.505(a)(1), you may correct these results by subtracting the permeation emissions from the total, consistent with good engineering judgment.

TABLE 1 OF § 1045.505—24-HOUR TEMPERATURE CYCLE FOR EMISSION TESTING

| Time (hours) | Temperature (°C) |
|---|---|
| 0 | 22.2 |
| 1 | 22.5 |
| 2 | 23.6 |
| 3 | 26.6 |
| 4 | 29.5 |
| 5 | 31.8 |
| 6 | 34.0 |
| 7 | 34.8 |
| 8 | 35.5 |
| 9 | 35.6 |
| 10 | 35.3 |
| 11 | 34.4 |
| 12 | 33.5 |
| 13 | 31.8 |
| 14 | 30.0 |
| 15 | 28.6 |
| 16 | 27.1 |
| 17 | 26.1 |
| 18 | 25.0 |
| 19 | 24.3 |
| 20 | 23.7 |
| 21 | 23.3 |
| 22 | 22.8 |
| 23 | 22.5 |
| 24 | 22.2 |

### § 1045.506 How do I test my fuel tank for permeation emissions?

Measure permeation emissions by weighing a sealed fuel tank before and after a temperature controlled soak.

(a) *Preconditioning.* To precondition your fuel tank, follow these six steps:

(1) Fill the tank and allow it to soak at 30°C ±10° C for 60 days.

(2) Determine the tank's fuel capacity as configured in the vessel to the nearest tenth of a gallon.

(3) Fill the fuel tank with the test fuel to its capacity. If you fill the tank within the SHED, do not spill any fuel.

(4) Allow the tank and its contents to equilibrate to 40°C ±2° C.

(5) Seal the fuel tank using nonpermeable fittings, such as metal or Teflon™.

(b) *Test run.* To measure emissions from your fuel tank, follow these nine steps:

(1) Weigh the sealed fuel tank, and record the weight to the nearest 0.1 grams. (You may use less precise weights, provided that the difference in mass from the start of the test to the end of the test has at least three significant figures.)

(2) Carefully place the tank within the temperature controlled container or SHED. Do not spill any fuel.

(3) Close the container or SHED and record the time.

(4) Ensure that the measured temperature within the container or SHED is 40°C ±2° C.

(5) Leave the tank in the container or SHED for 10 to 30 days, consistent with good engineering judgment (based on the expected permeation rate).

(6) Hold the temperature of the container or SHED to 40°C ±2° C and record at least daily.

(7) At the end of the soak period, weigh the sealed fuel tank and record the weight to the nearest 0.1 grams. (You may use less precise weights, provided that the difference in mass from the start of the test to the end of the test has at least three significant figures.)

(8) Subtract the weight of the tank at the end of the test from the weight of the tank at the beginning of the test, and divide the difference by the capacity of the fuel tank. Divide this gram/gallon value by the number of test days to calculate the gram/gallon/test-day emission rate. Example: If a 20.4-gallon tank weighed 31782.3 grams at the beginning of the test, weighed 31760.2 grams after soaking for 25.03 days, then the gram/gallon/test-day emission rate would be:

(31882.3 g—31760.2 g) / 20.4 gal / 25.03 test days = 0.239 g/gal/test-day

(9) Round your result to the same number of decimal places as the standard.

## Subpart G—Compliance Provisions

### § 1045.601 What compliance provisions apply to these vessels?

Vessel manufacturers, as well as owners, operators, and rebuilders of these vessels, and all other persons, must observe the requirements and prohibitions in part 1068 of this chapter.

## Subpart H—Averaging, Banking, and Trading for Certification

### § 1045.701 General provisions.

(a) You may average, bank, and trade emission credits for certification as described in this subpart to meet the average standards of this part. You must comply with the averaging requirements if you certify with an emission level higher than the applicable average standard. Participation in banking and trading is voluntary. Note: Some standards, such as the tank permeation standard, do not allow you to comply on average.

(b) The definitions of Subpart I of this part apply to this subpart. The following definitions also apply:

(1) *Average standard* means the standard that applies on average to all your vessels, engines, or fuel systems that are subject to this part (except portable fuel tanks).

(2) *Broker* means any entity that facilitates a trade between a buyer and seller.

(3) *Buyer* means the entity that receives credits as a result of trade or transfer.

(4) *FEL* means the familiy emission limit to which an emission family is certified

(5) *Group* means a group of vessels having the same evaporative control technology, model year, and fuel-tank capacity.

(6) *Reserved credits* means credits generated but not yet verified by EPA in the end of year report review.

(7) *Seller* means the entity that provides credits during a trade or transfer.

(8) *Transfer* means to convey control of credits an individual tank generates—

(i) From a certifying tank manufacturer to a vessel manufacturer that buys the tank; or

(ii) To a certifying tank manufacturer from a vessel manufacturer that buys the tank.

(c) Do not include any exported vessel, engine, or tank in the certification averaging, banking, and

trading program. Include only vessels, engines, or fuel tanks certified under this part.

**§ 1045.705 How do I average emission levels?**

(a) As specified in subpart B of this part, certify each emission family that you are including the averaging program to an FEL.

(b) Calculate a preliminary average emission level according to § 1045.720 using projected production volumes for your application for certification.

(c) After the end of your model year, calculate a final average emission level according to § 1045.720 using actual production volumes.

(d) If your preliminary average emission level is below the allowable average standard, see § 1045.710 for information about generating and banking emission credits. These credits will be considered reserved until verified by EPA during the end of year report review.

**§ 1045.710 How do I generate and bank emission credits?**

(a) If your average emission level is below the average standard, you may calculate credits according to § 1045.720.

(b) You may generate credits if you are a certifying manufacturer. You may hold them if you are a fuel tank or vessel manufacturer

(c) You may bank unused emission credits, but only after the end of the calendar year and after we have reviewed your end-of-year reports.

(d) During the calendar year and before you send in your end-of-year report, you may consider reserved any credits you originally designate for banking during certification. You may redesignate these credits for trading or transfer in your end-of-year report, but they are not valid to demonstrate compliance until verified.

(e) You may use for averaging or trading any credits you declared for banking from the previous calendar year that we have not reviewed. But, we may revoke these credits later—following our review of your end-of-year report or audit actions. For example, this could occur if we find that credits are based on erroneous calculations; or that emission levels are misrepresented, unsubstantiated, or derived incorrectly in the certification process.

**§ 1045.715 How do I trade or transfer emission credits?**

(a) You may trade only banked credits, not reserved credits.

(b) Whether or not you hold a certificate, you may transfer unbanked credits to a manufacturer that is supplying a fuel tank to you or a vessel manufacturer that is buying a fuel tank from you.

(c) How you handle unused transferred credits at the end of a model year depends on whether or not you hold a certificate.

(1) If you hold a certificate, you may bank these credits.

(2) If you do not hold a certificate, you may not bank these credits; you may only transfer them to a certificate holder.

(d) If a negative credit balance results from a credit trade or transfer, both buyers and sellers are liable, except in cases involving fraud. We may void the certificates of all emission families participating in a negative trade.

(1) If you buy credits but have not caused the negative credit balance, you must only supply more credits equivalent to the amount of invalid credits you used.

(2) If you caused the credit shortfall, you may be subject to the requirements of § 1045.730(b)(6).

**§ 1045.720 How do I calculate my average emission level or emission credits?**

(a) Calculate your average emission level for each model year according to the following equation and round it to the nearest tenth of a gram per gallon. Use consistent units throughout the calculation.

(1) Calculate the average emission level as:

$$\text{Emission level} = \left[\sum_i (\text{FEL})_i \times (\text{Capacity})_i \times (\text{Production})_i\right] \Big/ \left[\sum_i (\text{Production})_i \times (\text{Capacity})_i\right]$$

Where:

$FEL_i$ = The FEL to which the engine family is certified.

$Capacity_i$ = The capacity of the fuel tanks.

$Production_i$ = The number of fuel tanks produced in that model year with a capacity of $Capacity_i$.

(2) Sum the emissions for each unique combination of emission family and fuel tank capacity.

(3) Use production projections for initial certification, and actual production volumes to determine compliance at the end of the model year.

(b) If your average emission level is below the average standard, calculate credits available for banking according to the following equation and round them to the nearest tenth of a gram:

$$\text{Credit} = \left[(\text{Average standard-Emission level})\right] \times \left[\sum_i (\text{Production})_i \times (\text{Capacity})_i\right]$$

(c) If your average emission level is above the average standard, calculate your preliminary credit deficit according to the following equation, rounding to the nearest tenth of a gram:

$$\text{Deficit} = \left[(\text{Emission level-Average standard})\right] \times \left[\sum_i (\text{Production})_i \times (\text{Capacity})_i\right]$$

**§ 1045.725 What information must I keep?**

(a) Maintain and keep five types of properly organized and indexed records for each group and for each emission family:

(1) Model year and EPA emission family.

(2) Bin standard.

(3) Fuel tank capacity.

(4) Projected production volume for the model year.

(5) Actual production volume for the model year.

(b) Keep paper records of this information for three years from the due date for the end-of-year report. You may use any additional storage formats or media if you like.

(c) Follow § 1045.730 to send us the information you must keep.

(d) We may ask you to keep or send other information necessary to implement this subpart.

**§ 1045.730 What information must I report?**

(a) Include the following information in your applications for certification:

(1) A statement that, to the best of your belief, you will not have a negative credit balance when all credits are calculated. This means that if you believe that your average emission level will be above the standard (*i.e.,* that you will have a deficit for the model year), you must have banked credits (or project to have traded credits) to offset the deficit.

(2) Detailed calculations of projected emission credits (zero, positive, or negative) based on production projections.

(i) If you project a credit deficit, state the source of credits needed to offset the credit deficit.

(ii) If you project credits, state whether you will reserve them for banking or transfer them.

(b) At the end of each model year, send an end-of-year report.

(1) Make sure your report includes three things:

(i) Calculate in detail your average emission level and any emission credits (zero, positive, or negative) based on actual production volumes.

(ii) If your average emission level is above the allowable average standard, state the source of credits needed to offset the credit deficit.

(iii) If your average emission level is below the allowable average standard, state whether you will reserve the credits for banking or transfer them.

(2) Base your production volumes on the point of first retail sale. This point is called the final product-purchase location.

(3) Send end-of-year reports to the Designated Officer within 120 days of the end of the model year. If you send reports later, you are violating the Clean Air Act.

(4) If you generate credits for banking and you do not send your end-of-year reports within 120 days after the end of the model year, you may not use or trade the credits until we receive and review your reports. You may not use projected credits pending our review.

(5) You may correct errors discovered in your end-of-year report, including errors in calculating credits according to the following table:

| If. . . | And if. . . | Then we. . . |
|---|---|---|
| (i) Our review discovers an error in your end-of-year report that increases your credit balance. | the discovery occurs within 180 days of receipt. | restore the credits for your use. |
| (ii) You discover an error in your report that increases your credit balance. | the discovery occurs within 180 days of receipt. | restore the credits for your use. |
| (iii) We or you discover an error in your report that increases your credit balance. | the discovery occurs more than 180 days after receipt. | do not restore the credits for your use. |
| (iv) We discover an error in your report that reduces your credit balance. | at any time after receipt ..... | reduce your credit balance. |

(6) If our review of your end-of year-report shows a negative balance, you may buy credits to bring your credit balance to zero. But you must buy 1.1 credits for each 1.0 credit needed. If enough credits are not available to bring your credit balance to zero, we may void the certificates for all families certified to standards above the allowable average.

(c) Within 90 days of any credit trade or transfer, you must send the Designated Officer a report of the trade or transfer that includes three types of information:

(1) The corporate names of the buyer, seller, and any brokers.

(2) Information about the credits that depends on whether you trade or transfer them.

(i) For trades, describe the banked credits being traded.

(ii) For transfers, calculate the credits in detail and identify the source or use of the credits.

(3) Copies of contracts related to credit trading or transfer from the buyer, seller, and broker, as applicable.

(d) Include in each report a statement certifying the accuracy and authenticity of its contents.

(e) We may void a certificate of conformity for any emission family if you do not keep the records this section requires or give us the information when we ask for it.

## Subpart I—Definitions and Other Reference Information

**§ 1045.801 What definitions apply to this part?**

The definitions in this section apply to this part. The definitions apply to all subparts unless we note otherwise. All undefined terms have the meaning the Act gives to them. The definitions follow:

*Act* means the Clean Air Act, as amended, 42 U.S.C. 7401 *et seq.*

*Adjustable parameter* means any device, system, or element of design that someone can adjust (including those which are difficult to access) and that, if adjusted, may affect emissions or vessel performance during emission testing or normal in-use operation.

*Aftertreatment* means relating to any system, component, or technology mounted downstream of the exhaust valve or exhaust port whose design function is to reduce exhaust emissions.

*Auxiliary emission-control device* means any element of design that senses temperature, engine rpm, boat speed, transmission gear, atmospheric pressure, manifold pressure or vacuum, or any other parameter to activate, modulate, delay, or deactivate the operation of any part of the emission-control system. This also includes any other feature that causes in-use emissions to be higher than those measured under test conditions, except as we allow under this part.

*Broker* means any entity that facilitates a trade of emission credits between a buyer and seller.

*Calibration* means the set of specifications and tolerances specific to a particular design, version, or application of a component or assembly capable of functionally describing its operation over its working range.

*Capacity* means the maximum volume of liquid fuel that a fuel tank can hold when installed in a vessel.

*Certification* means obtaining a certificate of conformity for an emission family that complies with the emission standards and requirements in this part.

*Compression-ignition* means relating to a type of reciprocating, internal-combustion vessel that is not a *spark-ignition* vessel.

*Crankcase emissions* means airborne substances emitted to the atmosphere from any part of the vessel crankcase's ventilation or lubrication systems. The crankcase is the housing for the crankshaft and other related internal parts.

*Designated Officer* means the Manager, Engine Compliance Programs Group (6403–J), U.S. Environmental Protection Agency, 1200 Pennsylvania Ave., Washington, DC 20460.

*Emission-control system* means any device, system, or element of design that controls or reduces the regulated emissions from an vessel.

*Emission-data vessel* means a vessel, engine, or fuel system that is tested for certification.

*Emission family* means a group of vessels, engines or fuel systems with similar emission characteristics, as specified in § 1045.230.

*Emission-related maintenance* means maintenance that substantially affects emissions or is likely to substantially affect emissions deterioration.

*Fuel system* means any or all of the components involved in transporting, metering, and mixing the fuel from the fuel tank to the combustion chamber(s), including the fuel tank, fuel tank cap, fuel pump, fuel filters, fuel lines, carburetor or fuel-injection components, and all fuel-system vents.

*Good engineering judgment* has the meaning we give it in § 1068.005 of this chapter.

*Hobby vessel* means a recreational vessel that is a reduced-scale model vessel that is not capable of transporting a person.

*Hydrocarbon (HC)* means the hydrocarbon group on which the emission standards are based for each fuel type. For gasoline- and LPG-fueled vessels, HC means total hydrocarbon (THC). For natural gas-fueled vessels, HC means nonmethane hydrocarbon (NMHC). For alcohol-fueled vessels, HC means total hydrocarbon equivalent (THCE).

*Identification number* means a unique specification (for example, model number/serial number combination) that allows someone to distinguish a particular vessel from other similar vessels.

*Manufacturer* has the meaning given in section 216(1) of the Act. In general, this term includes any person who manufactures a vessel, engine, or fuel system component for sale in the United States or otherwise introduces a new vessel, engine, or fuel system component into commerce in the United States. This includes importers and entities that treat fuel system components to reduce permeability.

*Maximum test power* means the power output observed with the maximum fueling rate possible at the maximum test speed.

*Maximum test speed* means the speed specified by 40 CFR 1065.515.

*Model year* means one of the following things:

(1) For freshly manufactured vessels (see definition of ''new vessel,'' paragraph (1), of this section), model year means one of the following:

(i) Calendar year.

(ii) Your annual new model production period if it is different than the calendar year. This must include January 1 of the calendar year for which the model year is named. It may not begin before January 2 of the previous calendar year and it must end by December 31 of the named calendar year.

(2) For a vessel modified by an importer (not the original vessel manufacturer) who has a certificate of conformity for the imported vessel (see definition of ''new vessel,'' paragraph (2), of this section), model year means one of the following:

(i) The calendar year in which the importer finishes modifying and labeling the vessel.

(ii) Your annual production period for producing vessels if it is different than the calendar year; follow the guidelines in paragraph (1)(ii) of this definition.

(3) For a vessel you import that does not meet the criteria in paragraphs (1) or (2) of the definition of ''new vessel'' in this section, model year means the calendar year in which the manufacturer completed the original assembly of the vessel. In general, this applies to used vessels that you import without conversion or major modification.

*New vessel* means any of the following things:

(1) A freshly manufactured vessel for which the ultimate buyer has never received the equitable or legal title. The vessel is no longer new when the ultimate buyer receives this title or the product is placed into service, whichever comes first.

(2) An imported vessel covered by a certificate of conformity issued under this part, where someone other than the original manufacturer modifies the vessel after its initial assembly and holds the certificate. The vessel is no longer new when it is placed into service.

(3) An imported nonroad vessel that is not covered by a certificate of conformity issued under this part at the time of importation.

*Noncompliant vessel* means a vessel, engine, or fuel system that was originally covered by a certificate of conformity, but is not in the certified configuration or otherwise does not comply with the conditions of the certificate.

*Nonconforming vessel* means a vessel, engine, or fuel system not covered by a certificate of conformity that would otherwise be subject to emission standards.

*Nonroad* means relating to nonroad engines or nonroad vehicles.

*Nonroad engine* has the meaning given in § 1068.025 of this chapter.

*Oxides of nitrogen* means nitric oxide (NO) and nitrogen dioxide ($NO_2$). Oxides of nitrogen are expressed quantitatively as if the NO were in the form of $NO_2$ (assume a molecular weight for oxides of nitrogen equivalent to that of $NO_2$).

*Physically adjustable range* means the entire range over which a vessel parameter can be adjusted, except as modified by § 1045.115(c).

*Placed into service* means used for its intended purpose.

*Portable fuel tank* means a fuel tank that has a permanently affixed handle, has a fuel capacity no greater than 12 gallons, and is not permanently mounted to a marine vessel.

*Propulsion marine engine* means a marine engine that moves a vessel through the water or directs the vessel's movement.

*Revoke* means to discontinue the certificate for an emission family. If we revoke a certificate, you must apply for a new certificate before continuing to produce the affected vessels. This does not apply to vessels you no longer possess.

*Round* means to round numbers according to ASTM E29–93a, which is incorporated by reference (see § 1045.810), unless otherwise specified.

*Scheduled maintenance* means adjusting, repairing, removing, disassembling, cleaning, or replacing components or systems that is periodically needed to keep a part from failing or malfunctioning. It also may mean actions you expect are necessary to correct an overt indication of failure or malfunction for which periodic maintenance is not appropriate.

*Spark-ignition* means relating to a type of engine with a spark plug (or other sparking device) and with operating characteristics significantly similar to the theoretical Otto combustion cycle. Spark-ignition engines usually use a throttle to regulate intake air flow to control power during normal operation.

*Spark-ignition marine vessel* means marine vessel that is powered by a spark-ignition engine.

*Stoichiometry* means the proportion of a mixture of air and fuel such that the fuel is fully oxidized with no remaining oxygen. For example, stoichiometric combustion in gasoline vessels typically occurs at an air-fuel mass ratio of about 14.7.

*Suspend* means to temporarily discontinue the certificate for an emission family. If we suspend a certificate, you may not sell vessels from that emission family unless we reinstate the certificate or approve a new one.

*Test sample* means the collection of vessels selected from the population of an emission family for emission testing.

*Test vessel* means a vessel, engine, or fuel system in a test sample.

*Total Hydrocarbon Equivalent* means the sum of the carbon mass contributions of non-oxygenated hydrocarbons, alcohols and aldehydes, or other organic compounds that are measured separately as contained in a gas sample, expressed as petroleum-fueled vessel hydrocarbons. The hydrogen-to-carbon ratio of the equivalent hydrocarbon is 1.85:1.

*Ultimate buyer* means ultimate purchaser.

*Ultimate purchaser* means, with respect to any new nonroad equipment or new nonroad vessel, the first person who in good faith purchases such new nonroad equipment or new nonroad vessel for purposes other than resale.

*United States* means the States, the District of Columbia, the Commonwealth of Puerto Rico, the Commonwealth of the Northern Mariana Islands, Guam, American Samoa, the U.S. Virgin Islands, and the Trust Territory of the Pacific Islands.

*U.S.-directed production volume* means the number of vessel units, subject to the requirements of this part, produced by a manufacturer for which the manufacturer has a reasonable assurance that sale was or will be made to ultimate buyers in the Unites States.

*Useful life* means the period during which the vessel or engine is designed to properly function in terms of reliability and fuel consumption, without being remanufactured, specified as a number of hours of operation or calendar years. It is the period during which a new vessel or new engine is required to comply with all applicable emission standards.

*Vessel* means marine vessel as defined in the General Provisions of the United States Code, 1 U.S.C. 3.

*Void* means to invalidate a certificate or an exemption. If we void a certificate, all the vessels produced under that emission family for that model year are considered noncompliant, and you are liable for each vessel produced under the certificate and may face civil or criminal penalties or both. If we void an exemption, all the vessels produced under that exemption are considered uncertified (or nonconforming), and you are liable for each vessel produced under the exemption and may face civil or criminal penalties or both. You may not produce any additional vessels using the voided exemption.

*Volatile liquid fuel* means any fuel other than diesel or biodiesel that is a liquid at atmospheric pressure.

### § 1045.805 What symbols, acronyms, and abbreviations does this part use?

The following symbols, acronyms, and abbreviations apply to this part:

| | |
|---|---|
| °C | degrees Celsius. |
| ASTM | American Society for Testing and Materials. |
| ATV | all-terrain vessel. |
| cc | cubic centimeters. |
| CO | carbon monoxide. |
| $CO_2$ | carbon dioxide. |
| EPA | Environmental Protection Agency. |
| FEL | Family emission limit. |
| g/kW-hr | grams per kilowatt-hour. |
| LPG | liquefied petroleum gas. |
| m | meters. |
| mm Hg | millimeters of mercury. |
| NMHC | nonmethane hydrocarbon. |
| NMHCE | nonmethane hydrocarbon equivalent. |
| $NO_X$ | oxides of nitrogen (NO and $NO_2$). |
| psig | pounds per square inch of gauge pressure. |
| rpm | revolutions per minute. |
| SAE | Society of Automotive Engineers. |
| SHED | Sealed Housing for Evaporative Determination. |
| SI | spark-ignition. |
| THC | total hydrocarbon. |
| THCE | total hydrocarbon equivalent. |
| U.S. | United States |
| U.S.C. | United States Code. |

### § 1045.810 What materials does this part reference?

We have incorporated by reference the documents listed in this section. The Director of the **Federal Register** approved the incorporation by reference as prescribed in 5 U.S.C. 552(a) and 1 CFR part 51. Anyone may inspect copies at U.S. EPA, OAR, Air and Radiation Docket and Information Center, 401 M Street, SW., Washington, DC 20460; or Office of the Federal Register, 800 N. Capitol St., NW., 7th Floor, Suite 700, Washington, DC.

(a) *ASTM material.* Table 1 of § 1045.810 lists material from the American Society for Testing and Materials that we have incorporated by reference. The first column lists the number and name of the material. The second column lists the sections of this part where we reference it. The second column is for information only and may not include all locations. Anyone may receive copies of these materials from American Society for Testing and Materials, 1916 Race St., Philadelphia, PA 19103. Table 1 follows:

TABLE 1 OF § 1045.810.—ASTM MATERIALS

| Document number and name | Part 1045 reference |
|---|---|
| ASTM E29–93a, Standard Practice for Using Significant Digits in Test Data to Determine Conformance with Specifications. | 1045.240, 1045.315, 1045.345, 1045.410, 1045.415. |

(b) *ISO material.* [Reserved]

(c) *SAE material.* [Reserved]

### § 1045.815 How should I request EPA to keep my information confidential?

(a) Clearly show what you consider confidential by marking, circling, bracketing, stamping, or some other method. We will store your confidential information as described in 40 CFR part 2. Also, we will disclose it only as specified in 40 CFR part 2.

(b) If you send us a second copy without the confidential information, we will assume it contains nothing confidential whenever we need to release information from it.

(c) If you send us information without claiming it is confidential, we may make it available to the public without further notice to you, as described in 40 CFR 2.204.

### § 1045.820 How do I request a public hearing?

(a) File a request for a hearing with the Designated Officer within 15 days of a decision to deny, suspend, revoke, or void your certificate. If you ask later, we may give you a hearing for good cause, but we do not have to.

(b) Include the following in your request for a public hearing:

(1) State which emission family is involved.

(2) State the issues you intend to raise. We may limit these issues, as described elsewhere in this part.

(3) Summarize the evidence supporting your position and state why you believe this evidence justifies granting or reinstating the certificate.

(c) We will hold the hearing as described in 40 CFR part 1068, subpart F.

## PART 1051—CONTROL OF EMISSIONS FROM RECREATIONAL ENGINES AND VEHICLES

17. The authority citation for part 1051 as proposed at 66 FR 51219 continues to read as follows:

**Authority:** 42 U.S.C. 7401–7671(q).

### Subpart A—[Amended]

18. Section 1051.1 as proposed at 66 FR 51220 is amended by adding a new paragraph (e) to read as follows:

**§ 1051.1 Does this part apply to me?**

* * * * *

(e) This part also applies to engines under 50 cc used in highway motorcycles if the manufacturer uses the provisions of 40 CFR 86.447–2006 to meet the emission standards in this part instead of the requirements of 40 CFR part 86. Compliance with the provisions of this part is a required condition of that exemption.

## PART 1068—GENERAL COMPLIANCE PROVISIONS FOR NONROAD PROGRAMS

19. The authority citation for part 1068 as proposed at 66 FR 51252 continues to read as follows:

**Authority:** 42 U.S.C. 7401–7671(q).

### Subpart A—[Amended]

20. Section 1068.1 as proposed at 66 FR 51253 is amended by revising paragraph (a) to read as follows:

**§ 1068.1 Does this part apply to me?**

(a) The provisions of this part apply to everyone with respect to the following engines or to equipment using the following engines:

(1) Marine vessels powered by spark-ignition engines we regulate under 40 CFR 1045.

(2) Large nonroad spark-ignition engines we regulate under 40 CFR part 1048.

(3) Snowmobiles, all-terrain vehicles, and off-highway motorcycles we regulate under 40 CFR part 1051.

* * * * *

[FR Doc. 02–19437 Filed 8–13–02; 8:45 am]

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Federal Register

**Wednesday,**
**August 14, 2002**

## Part III

# Department of Transportation

**Research and Special Programs Administration**

**49 CFR Part 171 et. al.**

**Hazardous Materials: Revision to Standards for Infectious Substances; Final Rule**

**DEPARTMENT OF TRANSPORTATION**

**Research and Special Programs Administration**

**49 CFR Parts 171, 172, 173, 177, and 178**

**[Docket No. RSPA–98–3971 (HM–226)]**

**RIN 2137–AD13**

## Hazardous Materials: Revision to Standards for Infectious Substances

**AGENCY:** Research and Special Programs Administration (RSPA), DOT.

**ACTION:** Final rule.

**SUMMARY:** RSPA is revising transportation requirements for infectious substances, including regulated medical waste, to: adopt defining criteria and packaging requirements consistent with international standards; revise the current broad exceptions for diagnostic specimens and biological products; and authorize bulk packaging options for regulated medical waste consistent with requirements in international standards and DOT exemptions. These revisions will assure an acceptable level of safety for the transportation of infectious substances, and facilitate domestic and international transportation.

**DATES:** *Effective Date:* This final rule is effective October 1, 2002.

*Voluntary Compliance Date:* Voluntary compliance is authorized 30 days following publication of this final rule.

*Incorporation by Reference Date:* The incorporation by reference of publications listed in this final rule has been approved by the Director of the Federal Register as of October 1, 2002.

**FOR FURTHER INFORMATION CONTACT:** Susan Gorsky (202) 366–8553, Office of Hazardous Materials Standards, Research and Special Programs Administration.

**SUPPLEMENTARY INFORMATION:**

**List of Topics**



### I. Background

On January 22, 2001, the Research and Special Programs Administration (RSPA, we) published a notice of proposed rulemaking (NPRM; 66 FR 6941) to revise the current requirements in the Hazardous Materials Regulations (HMR; 49 CFR Parts 171–180) applicable to the transportation of infectious substances, including regulated medical waste. The NPRM also proposed new requirements applicable to the transportation of genetically modified micro-organisms. The NPRM proposed the following changes to the HMR:

- Adoption of new classification criteria for infectious substances based on defining criteria developed by the World Health Organization (WHO) and consistent with standards contained in the United Nations Recommendations on the Transport of Dangerous Goods (UN Recommendations) and the International Civil Aviation Organization's Technical Instructions for the Safe Transport of Dangerous Goods by Air (ICAO Technical Instructions).
- Revision of current packaging requirements for Division 6.2 materials for consistency with international performance standards.
- Elimination of the current exception from requirements in the HMR for diagnostic specimens. We proposed certain packaging and hazard communication requirements. Diagnostic specimens transported in dedicated motor vehicles by private or contract carriers would continue to be excepted from most requirements in the HMR.
- Modification of the current exception from requirements in the HMR for biological products, limiting the exception to biological products licensed for use under current Food and Drug Administration (FDA) or U.S. Department of Agriculture (USDA) regulations.
- New transportation requirements for the transportation of genetically modified micro-organisms consistent with the UN Recommendations.
- New bulk packaging options for the transportation of regulated medical waste (RMW), based on current exemption provisions.
- New hazard communication requirements for shipments of Division 6.2 materials.

### II. Comment Summary

We received 46 comments on the NPRM from industry associations, laboratories, medical waste transporters, state departments of transportation and public health, a blood bank, and private citizens. Most were supportive of our effort to harmonize the HMR requirements applicable to the transportation of infectious substances with international requirements, and of proposals to enhance the safe transportation of diagnostic specimens and biological products. Based on comments received and our discussions with other Federal agencies responsible for regulating infectious substances and genetically modified micro-organisms, this final rule incorporates the following changes to the HMR:

- New classification criteria for infectious substances based on defining criteria developed by WHO and consistent with standards contained in the UN Recommendations and the ICAO Technical Instructions.
- Revised packaging requirements for Division 6.2 materials consistent with international performance standards.
- Revised materials of trade exceptions to include certain diagnostic specimens, biological products, and RMW. This final rule includes more specific packaging requirements for such materials of trade than were proposed in the NPRM.
- New packaging and hazard communication requirements for shipments of diagnostic specimens consistent with international requirements. Diagnostic specimens transported in dedicated motor vehicles by private or contract carriers are excepted from most requirements of the HMR. This final rule also clarifies that diagnostic specimens that contain a Risk Group 1 pathogen, do not contain a pathogen, or in which the pathogen is neutralized or inactive, are not subject to HMR requirements.
- Modification of the current exception from requirements in the HMR for biological products. This final rule revises the proposal in the NPRM to specify that the exception is limited to biological products, including experimental products, subject to Federal approval, permit, or licensing requirements, such as those required by FDA or USDA.

• New bulk packaging options for the transportation of RMW, based on current exemption provisions. The packaging options proposed in the NPRM are modified in this final rule to reflect commenters' concerns about specifications for the packagings.

• New hazard communication requirements for bulk shipments of RMW to assist emergency responders to identify such shipments.

In discussions during development of this final rule, several federal agencies involved in the regulation of genetically modified organisms (*i.e.,* the Environmental Protection Agency (EPA) and the Department of Agriculture (USDA)) commented that the process of genetically modifying an organism does not *a priori* make that organism a hazard. Rather, the product of the modification must be evaluated for potential risk. As several federal agencies currently regulate genetically modified organisms, the proposals in the NPRM concerning genetically modified organisms are not adopted in this final rule.

Comments we received in response to the NPRM are discussed in detail below.

*A. Pending Revisions to the UN Recommendations*

Most commenters support our proposal to harmonize the HMR requirements for infectious substances with the international standards. Two commenters note the United Nations may be developing a complete revision to its current recommendations for the transportation of infectious substances. According to these commenters, the UN may change the WHO risk group system as applied to transportation and may ''radically'' simplify current transportation requirements. These commenters advise us to postpone revising the HMR until the United Nations completes its work.

The commenters are correct. The UN Committee of Experts on the Transport of Dangerous Goods is considering revisions to the requirements in the UN Recommendations applicable to the transport of infectious substances and genetically modified micro-organisms. However, it is not certain whether any amendment will be adopted during the 2001–2002 biennium. Indeed, as yet the UN Committee of Experts has not received a formal proposal. Given this uncertainty, we do not agree with delaying action to harmonize the HMR requirements for infectious substances with current international standards. If the UN Committee of Experts adopts revisions to the UN Recommendations for transporting infectious substances, we will consider such revisions in a future rulemaking.

One commenter notes the proposal as it relates to diagnostic specimens is not consistent with current requirements for transporting diagnostic specimens in the ICAO Technical Instructions. This is true; as we noted in the January 2001 NPRM, the proposal for shipping diagnostic specimens is consistent with a proposal for the UN Recommendations, since adopted. Since publication of the NPRM, the ICAO Dangerous Goods Panel has also adopted these amendments. As a result, the 2003–2004 edition of the ICAO Technical Instructions will be consistent with the UN Recommendations and this final rule.

*B. Infectious Substance Definition*

In the NPRM, consistent with current requirements in the UN Recommendations, we proposed to define infectious substances, or Division 6.2 materials, to mean materials known to contain or suspected to contain a pathogen with the potential to cause disease upon exposure. We further proposed to require Division 6.2 materials to be assigned to risk groups using defining criteria developed by WHO. WHO defines four risk groups for infectious substances based on pathogenicity, mode and ease of transmission, degree of risk to individuals and communities, and reversibility of the disease through known and effective preventative agents and treatment. Risk Group 1 includes micro-organisms unlikely to cause human or animal disease. In the NPRM, we proposed that Risk Group 1 materials not be subject to regulation under the HMR.

Several commenters oppose using the WHO risk group criteria for infectious substances regulated under the HMR. They note that the WHO system was intended for assessing and addressing risks to researchers and health care workers in laboratory environments, not for transportation. We do not agree. While it is true the WHO risk groups were not originally intended for transportation environments, they do provide a relatively simple way to delineate and differentiate risks associated with specific pathogens. As such, the WHO risk groups are a useful tool for assessing the degree to which specific pathogens should be regulated in transportation, based on the potential risk to transportation workers and the general public. Other risk systems (for example, the biosafety level guidelines in the Centers for Disease Control and Prevention/National Institutes of Health (CDC/NIH) publication *Biosafety in Microbiological and Biomedical Laboratories)* were also developed for use in laboratories rather than in transportation. These systems can be more difficult to apply for transportation purposes than the WHO risk groups.

Some commenters opposed to the use of the WHO risk groups recommend we create an advisory group to assign risk group classifications for infectious substances in transportation. We do not believe this is a practical or feasible approach because of the length of time that would be involved in establishing the advisory group and awaiting the results of its deliberations. Other commenters opposed to use of the WHO risk groups suggest we adopt government or industry consensus standards for risk group assignments, such as those developed by NIH. The NIH and WHO lists are very similar; NIH has published specific names of micro-organisms assigned to each risk group in a table. Although not complete, the NIH list is a useful reference source for identifying the appropriate risk group for a given pathogen. (The NIH guidelines can be found at *http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html*). There are other risk group listings that also provide useful guidance for assigning a specific pathogen to a risk group, including a list developed by the American Biological Safety Association (available on line at *http://www.absa.org/riskgroups/index.htm*) and the list of agents in the CDC/NIH publication *Biosafety in Microbiological and Biomedical Laboratories* (available on line at *http://www.cdc.gov/od/ohs/biosfty/biosfty.htm*). We do not agree the HMR should incorporate one or more of these lists by reference into the HMR. However, in this final rule we are including these lists in the table of informational materials in § 171.7(b).

Instead of the WHO risk groups, one commenter suggests we utilize the existing Packing Group system in the HMR to address differing risks associated with the transportation of specific infectious substances. Thus, the commenter suggests Packing Group I would contain virulent pathogens that have a high risk of airborne infection, readily penetrate unbroken skin, are extremely persistent in the environment, and for which effective preventative or treatment measures are not readily available. Packing Group II would contain pathogens with a significantly lower risk of airborne infection, the primary exposure risk of which is entry through broken skin or contact with mucous membranes, and for which effective preventative or

treatment measures are readily available. Packing Group III would contain pathogens classed as WHO Risk Group 2 materials.

We do not agree the existing Packing Group system provides a viable alternative to the WHO risk groups. As set forth in the NPRM, the WHO risk groups are used to identify pathogens not subject to regulation (Risk Group 1) or to identify certain pathogens (Risk Group 2 and 3) that may be shipped under certain exceptions, such as materials of trade. Unless an exception is authorized, all Risk Group 2, 3, and 4 infectious substances must be transported in specification triple packagings authorized under the HMR. In addition, they must be marked and labeled in accordance with applicable requirements, and accompanied by appropriate shipping and emergency response documentation. The packing group system suggested by the commenter would require shippers to distinguish between Risk Group 2 and 3 infectious substances when making packaging decisions, and would be more difficult, confusing, and burdensome to implement than the system proposed in the NPRM.

The NPRM proposed to assign infectious substances to risk groups based on the known medical history of the patient or animal, endemic local conditions, symptoms of the patient or animal, or professional judgement concerning the individual circumstances of the patient or animal. One commenter suggests this provision could endanger patient confidentiality and violate medical privacy regulations. We disagree. The proposal does not require health care professionals to disclose medical histories or patient symptoms. Rather, the proposal suggests these factors should be considered as the health care professional assigns an infectious substance to a risk group for purposes of transportation. Disclosure of the factors contributing to this determination or the name of the patient is not required. Further, the requirement for inclusion of an itemized list of contents within a package containing Division 6.2 materials requires a shipper only to identify the material. There is no requirement to include a patient name on the itemized list.

One commenter suggests we modify the list of factors used to determine risk group assignments to include the type of test ordered on the specimen. We do not believe it is necessary to specify this information as a factor in making risk group determinations. Shippers should make risk group assignments based, in part, on professional judgement concerning the individual circumstances of the patient or animal. Such professional judgement should include the types of tests ordered or other factors.

One commenter recommends we regulate infectious substances meeting the defining criteria for a Risk Group 1 material for transportation purposes We disagree. By definition, Risk Group 1 infectious substances are micro-organisms unlikely to cause human or animal disease. Risk Group 1 infectious substances in transportation pose little or no risk to transportation workers or to the general public. Risk Group 1 infectious substances are not subject to regulation under international transportation requirements because the risk posed by such materials is very low. There is no compelling safety rationale for regulating such materials under the HMR.

A number of commenters suggest specific revisions to the proposed definition of infectious substances. For example, several recommend including prions in the definition. Prions are not micro-organisms, but are proteinaceous infectious particles consisting of an abnormal isoform of a normal cellular protein. Prions are implicated as a cause for neuro-degenerative diseases such as kuru and Creutzfeldt-Jacob disease in humans, and bovine spongiform encephalopathy and scrapie in animals. We agree with commenters that a strict reading of the proposed definition in the NPRM would appear to exclude prions; therefore, we have modified the definition to specifically include them. We further revised the definition for clarity and to remove superfluous or inaccurate terminology.

One commenter suggests limiting regulation of infectious substances in transportation to those capable of infecting ''immunocompetent humans and animals.'' For purposes of the HMR, ''immunocompetent'' would mean the human or animal possesses an effective body immune mechanism with no reduced immunity to infection by any known cause. We disagree. The WHO risk group system assigns infectious substances to risk groups based on their ability to infect immunocompetent humans and animals. Thus, it is not necessary to make this explicit in the HMR.

Accordingly, in this final rule we are defining Division 6.2 materials using the WHO risk group criteria. Division 6.2 materials must be assigned to risk groups based on the degree to which they cause injury through disease, with Risk Group 1 presenting the lowest risk and Risk Group 4 presenting the highest risk. Assignments to risk groups are based on the known medical history of the patient or animal, endemic local conditions, symptoms of the patient or animal, or professional judgement concerning the individual circumstances of the patient or animal. Division 6.2 materials assigned to Risk Group 1 are excepted from all HMR requirements, unless they meet the definition of another hazard class.

*C. Packaging Requirements for Infectious Substances*

In the NPRM, we proposed to incorporate several changes to the infectious substances regulations applicable to packaging requirements and performance tests. The changes were intended to make the HMR requirements consistent with the UN Recommendations and ICAO Technical Instructions For example, we proposed to require manufacturers to meet UN marking requirements for packagings represented as conforming to the specifications for infectious substances packagings in the HMR. In addition, we proposed to require manufacturers to retain packaging design qualification records and to retest packagings every 24 months. Further, we proposed to replace the current requirement for a water immersion test with a water-spray test to simulate exposure to rainfall, as required by the ICAO Technical Instructions. Similarly, we proposed to incorporate the selective testing provisions in the UN Recommendations and ICAO Technical Instructions. These provisions allow variations in the primary receptacles within the secondary packaging, without further testing of the completed package, if an equivalent level of performance is maintained. Commenters endorse these proposals. We are adopting them in this final rule without change.

One commenter suggests a more stringent packaging requirement for infectious substances. The commenter recommends we replace the current triple packaging requirement (water-tight primary receptacle, water-tight secondary packaging, and outer packaging) with a quintuple packaging. In the quintuple packaging, the primary receptacle is enclosed in a sealed plastic bag with absorbent material inside a watertight primary container inside a watertight secondary container inside a tertiary container or overpack. We disagree. The accident record demonstrates a triple packaging meeting the performance standard established in the HMR is sufficient to contain the material under normal conditions of transportation.

*D. Exceptions for Domestic Shipments of Infectious Substances*

In the NPRM, we proposed to expand the materials of trade (MOTS) exceptions currently permitted under § 173.6 of the HMR. The proposal expanded the MOTS exception to include certain biological products, diagnostic specimens, and RMW, including cultures and stocks. MOTS include hazardous materials carried by private motor carriers engaged in a principal business other than transportation, such as lawn care, plumbing, welding, and door-to-door sale of consumer goods. The MOTS exception limits the maximum gross weight of MOTS that may be carried on a motor vehicle and includes minimum packaging and hazard communication requirements. As proposed in the NPRM, the MOTS exception for infectious substances specified combination packagings, with limitations on capacity.

A number of commenters address the proposed MOTS exception for infectious substances. Several commenters oppose the exception, suggesting it is too broad and does not provide adequate packaging or hazard communication. Other commenters support the exception, but recommend we incorporate minimal acceptable standards for packaging. These commenters note that most items shipped under the MOTS exception must be shipped in their original packaging or the equivalent. However, biological products, diagnostic specimens, and RMW are packaged for the first time when they are collected at the site from which they will be shipped. Thus, these commenters suggest the inner packaging should be puncture- and leak-resistant and there should be sufficient absorbent material for the contents of the inner packaging.

We agree with commenters that the MOTS exception for Division 6.2 materials should include general packaging standards. Therefore, in this final rule, we are adding performance requirements for combination packagings authorized under the MOTS exception for transportation of Division 6.2 materials. The inner packaging of the combination packaging must be leak tight for liquids, and the outer packaging must contain absorbent material sufficient to absorb the entire contents of the inner packagings. For sharps, which are objects that can pierce certain types of packaging, the inner packaging of the combination packaging must be constructed of a rigid, puncture-resistant material. For all Division 6.2 materials, the outer packaging must be a strong, tight packaging that is securely sealed. Note that Division 6.2 materials shipped in conformance with the MOTS exception are subject to all applicable requirements in § 173.6. This includes requirements to mark packages with a common name or proper shipping name, and to inform the motor vehicle operator of the presence of a hazardous material and the requirements of § 173.6.

A commenter asks us to clarify the MOTS exception for RMW, with respect to home health care providers. Specifically, this commenter believes the NPRM was confusing in its treatment of waste generated from households. The commenter states the NPRM proposed the MOTS exception in § 173.6 as appropriate for home health care providers. At the same time, the NPRM provided a complete exception in § 173.134 from HMR requirements for medical waste generated from households and transported in accordance with applicable state or local requirements. The exception for medical waste generated from households applies to waste collected by local sanitation workers along with trash, garbage, and other non-medical household waste. The MOTS exception applies to RMW generated through home treatment of medical conditions by professional health care providers. These health care providers remove such waste and transport it elsewhere for disposal.

One commenter recommends the HMR include an exception from all transportation regulatory requirements, except for minimal packaging standards, for Risk Group 2 materials transported by highway. The commenter did not provide a reason for this recommendation. We disagree. Risk Group 2 infectious substances can pose risks to transportation workers and the general public. We believe they should be regulated in the same manner as Risk Group 3 infectious substances.

One commenter suggests the final rule should include an exception for environmental microbiological samples collected in the field to evaluate occupational and residential exposure risks. An example is a piece of moldy wallboard. The organisms in such samples are predominantly from the environment rather than humans, and therefore pose a limited risk of infection to the individual or the community. We agree and so modified the list of materials excepted from the HMR to include environmental microbiological samples being transported for analysis and/or testing. Note, however, that a material or object known or suspected to be contaminated with an infectious substance must be transported in accordance with all applicable HMR requirements.

The same commenter also expresses a concern about the effect of the proposals in the NPRM on samples shipped to laboratories to evaluate their proficiency in analyzing and identifying pathogens and other materials. The commenter is concerned the NPRM would require such samples to be identified in shipping documentation or on labels. In fact, this is not the case. The HMR requires the technical name of an infectious substances to be shown in parentheses as part of the basic shipping description on shipping papers and package markings. However, the definition of ''technical name'' in § 171.8 of the HMR permits use of a generic description in place of the technical name for proficiency testing. Thus, an infectious substance sample sent to a laboratory for proficiency testing may show a generic microbiological description, such as bacteria, myobacteria, fungus, or viral sample, as part of the shipping description. Packaging, marking, and labeling the proficiency testing sample as an infectious substance and using a generic technical name should not compromise proficiency testing programs.

*E. Diagnostic Specimens*

In the NPRM, we proposed regulations applicable to the transportation of diagnostic specimens consistent with the UN Recommendations. Diagnostic specimens are human or animal material being transported for diagnostic or investigational purposes. We proposed a new entry in the Hazardous Materials Table—''Diagnostic Specimen.'' We did not propose a UN number, warning label, or packing group assignment.

As proposed in the NPRM, diagnostic specimens meeting the definition of a Risk Group 4 material would be classed and required to be transported as Division 6.2 materials, UN 2814 or UN 2900. All other diagnostic specimens would be packaged in non-specification packagings meeting minimum performance criteria. Under the proposal, packages containing diagnostic specimens would be required to be marked ''Diagnostic Specimens.'' Diagnostic specimens shipped in accordance with these provisions would be excepted from all other HMR requirements, except for incident reporting for diagnostic specimens transported by aircraft.

Several commenters oppose the NPRM proposal for diagnostic specimens. These commenters suggest that requirements for the shipment of diagnostic specimens should be applied based on whether a specimen could reasonably be suspected of being infectious. According to these commenters, any shipments other than routine screening samples or samples transported to investigate non-communicable diseases or conditions should be fully regulated as Division 6.2 materials. As we noted in the NPRM (66 FR 6944), we issued an ANPRM under this docket (63 FR 46844; September 2, 1998) proposing a regulatory regime for diagnostic specimens similar to this commenter's suggestion. Commenters to the ANPRM almost unanimously opposed this approach, stating it would be difficult and costly to implement. Commenters to the ANPRM also stated such a requirement could result in shipment delays. This would make early detection and treatment of disease difficult, and could significantly increase health care costs. We agreed. The NPRM proposal specifies a more practical, cost-effective, and easy-to-understand regulatory system for diagnostic specimens, consistent with requirements established in the UN Recommendations.

A number of commenters suggest the table entry for diagnostic specimens is ambiguous and may cause confusion. The table entry indicates that diagnostic specimens are regulated as hazardous materials. However, the specific provisions proposed for transportation of diagnostic specimens except such shipments from most requirements applicable to hazardous materials. Several commenters recommend we remove the entry from the table, to clarify that diagnostic specimens are not regulated as hazardous materials.

We disagree. In fact, the NPRM proposed a table entry for diagnostic specimens precisely to indicate diagnostic specimens would be regulated as hazardous materials under the HMR. There are a number of materials listed in the table as hazardous materials that are excepted from most HMR requirements, as we proposed to do for diagnostic specimens. For example, lithium batteries are regulated for transportation purposes as a hazardous material and are listed in the table, but are excepted from many requirements of the HMR when shipped in accordance with the provisions in § 173.185.

One commenter notes that diagnostic specimens are usually shipped with a transport media. The transport media preserves the specimen, prevents overgrowth, and facilitates isolation and analysis. This transport media may inactivate or disable any pathogens contained in the specimen. The commenter states that the NPRM overlooks this aspect of diagnostic specimens shipments, exaggerating the risk associated with transportation. Other commenters agree and suggest the final rule should clarify that if no pathogen is present in the diagnostic specimen or if the pathogen is neutralized, then the specimen is not regulated under the HMR. We agree. In this final rule, we added diagnostic specimens in which no pathogen is present or the pathogen is neutralized to the list of materials not subject to regulation as infectious substances under the HMR. Note, however, that a transport media used in the shipment of infectious substances may itself be a hazardous material—i.e., it meets the definition of one of the defined hazard classes based on flammability, corrosivity, toxicity, or other hazard characteristic. If so, the shipment must be transported in accordance with HMR requirements for the specific hazard class. Note, also, that a diagnostic specimen shipped in a packaging with a neutralizing agent designed to function only if the inside packaging containing the diagnostic specimen ruptures or breaks, must be shipped in accordance with the requirements applicable to diagnostic specimens in § 173.199.

Several commenters suggest the regulations should take into account the physical nature of a diagnostic specimen when prescribing packaging requirements. For example, commenters state certain diagnostic samples, such as dried blood spots, fecal smears, and skin punches, do not present the same risks in transportation as liquid or semi-solid diagnostic samples. Similarly, commenters state urine and oral tissues are incapable of transmitting disease in the same manner as blood. These commenters recommend modification of the regulations to distinguish between diagnostic specimens that pose a threat of infection to transport workers and the general public, and those that do not. We disagree. Solid-form diagnostic specimens potentially containing infectious substances do present a risk of infection, as do urine and oral tissues. Although this risk may be less than for blood, we believe the minimal packaging standards for the transportation of diagnostic specimens should apply consistently to all materials meeting the definition of a diagnostic specimen in this final rule. Moreover, the packaging standards established in this final rule do distinguish between solid- and liquid-form diagnostic specimens. For example, the capacity limits for liquid diagnostic specimens are less. Further, liquid diagnostic specimen packagings transported by aircraft must be capable of withstanding, without leakage, an internal pressure producing a pressure differential of not less than 95 kPa.

Several commenters address the specific packaging requirements proposed for the transportation of diagnostic specimens. The NPRM proposed to require diagnostic specimens to be packaged in primary receptacles packed inside secondary packaging, secured in an outer packaging with suitable cushioning material. One commenter states there is no need to secure the secondary packaging inside the outer packaging, because the specimen is twice contained in leak-proof, watertight packaging with absorbent material in between. This commenter asserts the proposal adds to overall packaging costs with no transportation safety benefit. We disagree. The requirement to secure secondary packaging inside the outer packaging helps assure the integrity of the entire packaging, by preventing damage to the secondary packaging resulting from handling during transportation. Moreover, the requirement is consistent with international standards. Further, secondary packaging can be secured inside an outer packaging in several ways that do not necessarily involve tying or fastening the secondary packaging to the outer packaging. For example, if the secondary packaging fits snugly within the outer packaging, the secondary packaging would be considered to be secured within the outer packaging.

In addition, several commenters state the proposed capacity limits on packages of diagnostic specimens should be more flexible to accommodate dry ice for preservation of specimens. The NPRM proposed an outer packaging capacity limit of 4L (1 gallon) for liquid diagnostic specimens, and 4 kg (8.8 pounds) for solid diagnostic specimens. These capacity limits apply to the diagnostic specimen only; packagings may be larger to accommodate dry ice used for preservation of specimens. Note, however, that shipments using dry ice are subject to applicable requirements in § 173.217.

Another commenter suggests the packaging requirements for diagnostic specimens should be more stringent than in the NPRM. This commenter recommends a quintuple packaging, consisting of a primary receptacle

enclosed in a sealed plastic bag contained in a primary container, inside a secondary container, inside a tertiary container. We disagree. The packaging for diagnostic specimens proposed in the NPRM is consistent with packaging requirements in the UN Recommendations. Further, the packaging suggested by the commenter would add significantly to the cost of shipping diagnostic specimens.

One commenter addresses the ''diagnostic specimen'' marking requirement proposed in the NPRM. This commenter states the proposed marking requirement is redundant and provides no transportation benefit. We disagree. Under the proposal in the NPRM, packages containing diagnostic specimens must be marked ''Diagnostic Specimen.'' No other marking or labeling is required, nor are shipping papers required; thus, it is difficult to see how the proposed marking could be ''redundant.'' The marking is intended to communicate a potential hazard to transportation workers. Diagnostic specimens shipped in accordance with the provisions in the NPRM could contain infectious material, and the marking indicates transportation workers should take appropriate precautions if the package is damaged or leaking.

Another commenter suggests we adopt and modify the ''Excepted Quantities Label'' authorized by International Air Transport Association (IATA) standards, to indicate a shipment contains a diagnostic specimen. We believe the marking requirement in this final rule accomplishes the same goal without the additional regulatory burden that would result from a new labeling requirement. However, this final rule does not prohibit shippers from voluntarily applying the ''Excepted Quantities Label'' to such packages in addition to the ''Diagnostic Specimen'' marking.

In addition to the MOTS exception previously discussed, the NPRM also proposed a complete exception from the HMR for diagnostic specimens transported by private or contract motor carriers. One commenter opposes this exception, out of concern that inadequate packaging would expose untrained emergency response personnel to potentially infectious materials. However, most commenters generally are supportive of this proposal, agreeing the packaging and procedures used for courier shipments of diagnostic specimens are sufficient to assure the safety of such shipments in transportation. Further, couriers are familiar with the materials they transport, and are trained in the application of the Occupational Safety and Health Administration (OSHA) standards for Universal Precautions for handling materials potentially containing infectious substances. Therefore, this exception is adopted as proposed in this final rule.

The NPRM proposed to except diagnostic specimens prepared in accordance with proposed § 173.199 from training requirements in Subpart H of Part 172 of the HMR. In lieu of training, the NPRM proposed to require offerors and transporters of diagnostic specimens to be informed of the diagnostic specimen packaging requirements. Commenters did not specifically address this aspect of the proposed requirements for diagnostic specimens in the NPRM. One commenter asked us to clarify the meaning of ''must be informed'' as used in proposed § 173.199.

As used in new § 173.199 of this final rule, ''must be informed'' means persons who offer or transport diagnostic specimens for transportation in accordance with § 173.199 must know about and be able to apply the requirements of § 173.199 to specific shipments. There are no record-keeping or certification requirements associated with this provision, which distinguishes this requirement as a less formal type of training requirement than would otherwise be required by subpart H of part 172. In this final rule, we modified the NPRM proposal to indicate persons who ship or transport diagnostic specimens must know about the provisions in § 173.199.

The NPRM proposed to subject diagnostic specimens transported by aircraft to incident reporting requirements. Several commenters oppose this proposal. They suggest an incident-reporting requirement may cause air carriers to refuse shipments of diagnostic specimens, which could lead to serious delays in the testing process and adversely affect the provision of quality health care to patients. We disagree that the incident reporting requirement should be removed from this final rule. Commenters' suggestion that air carriers may refuse shipments as a result of this requirement is speculative; no air carriers indicated they would refuse shipments as a result of this provision. Further, we believe the benefits of incident reporting will be significant. Since diagnostic specimens are currently excepted from all regulatory requirements in the HMR, we currently have only anecdotal information concerning incidents involving diagnostic specimens. Information provided through incident reports will allow us to more fully evaluate the risks posed by these materials in transportation and to assess the efficacy of the packaging requirements imposed by this final rule.

One commenter suggests air carriers may not be able to identify a leak as coming from a package containing a diagnostic specimen. Since the package must be marked with the words ''Diagnostic Specimen,'' we do not believe such identification will be difficult.

Two commenters suggest the proposed requirements for transporting diagnostic specimens will be ''prohibitively expensive'' for the industry. However, these commenters do not provide supporting evidence for this assertion. We disagree. The provisions for air shipment of diagnostic specimens are consistent with the UN Recommendations and will be consistent with the 2003–2004 Edition of the ICAO Technical Instructions, which most air carriers follow for both domestic and international transportation. Further, the final rule includes several exceptions for ground transportation of diagnostic specimens, thus minimizing new costs for health care providers.

Accordingly, this final rule adopts the provisions applicable to the transportation of diagnostic specimens proposed in the NPRM. Diagnostic specimens meeting the definition of a Risk Group 4 material must be classed and transported as Division 6.2 materials, UN 2814 or UN 2900. Diagnostic specimens known or suspected to contain a Risk Group 2 or 3 infectious substance must be packaged in primary receptacles packed inside secondary packaging to preclude breakage, punctures, or leakage. For liquids, there must be sufficient absorbent material to absorb the entire contents of the primary receptacle. The secondary packaging must be secured in outer packagings with suitable cushioning material. For liquids transported by aircraft, either the primary receptacle or the secondary packaging must be capable of withstanding an internal pressure producing a pressure differential of at least 95kPa (0.95 bar, 14 psi). The completed package must be capable of passing a drop test from a height of at least 1.2 meters (3.9 feet). The package must be marked with the words ''Diagnostic Specimen.'' Diagnostic specimens shipped in conformance with these provisions are excepted from all other requirements in the HMR, with one exception. Diagnostic specimens transported on board aircraft are subject to the incident reporting requirements in §§ 171.15 and 171.16. Under this

final rule, offerors and transporters of diagnostic specimens must know about the diagnostic specimen packaging requirements. A commenter asked if diagnostic specimens shipped in conformance with these provisions would be subject to HMR requirements for notification-of-pilot-in-command. The answer is no.

We note that waste diagnostic specimens—diagnostic specimens meeting the definition for RMW in this final rule—may not be transported under the exceptions established in this final rule for the transportation of diagnostic specimens. Waste diagnostic specimens lose their identity as diagnostic specimens for purposes of the HMR, and must be transported in accordance with the HMR requirements applicable to RMW.

*F. Biological Products*

Commenters to the NPRM generally support its proposals concerning transportation of biological products. Currently, biological products are excepted from the HMR provided they meet FDA or USDA regulations governing the transfer of biological products. In the January 2001 NPRM, we proposed to limit this exception to biological products meeting the definition of a Risk Group 1 material or licensed for use under current FDA or USDA regulations. We proposed to require unlicenced biological products meeting the definition of a Risk Group 2, 3, or 4 infectious substance to be classed as infectious substances, Division 6.2, and packaged in specification packagings authorized for the transportation of infectious substances.

In addition, we proposed to add a special provision in § 172.102 relating to the transportation of blood and blood products. For consistency with ICAO Technical Instruction Special Provision A81, this special provision would except blood and blood products from current quantity limits for shipments by air when the materials are packaged in primary receptacles not exceeding 500 mL (17 ounces) and contained in outer packagings not exceeding 4 L (1 gallon).

We also proposed to except from all HMR requirements the following: blood collected for blood transfusions; blood collected for the preparation of blood products; blood products intended for transplant; and tissues and organs intended for transplant.

A number of commenters note that veterinary biological products are regulated by USDA, regardless of their licensing status. Such veterinary biological products are subject to comprehensive regulation (9 CFR Parts 101 through 124). For example, veterinary biological products in pre-license status are regulated by USDA under 9 CFR 103.3 and are shipped only after USDA review and approval. The USDA requirements are designed to assure that the biological materials are not contaminated during shipment and pose no threat to agriculture or livestock. Similarly, under the Virus-Serum-Toxic Act of 1913 (21 U.S.C. 151 *et seq.*), imported veterinary biological products are subject to permit rather than licensing requirements. USDA regulations assure that imported veterinary biological products meet the same high standards for distribution and sale in the United States as domestically produced biological products. Based on USDA's comprehensive regulatory scheme, commenters recommend that imported veterinary biological products subject to USDA permitting procedures be excepted from HMR requirements. We agree biological products subject to USDA regulation should be excepted from HMR requirements, and have modified the list of exceptions in this final rule accordingly.

A commenter recommends we expand the exception from regulation for biological products subject to Federal approval and licensing requirements, to include products manufactured by facilities licensed by or registered with a Federal agency. We disagree. The current exception is product-specific because Federal requirements for approval and licensing of biological products assure their safety. Products manufactured by licensed or registered facilities may or may not be subject to Federal approval processes and so may or may not have a record demonstrating their safety.

One commenter disagrees with the proposed exception in the NPRM for blood collected for transfusions. The commenter states all human blood should be treated as infectious material. If not, transport workers would be subject to less stringent protective requirements than laboratory and hospital workers. We disagree. Blood collection facilities are subject to the OSHA regulations for handling potentially infectious blood and blood products (29 1910.1030). The OSHA regulations include requirements for handling, packaging, and shipping blood. Because blood collection facilities are subject to OSHA regulations, we believe an exception from the HMR for blood collected for transfusion is justified.

One commenter suggests the exception for blood collected for transfusion and blood products should be expanded to include blood and plasma transported for testing as part of the donor process. We agree that blood sent for testing as part of the donor process should be excepted from regulation under the HMR. Therefore, we modified the proposal in the NPRM to except from the HMR blood sent for testing as part of the donor process, unless the person collecting the blood has reason to believe the sample contains an infectious substance. In such instances, the blood sent for testing must be packaged and shipped as a diagnostic specimen. Note also that blood and blood products transported for testing as part of the donor process is subject to OSHA requirements for handling and shipping.

Several commenters suggest the proposed exception from HMR requirements for blood collected for transfusion and blood products, organs, and tissues intended for transplant, should be expanded to include plasma derivatives. Plasma derivatives are derived from the same units of pre-screened blood used for transfusion. However, plasma derivatives are not ''transfused.'' They are ''infused.'' These commenters request clarifying the final rule to specify plasma derivatives are covered by the same exception as blood collected for transfusion. Plasma derivatives are covered under the exception for biological products in § 173.34(b) of this final rule. Therefore, no additional clarifying language is necessary.

A number of commenters note the proposed addition of Special Provision A81 does not reflect the most recent amendments to the UN Recommendations and the ICAO Technical Instructions. Effective June 20, 2001, the UN Recommendations and ICAO Technical Instructions include a Special Provision to except from aircraft quantity limits, body fluids packed in primary receptacles not exceeding 1,000 mL in outer packagings not exceeding 4 L. In this final rule, we revised Special Provision A81 for consistency with the most recent editions of the UN Recommendations and ICAO Technical Instructions. Thus, under this final rule, Special Provision A81 applies to shipments of any body fluid (*e.g.,* blood, plasma, urine, semen, saliva, spinal fluid, amniotic fluid, and the like).

One commenter recommends we expand the exception from HMR requirements for blood collected for transfusions or blood products, to include waste generated from the collection and testing of blood and blood products. We disagree. Waste is not packaged and transported with the same care as blood and blood products intended for transfusion, even under the

exception granted in this final rule. Further, waste generated from the collection of blood may include sharps and similar objects.

We note that all waste biological products—biological products meeting the definition for RMW in this final rule—may not be transported under the exceptions in this final rule for the transportation of biological products. Waste biological products lose their identity as biological products for purposes of the HMR and, if they contain infectious substances, must be transported in accordance with the HMR requirements applicable to RMW.

*G. Genetically Modified Micro-Organisms*

In the NPRM, we proposed adding ''Genetically modified micro-organism'' to the Hazardous Materials Table as a Class 9 material. We proposed to require these materials to be packaged in conformance with the requirements for packaging infectious substances, except that the packagings need not be marked or tested in accordance with part 178 requirements.

The NPRM also proposed two exceptions applicable to the transportation of genetically modified micro-organisms. First, we proposed to except genetically modified micro-organisms from all requirements in the HMR if a Federal government agency authorizes their final distribution and use. Second, we proposed to except genetically modified micro-organisms from HMR requirements when transported in a non-passenger-carrying transport vehicle operated by a private or contract motor carrier.

A number of commenters address the proposals for genetically modified micro-organisms. Of major concern to the commenters is that the proposed requirements are not risk-based, but instead assume genetically modified micro-organisms pose a threat during transportation merely because of the fact that they are genetically modified. One commenter asserts the proposed Class 9 definition for genetically modified micro-organisms is scientifically meaningless, burdensome, and likely to impede essential research and development involving these materials. Other commenters are concerned that, as defined in the NPRM, genetically modified micro-organisms could include products enhanced through biotechnology. They fear that the requirement to transport genetically modified micro-organisms as Class 9 materials could be interpreted to apply to bulk shipments of biotechnology-enhanced agricultural commodities or products. Most commenters recommend we regulate genetically modified micro-organisms only when they also meet the definition of an infectious substance.

We agree the NPRM proposals applicable to genetically modified micro-organisms may be unnecessarily broad, confusing, and difficult to apply and interpret. Further, there are a host of other stringent Federal requirements applicable to research, licensing, permitting, movement, and use of genetically modified micro-organisms. These regulatory systems were initially described in the policy statement referred to as ''The Coordinated Framework'' (51 FR 23302, June 26, 1986). For more specific details, please see the appropriate agency websites—for example, the EPA Biopesticides and Pollution Prevention Division at *http://www.epa.gov/pesticides/biopesticides/;* the EPA Office of Pollution Prevention and Toxics at *http://www.epa.gov/opptintr/biotech/index.html;* the Animal and Plant Health Inspection Service at *http://www.aphis.usda.gov;* and the FDA Center for Food Safety and Applied Nutrition at *http://vm.cfsan.fda.gov/list.html.*

Because a number of Federal regulatory agencies have rigorous programs in place to regulate the safety and distribution of genetically modified micro-organisms, and because the United States is engaged in ongoing international negotiations concerning global regulation of these materials, the proposals in the NPRM applicable to genetically modified micro-organisms are not adopted in this final rule. Note, however, that genetically modified micro-organisms meeting the definition of a Division 6.2 material are subject to regulation under the HMR.

*H. Regulated Medical Waste*

Commenters generally support the proposals in the NPRM to permit transportation of RMW in certain non-specification bulk packagings. However, commenters suggest several modifications to the proposals in the NPRM.

The NPRM defines ''regulated medical waste'' to mean waste or reusable material containing or suspected of containing an infectious substance in Risk Groups 2 or 3. RMW is generated in the diagnosis, treatment, or immunization of human beings or animals; research on the diagnosis, treatment, or immunization of human beings or animals; or the production or testing of biological products. RMW containing an infectious substance in Risk Group 4 must be classed as Division 6.2, described as an infectious substance, and assigned to UN 2814 or UN 2900, as appropriate. One commenter states the RMW definition is impossible to implement because generators of RMW will not know the specific materials contained in the waste. We disagree. Generators of RMW know the nature of the waste because of the materials they handle during the course of their operations. Further, Risk Group 4 materials are very closely regulated by the CDC, so a generator of RMW should know whether the waste contains a Risk Group 4 material.

One commenter recommends we require RMW containing Risk Group 1 infectious material to meet ''minor'' regulatory requirements. We disagree. As stated above, Risk Group 1 infectious substances are unlikely to cause human or animal disease, and so pose little or no risk to transportation workers or to the general public. There is no compelling safety rationale for regulating RMW containing only Risk Group 1 infectious material.

The NPRM proposed to authorize certain non-specification bulk containers for use as outer packagings for the transportation of RMW. Two commenters oppose this proposal out of concern that it represents a relaxation of current requirements for authorized RMW packagings to meet Packing Group II performance standards. We disagree. This final rule retains the Packing Group II performance requirements for non-bulk packagings. For bulk packagings, which are currently authorized under the terms of 29 exemptions, this final rule permits RMW to be transported in certain non-specification packagings with proven safety records gained through exemptions experience. These packagings have a demonstrated safety record. In addition, this final rule establishes performance standards for the authorized bulk packagings, including a requirement for certain packagings to be capable of passing a drop test at the Packing Group II performance level.

One commenter suggests the proposal would permit regulated medical waste to be transported in large, open-top, roll-off bulk containers. This is not the case. The non-specification bulk packagings authorized for the transportation of RMW must be closed with a lid or closure, to prevent intrusion of water into the packaging or release of contents from the packaging.

Several commenters suggest the provisions applicable to authorized bulk packagings are needlessly detailed. For example, commenters question the necessity of the proposed requirement for a wheeled cart (Cart) to be mounted on a minimum of four wheels and to have a gasketed lid. We agree. In this

final rule, we modified the bulk packaging provisions to provide for more flexibility in their design.

Other commenters suggest we should permit more flexibility for inner packagings inside bulk outer packagings. For example, one commenter notes that the 10-gallon limit on the size of sharps containers used as inner packagings, could preclude shipment of such items as specialized single-use drills, skin staple guns, and heart/lung machine and cell saver canisters, as RMW. We agree and modified this final rule accordingly. For sharps containers, this final rule requires a container with a capacity greater than 20 gallons to be capable of passing the performance tests in § 178.601 of the HMR at the Packing Group II performance level. A sharps container with a capacity of 20 gallons or less must be puncture resistant, but need not be capable of passing the Part 178 performance tests.

Commenters do not address our proposal to allow RMW to be transported in ''Large Packagings,'' which are intermediate bulk packagings containing one or more inner packagings consistent with the requirements of the UN Recommendations. We adopted a definition for these packagings in a final rule issued under Docket HM–215D, published June 21, 2001 (66 FR 33316). The International Maritime Dangerous Goods Code also incorporates this definition. As defined under HM–215D, a Large Packaging consists of an outer packaging containing articles or inner packagings and designed for mechanical handling. A Large Packaging has a capacity greater than 400 kg (882 lbs) or 450 liters (119 gallons), but does not exceed 3 cubic meters (7,000 liters, 793 gallons, or 106 cubic feet) in volume. The proposals in the NPRM concerning Large Packagings are adopted without change in this final rule.

One commenter raises concerns about the ''certification'' process for RMW packagings. The commenter suggests the ''certification'' standards are vague and assume manufacturing uniformity, which may or may not be present, according to the commenter. The commenter asserts ''only the most sophisticated parties, that is, the larger transporters, have had containers certified'' and this limits generators' flexibility in selecting the most appropriate, cost-effective packaging for transporting RMW. We disagree. Currently, the packaging standards in § 173.197 specify that non-bulk packagings for RMW must conform to the requirements of Part 178 at the Packing Group II performance level. This means each packaging must be marked to certify the packaging conforms to all applicable requirements. The packaging design and manufacturing requirements apply to any manufacturer of a specification packaging, not just ''the most sophisticated parties.'' Further, bulk packagings for transportation of RMW are currently authorized only under the terms of exemptions. The proposals in the NPRM in fact increase flexibility, and thus reduce costs for offerors and transporters of RMW by providing a range of bulk packaging options. These options include non-specification packaging options, not currently authorized under the HMR. We are adopting the NPRM proposals in this final rule.

The NPRM proposed to require inner packagings authorized for Large Packagings, Carts, and bulk outer packagings (BOP) to be marked or tagged with the name and location of the offeror. The proposal included an exception from these marking requirements when the entire contents of the Large Packaging, Cart, or BOP originate at a single facility and are delivered to a single location. One commenter opposes this exception. The commenter describes two incidents involving RMW found along public highways, presumably fallen from a transport vehicle. The bags within which the RMW was contained were not marked with the name and location of either the offeror or the consignee, and so could not be traced. The commenter suggests a lack of identification on inner packagings may exacerbate problems related to illegal dumping of RMW or poor package handling. We disagree. This exception is consistent with the current exception from marking for all hazardous materials shipments transported by highway without transfer from one motor carrier to another. This exception is also consistent with the current marking exception for shipments where the entire contents of a transport vehicle or freight container are shipped from one consignor to one consignee.

In response to a petition for rulemaking, the NPRM proposed to revise the HMR to permit transportation of Risk Group 2 or 3 waste cultures or stocks in non-specification packagings when transported by common or contract carriers in dedicated vehicles. Commenters did not specifically address this proposal. It is adopted as proposed in this final rule.

One commenter opposes the proposal in the NPRM to revise the quantity limitations applicable to shipments of RMW on aircraft. Currently, such shipments are forbidden. We proposed to revise the quantity limitations for non-bulk shipments of RMW on board aircraft to read ''No limit'' for consistency with the ICAO Technical Instructions applicable to quantity limitations for RMW on airplanes. We proposed to continue to prohibit bulk shipments of RMW on board aircraft. The commenter suggests RMW shipments are not time critical, and thus do not need to be transported by air, except in the rare instances already authorized by Special Provision A14. (Special Provision A14 permits air shipments of small quantities of RMW when other means of transportation are impracticable or unavailable.) We disagree. The proposals for transporting RMW on board aircraft are adopted in this final rule for consistency with the UN Recommendations and ICAO Technical Instructions. When properly packaged, non-bulk shipments of RMW may be safely transported by air.

One commenter notes many RMW generators depend on the entity transporting the RMW for many services related to the management of the waste. The commenter suggests the proposals applicable to RMW in the NPRM would require both generators and carriers to perform the same functions, greatly increasing the costs of compliance for generators. We disagree. A health care facility may contract with a waste hauler to perform all offeror functions associated with the transportation of its RMW. In this case, the waste hauler becomes the offeror of the RMW and is responsible for classifying the RMW, selecting appropriate packagings, assuring packagings are not overfilled, securing the closures on packagings, marking and labeling the packagings as appropriate, and generating shipping papers in accordance with the HMR. Workers in the health care facility who perform no offeror functions affecting the transportation safety of the shipment, but merely deposit medical waste in containers provided by the waste hauler, are not subject to HMR requirements. However, workers at a health care facility who perform offeror functions are subject to applicable requirements of the HMR. If a health care facility and a waste hauler split the performance of offeror functions, both the facility and the waste hauler are subject to the HMR as offerors.

In the NPRM, we noted in the preamble that waste diagnostic specimens and waste biological products—diagnostic specimens and biological products meeting the definition for RMW—could not be transported under the exceptions proposed in the NPRM for these

materials. One commenter opposes this distinction, stating that excepted products should continue to be excepted from HMR requirements when their status changes to waste. The commenter states regulating a material differently at various stages places an undue and unrealistic burden on medical staff in the field. We disagree. By definition, RMW is a waste or reusable material containing or suspected of containing a Risk Group 2 or 3 infectious substance. If a diagnostic specimen is found not to contain a pathogen, then it is not subject to regulation as RMW. Similarly, if an excepted biological product is not contaminated during use or handling with an infectious material, then it is not subject to regulation as RMW. Laboratory workers, health care providers, and medical staff should have no problem identifying those diagnostic specimens or biological products meeting the RMW definition, and transporting them with other RMW generated by the facility.

*I. Used Health Care Products*

In the NPRM we proposed to except from the HMR used health care products returned to the manufacturer, provided the products are shipped in a triple packaging conforming to certain manufacturing and marking requirements. The proposal required the primary and secondary containers to be marked with the OSHA BIOHAZARD symbol. In addition, we proposed to require the secondary container to be a watertight metal or plastic packaging designed and constructed in a manner to assure the used health care product and primary container remain intact during transportation. The NPRM proposed to require offerors and transporters of used health care products potentially contaminated with an infectious substance to be informed about the used health care product packaging requirements.

Several commenters address this proposal. Most suggest that the proposal is too broad. Further, commenters suggest that, for purposes of the HMR, the definition of used health care products should be limited to used products contaminated with potentially infectious body fluids or materials. Transportation requirements should apply only to products where the infectious hazards cannot be removed or mitigated prior to transportation. We agree and modified this final rule accordingly.

Commenters also suggest the packaging requirements for shipment of used health care products should be risk-based performance standards rather than triple-pack specification standards, as proposed in the NPRM. We agree. Therefore, in this final rule we are revising the packaging requirements proposed in the NPRM to provide more flexibility for shippers.

Note that the person offering a used health care product for transportation under the HMR, not the original manufacturer of the product, is responsible for assuring compliance with the transportation requirements.

*J. Hazard Communication*

In the NPRM, we proposed to require bulk packagings containing RMW to be marked with the appropriate UN identification number and with a BIOHAZARD marking. The BIOHAZARD marking would have to conform to OSHA specifications for the BIOHAZARD marking in 29 CFR 1910.1030(g)(1)(i) to communicate to emergency response personnel the nature of the material being transported. We proposed to require the size of the BIOHAZARD marking to measure at least 273 mm (10.8 inches) on each side. Two commenters note many states require a 152.4 mm (6 inches) size marking, and ask us to consider changing our proposed size requirement. We agree and modified this final rule accordingly. In addition, the final rule includes a graphic representation of the BIOHAZARD symbol.

One commenter requests we allow a transition period for the new BIOHAZARD marking for bulk shipments of RMW, and for the marking requirements on inner packagings authorized for use inside bulk packagings authorized for the transportation of RMW. We agree. In this final rule we are specifying the effective date for both marking requirements as one year after the effective date of this final rule.

One commenter suggests all unique marking requirements for infectious substances, including regulated medical wastes, should be consolidated into one section in subpart D of part 172, rather than located in sections authorizing exceptions from certain requirements or in packaging authorization sections. We disagree. Placing some marking requirements with authorized exceptions or with packaging authorization requirements helps shippers easily identify all requirements with which they must comply when preparing packages for transportation.

Several commenters note certain packages of infectious substances may be subject to labeling requirements under both the HMR and the OSHA BIOHAZARD labeling requirements in 29 CFR 1910.1030. These commenters suggest we adopt a single labeling requirement, or we work cooperatively with OSHA to clarify that the OSHA BIOHAZARD label should not be used for transportation. While we agree with commenters that a dual labeling requirement for certain packages of infectious substances may be confusing, we determined that the OSHA BIOHAZARD label is not prohibited under § 172.401 of the HMR. We do permit use of the BIOHAZARD label in place of the INFECTIOUS SUBSTANCE label under certain conditions. However, substituting the BIOHAZARD label for the INFECTIOUS SUBSTANCE label in all cases is not feasible. The INFECTIOUS SUBSTANCE label is consistent with labels authorized by the UN Recommendations and the ICAO Technical Instructions for international shipments of infectious substances. We do work with OSHA to minimize regulatory duplications and inconsistencies and will continue to do so.

State, local, and tribal governments should be aware the Federal hazardous materials transportation law (Federal hazmat law; 49 U.S.C. 5101 *et seq.*) contains an express preemption provision preempting state, local, and Indian tribe requirements on certain covered subjects (49 U.S.C. 5125(b)). The covered subject areas are:

(a) The designation, description, and classification of hazardous material.

(b) The packing, repacking, handling, labeling, marking, and placarding of hazardous material.

(c) The preparation, execution, and use of shipping documents related to hazardous material and requirements related to the number, contents, and placement of those documents.

(d) The written notification, recording, and reporting of the unintentional release in transportation of hazardous material.

(e) The design, manufacturing, fabrication, marking, maintenance, reconditioning, repairing, or testing of a package or container represented, marked, certified, or sold as qualified for use in transporting hazardous material.

The marking of a hazardous material for purposes of transportation in commerce is a covered subject for purposes of preemption. Thus, unless authorized by another Federal law or a waiver of preemption from the Secretary of Transportation, a non-Federal marking requirement applicable to transportation in commerce is preempted when it is not ''substantively the same'' as Federal hazmat law or a regulation issued under it. 49 U.S.C.

5125(b)(1). After August 14, 2003, non-Federal marking requirements applicable to hazardous materials transportation not substantively the same as the marking requirements for RMW included in this final rule are preempted, unless authorized by another Federal law or a waiver of preemption.

*K. Training*

Several commenters addressed training requirements associated with the regulation of infectious substances under the HMR. Currently, Subpart H of Part 172 requires a hazmat employer to assure each of its hazmat employees is trained, including general awareness/familiarization training, function-specific training, and safety training. A hazmat employee may not perform any function regulated under the HMR unless he or she is trained. One commenter states this level of training is infeasible and unnecessary for health care professionals, and suggests training should be more abbreviated and targeted to specific functions. This commenter further suggests we consider increasing the packaging integrity for shipments of infectious substances, in lieu of applying the hazmat employee training requirements to health care professionals.

We disagree that application of the training requirements to health care professionals is ''infeasible'' and ''unnecessary.'' Training is essential to successful compliance with the HMR. Most health care professionals are already familiar with and trained in requirements that can be used to satisfy some training obligations under the HMR, such as the OSHA Universal Precautions procedures. Further, increased packaging integrity cannot be a substitute for training. Health care professionals need training to properly use any packaging authorized for the transportation of infectious substances, or the regulatory requirements would be meaningless. Moreover, for shipments conforming to requirements for materials of trade or diagnostic specimens in this final rule, the associated training requirements are minimal. They do not include the certification and record keeping provisions in subpart H of part 172.

Another commenter recommends we specify the level of training required for health care professionals, and other offerors and transporters of infectious substances. We disagree. Flexibility is built into the HMR training requirements, allowing hazmat employers to determine the method of training and the level to which each employee must be trained. This flexibility helps to minimize the training burden on both hazmat employers and hazmat employees. This commenter also recommends we delay enforcement of the new requirements in this final rule to allow an appropriate period for retraining. Again, we disagree. This final rule is effective October 2, 2002; this should provide ample time to assure hazmat employees are trained in the new requirements.

*L. Contaminated Food and Food Products*

One commenter states that the definition of ''infectious substance'' in § 173.134, as proposed, could be read to require food and food ingredients tainted with salmonella to be shipped in accordance with requirements for transportation of infectious substances. Salmonella is listed in 42 CFR 72.3 as an infectious substance. This commenter notes salmonella-tainted food does not pose a significant, acute threat to transport workers or to the general public since it must normally be ingested to cause disease. This commenter suggests the final rule incorporate an exception from regulation for food and food ingredients tainted with salmonella or other bacteria. We agree. Indeed, there is no significant threat to life or property from the transportation of food, food ingredients, or food products contaminated with bacteria or other types of pathogens, particularly when such food is being transported as a result of a recall by the original processor. We modified the list of exceptions from HMR requirements in the final rule accordingly.

## III. Section-by-Section Review

### Part 171

*Section 171.7*

We are revising the table of material incorporated by reference to add two new references to test methods developed by the American Society for Testing and Materials. These tests are required for plastic inner packagings used to transport RMW inside Large Packagings and non-specification bulk packagings. We are also revising the table of informational material not requiring incorporation by reference. This revision will add three resources for shippers to use to assign a risk group to a specific infectious substance.

*Section 171.8*

We are adding definitions for ''biological product,'' ''cultures and stocks,'' ''diagnostic specimen,'' ''risk group,'' ''sharps,'' and ''toxin.'' These definitions refer readers to the definitions in § 173.134 of the HMR.

*Section 171.14*

We are allowing a two-year transition period for the revised Division 6.2 labels adopted in this final rule.

*Section 171.15*

We are removing the term ''etiologic agents'' from paragraphs (a)(3) and (b) and replacing it with ''infectious substances.'' In addition, in paragraph (b) we are adding wording to emphasize that a written report of an incident involving infectious substances must be submitted to RSPA.

### Part 172

*Section 172.101*

For the entry ''Regulated medical waste,'' we are removing the letter ''D'' in column (1). In column (7), we are removing the reference to Special Provision A14 and revising columns (9A) and (9B) to replace ''Forbidden'' with ''No Limit'' for quantity limitations on board aircraft. These changes harmonize requirements in the HMR with those in the ICAO Technical Instructions, and facilitate the transportation of RMW in non-bulk packagings by aircraft. In addition, column 8C is revised to replace ''none'' with ''197'', to indicate bulk packagings authorized for the transportation of RMW can be found in § 173.197 of the HMR. Finally, we are revising Special Provision A13 to prohibit the transportation of bulk packagings of RMW by aircraft.

For the entries ''Infectious substances, affecting animals only'' and ''Infectious substances, affecting humans,'' we are adding new special provisions in column (7). Special Provision A81 provides relief from quantity limits for the transport of body fluids containing infectious substances, when in primary receptacles not exceeding 1,000 mL (34 ounces) and in outer packagings not exceeding 4L (1 gallon) and packaged in accordance with § 173.196. Special Provision A82 provides relief from UN standard packaging for transporting body parts, whole organs, and whole bodies.

In addition, we are adding a new entry, ''Diagnostic specimen'', to the Table as a Division 6.2 material. There is no UN number, hazard warning label, or packing group assignment.

We are also adding two new entries for ''Toxins, extracted from living sources, liquid, n.o.s., UN 3172'' and ''Toxins, extracted from living sources, solid, n.o.s., UN 3172.'' For both entries, a ''G'' in column (1) indicates that the

shipping description on shipping papers must include the technical names for the materials. Both entries indicate the materials are Division 6.1 materials, UN 3172, PG I, II, or III. We are adding Special Provision 141 to state that toxins containing infectious substances or contained in infectious substances must be classed as Division 6.2 materials and assigned to UN 2814 or UN 2900, as appropriate.

*Section 172.102*

We are revising this section by removing Special Provision A14, revising Special Provision A13, and adding Special Provisions 141, A81, and A82, as above detailed.

*Section 172.323*

We are adding this section to require bulk packagings containing RMW to be marked with a BIOHAZARD marking conforming to OSHA regulations at 29 CFR 1910.1030. In response to comments, this final rule requires the size of the marking to be at least 152.4 mm (6 inches) on each side. In this final rule, we are adding new paragraph (c) to require the BIOHAZARD marking to be displayed on a background of contrasting color. In addition, this final rule includes a graphic representation of the BIOHAZARD symbol.

*Section 172.432*

We are revising the INFECTIOUS SUBSTANCE label to incorporate the new toll-free telephone number (1–800–232–0124) for reporting incidents to the CDC.

*Section 172.502*

We are revising paragraph (b) to indicate the restrictions on placarding in paragraph (a) of this section do not apply to the display of a BIOHAZARD marking on a white square-on-point background.

**Part 173**

*Section 173.6*

We are adding a MOTS exception for diagnostic specimens, biological products, and RMW, other than Risk Group 4 materials. The exception includes packaging requirements and quantity limitations. As suggested by commenters, this section incorporates minimum performance packaging standards for MOTS that are diagnostic specimens, biological products, or RMW.

*Section 173.28*

We are adding a requirement for Division 6.2 packagings to be disinfected prior to reuse. As suggested by a commenter, this requirement is modified from the NPRM proposal to substitute the term ''disinfect'' for ''decontaminate.''

*Section 173.134*

In paragraph (a), we are revising the definitions and classification criteria for ''infectious substance,'' ''biological product,'' ''diagnostic specimen,'' and ''regulated medical waste;'' and adding definitions for ''cultures and stocks,'' ''risk group,'' ''sharps,'' ''toxin,'' and ''used health care product.''

We are revising the definition of ''infectious substance'' for consistency with international standards, and to require materials meeting the definition of an infectious substance to be assigned to risk groups based on the degree to which they cause injury through disease. Infectious substances assigned to Risk Group 1 are not subject to regulation under the HMR. In response to comments, we revised the definition proposed in the NPRM for clarity and specificity.

We are revising the definition of ''biological product'' to require biological products known to contain or suspected to contain a pathogen in Risk Groups 2, 3, or 4, to be classed as Division 6.2 materials, unless otherwise excepted.

We are defining ''cultures and stocks'' to mean a material prepared and maintained for growth and storage, and containing a Risk Group 2, 3, or 4 infectious substance.

We are revising the definition of ''diagnostic specimen'' to require a diagnostic specimen known to contain or suspected to contain a Risk Group 4 pathogen to be classed as a Division 6.2 material and described by the proper shipping name ''Infectious Substance''. This determination is based on the known medical history and condition of the patient or animal, endemic local conditions, symptoms of the source patient or animal, or professional judgement concerning the individual circumstances of the patient or animal.

We are revising the definition for ''regulated medical waste'' to indicate regulated medical waste is a waste or reusable material containing or suspected to contain a Risk Group 2 or 3 infectious substance. Regulated medical waste containing a Risk Group 4 infectious substance must be classed and transported as a Division 6.2 material, UN 2900 or UN 2814.

We are adding a definition for ''risk group'' to mean a ranking of a micro-organism's ability to cause injury through disease. For consistency with terminology used by other entities that use risk group definitions, in this final rule the definition is modified to substitute ''the severity of the disease caused by the organism'' for ''the pathogenicity of the organism'' as proposed in the NPRM. Thus, risk group assignment criteria include: the severity of the disease caused by the organism; the mode and relative ease of transmission; the degree of risk to both an individual and a community; and the reversibility of the disease through the availability of effective preventive agents and treatments.

We are defining ''sharps'' to mean any object that may be contaminated with an infectious substance, and is able to cut or penetrate the skin or packaging material. The term includes needles, syringes, scalpels, broken glass, culture slides, culture dishes, broken capillary tubes, broken rigid plastic, and exposed ends of dental wires. In response to comments, we have the definition proposed in the NPRM to include uncontaminated objects that may become contaminated during handling and transportation.

We are defining ''toxin'' to mean a Division 6.1 material obtained from a plant, animal, or bacterial source. The definition notes toxins containing an infectious substance or contained in an infectious substance, must be classed as Division 6.2 materials.

In paragraph (b), we are listing exceptions from the HMR requirements applicable to Division 6.2 materials. These exceptions include:

1. Biological products subject to Federal approval, permit, or licensing requirements.
2. Blood collected for transfusions or the preparation of blood products; and blood products, tissues, and organs intended for transplant.
3. Diagnostic specimens or biological products transported by private or contract motor carriers in dedicated motor vehicles.
4. Material treated so that it no longer contains an infectious substance, including diagnostic specimens that do not contain a pathogen or in which the pathogen is inactivated or neutralized.
5. Sanitary waste and sewage.
6. Sewage sludge and compost.
7. Animal waste generated in animal husbandry or food production.
8. Corpses and anatomical parts intended for interment, cremation, or research.
9. Environmental microbiological samples collected to evaluate occupational and residential exposure risks.
10. Agricultural and food products.

In the NPRM, we proposed an exception from most HMR requirements for forensic material transported on behalf of the Federal government or a

state, local government, or tribal government agency, provided the material was shipped in a packaging conforming to the provisions of § 173.24. After the NPRM was published, we discussed this exception with officials from the Federal Bureau of Investigation (FBI). We were particularly concerned with shipments of forensic material associated with bio-terrorism incidents. Based on our discussions with the FBI, this final rule modifies the exception proposed in the NPRM. This final rule requires forensic material known or suspected to contain a Risk Group 4 infectious substance or an infectious substance listed as a select agent in 42 CFR part 72 to be transported in packaging capable of meeting the HMR performance test standards for infectious substance packaging. In addition, the secondary packaging must be marked with a BIOHAZARD symbol conforming to specifications in 29 CFR 1910.1030(g)(1)(i). An itemized list of contents must be enclosed between the secondary packaging and the outer packaging.

We are also modifying the exception for medical waste generated from households, to indicate such medical waste must be transported in accordance with applicable state, local, or tribal government requirements.

In addition, we are revising the exception for laundry or medical equipment conforming to OSHA regulations in 29 CFR 1910.1030. This final rule clarifies that this exception applies to medical equipment intended for reuse and equipment used for testing. The revised definition further clarifies that the exception does not apply to medical equipment transported for disposal.

In this final rule, we modified the exception for blood and blood products to add human cell, tissues, and cellular and tissue-based products regulated under authority of the Public Health Service Act and/or the Food, Drug, and Cosmetic Act.

In paragraph (c), we are modifying the exception for RMW transported by contract or private carriers, to include waste cultures and stocks containing Risk Group 2 or 3 infectious substances.

Finally, we are adding paragraph (d) to clarify that if an item listed in paragraphs (b) or (c) of this section meets the definition of another hazard class, it must be offered for transportation and transported in accordance with applicable requirements of the HMR. Similarly, if an item listed in paragraphs (b) or (c) of this section is a hazardous substance, hazardous waste, or marine pollutant, it must be offered for transportation and transported in accordance with applicable requirements of the HMR.

*Section 173.196*

We are revising this section for clarity and consistency with the UN Recommendations and ICAO Technical Instructions. These revisions include packaging requirements to ensure the integrity of the packagings during air transport, including circumstances where the refrigerant is dissipated or lost. We are adding new paragraph (d) to prescribe non-specification packaging provisions for body parts.

*Section 173.197*

We are revising this section to authorize certain bulk packagings for the transportation of RMW. Paragraph (a) includes general requirements for non-bulk and bulk packagings. Paragraph (b) requires non-bulk packagings to conform to the requirements of part 178 at the Packing Group II performance level. Paragraphs (c) and (d) authorize Large Packagings and non-specification bulk containers for the transportation of RMW. Paragraph (c) sets forth conditions governing the use of Large Packagings. Paragraph (d) sets forth the conditions governing the use of non-specification carts and bulk outer packagings. Paragraph (e) specifies the inner packagings authorized for use with bulk outer packagings.

*Section 173.199*

We are adding § 173.199 to address packaging requirements for diagnostic specimens and used health care products. Diagnostic specimens meeting the definition of a Risk Group 4 material must be classed and transported as infectious substances, UN 2814 or UN 2900, as appropriate. Generally, all other diagnostic specimens may be shipped in triple packagings capable of passing a 1.2 meter (3.9 feet) drop test.

Liquid diagnostic specimens must be packaged in leakproof primary receptacles with a volumetric capacity of not more than 500 mL (17 ounces). For shipments by aircraft, the primary receptacle or secondary packaging must be able to withstand, without leakage, an internal pressure producing a pressure differential of not less than 95 kPa (0.95 bar, 14 psi). The secondary packaging must be leakproof. The volumetric capacity of the outer packaging may not exceed 4 L (1 gallon).

Solid diagnostic specimens must be packaged in a siftproof primary receptacle with a capacity of not more than 500 g (1.1 pounds). The secondary packaging must be leakproof. The capacity of the outer packaging may not exceed 4 kg (8.8 pounds).

Shipments of used health care products contaminated with an infectious substance and being returned to the manufacturer, must be transported in triple packagings and must be marked with the OSHA BIOHAZARD symbol. A used health care product that can cut or penetrate skin or packaging material must be transported in a puncture-resistant primary container. In response to comments, we revised this section to provide more packaging flexibility.

Diagnostic specimens and used health care products shipped in accordance with these provisions are not subject to most other requirements in the HMR. However, these shipments are subject to minimal training requirements. Further, diagnostic specimens are subject to incident reporting for shipments offered for transportation or transported by aircraft.

**Part 177**

*Section 177.834*

We are revising paragraphs (a) and (g) to indicate packages containing Division 6.2 materials must be properly secured in a transport vehicle.

*Section 177.843*

We are adding paragraph (d) to require a transport vehicle to be disinfected prior to reuse if a Division 6.2 material is released from its packaging inside the vehicle. As suggested by a commenter, we modified this requirement to substitute the term ''disinfect'' for ''decontaminate.''

**Part 178**

*Section 178.503*

We are adding paragraph (f) to incorporate markings for infectious substances packagings consistent with those in the ICAO Technical Instructions and the UN Recommendations.

*Section 178.601*

We are adding a sentence to paragraph (c)(1) of this section to include the tests for infectious substance packaging in the definition of design qualification testing. As a result, manufacturers of infectious substances packagings are required to retain design qualification records in accordance with § 178.601(c)(l). In addition, we are adding a sentence to paragraph (c)(2) to indicate, for infectious substances packagings, periodic retesting is the performance of tests specified in § 178.609 at the frequency specified in § 178.601(e). Finally, we are adding a

sentence to paragraph (e) to require packagings used for transporting infectious substances to pass periodic retests.

*Section 178.609*

We are revising the section heading to remove the wording ''(etiologic agents).'' We are revising paragraph (c) to permit the use of expanded plastics for inner packagings and require the packaging tests to be determined by the most fragile inner packaging. Paragraphs (d)(1)(i), (d)(1)(iii), and (d)(1)(iv) are revised for clarity. We are revising paragraph (e) to replace the current water immersion test with a water spray test to simulate exposure to rainfall consistent with the ICAO Technical Instructions. We are revising paragraphs (h)(1) and (h)(2) to clearly indicate that, during the penetration test, penetration of the primary receptacle is not acceptable. We are deleting current paragraph (i). We are adding new paragraph (i) to incorporate the selective testing provisions in the UN Recommendations and ICAO Technical Instructions. These provisions allow variations in the primary receptacles within the secondary packaging without further testing of the completed packaging, if an equivalent level of performance is maintained.

## IV. Coordination with Other Federal Agencies

In addition to RSPA, several Federal agencies have responsibility for regulating infectious substances. We provided CDC, USDA, FDA, EPA, and OSHA with copies of this final rule in advance of publication in the **Federal Register** for their information and comment. We asked them specifically to identify potential areas of conflict between their regulations and the provisions of this final rule. None of these agencies identified any potentially conflicting regulatory requirements.

## V. Security Issues

As a result of the terrorist attacks of September 11, 2001, and subsequent threats related to biological materials, we are reviewing the HMR to determine if additional requirements are necessary to assure the security of hazardous materials in transportation. Certain infectious substances, including *Bacillus anthracis* (anthrax) and other materials listed as select agents by the CDC (42 CFR part 72), are materials that may pose a potential security risk. We initiated a project to address security issues related to infectious substances and other hazardous materials to determine if rulemaking action is necessary.

## VI. Regulatory Analyses and Notices

*A. Executive Order 12866 and DOT Regulatory Policies and Procedures*

This final rule is considered a significant regulatory action under Executive Order 12866, and the Regulatory Policies and Procedures of the Department of Transportation (44 FR 11034). A regulatory evaluation is available for review in the public docket.

The costs identified in the regulatory evaluation are minimal. They are primarily attributed to the regulation of shipments of diagnostic specimens containing a Risk Group 2, 3 or 4 pathogen and of new specification packaging requirements for infectious substances. Our estimate of costs is for a one-time initial cost of $33,332, and a subsequent annual cost of $28,351.

Because of a lack of reliable information concerning deaths, injuries, property damage, and other costs attributable to incidents involving the release of an infectious substance, we are unable to quantify potential savings that may result from this final rule. Reported incidents to RSPA between 1990 and the present resulted in 2 minor injuries and $3,281 in property damage. However, we believe that incidents are significantly under-reported.

Benefits resulting from implementation of this final rule include the following:

1. *International harmonization.* Harmonization of requirements in the HMR with standards specified in the UN Recommendations, ICAO Technical Instructions, and IMDG Code will remove current inconsistencies among the regulations. This action will facilitate efficient transportation of infectious substances across national borders. More importantly, harmonized regulations reduce the potential for misunderstanding and confusion, enhancing safety.

2. *Conversion of exemptions to regulations of general applicability.* Conversion of 29 exemptions applicable to the bulk transportation of RMW to regulations of general applicability, will result in a slight cost savings to the 29 exemptions holders and 65 parties-to-the-exemption holders. In addition, the entire industry will be able to take advantage of the added flexibility provided by the increased number of packaging options for transporting RMW.

3. *Modification of current exceptions for diagnostic specimens and biological products.* We believe potentially infectious diagnostic specimens and biological products should be transported in authorized packaging. Further, such shipments should include communication of hazard to those who may come into contact with them. The HMIS data base and anecdotal information indicate packages of these currently excepted materials are sometimes damaged during transportation. This damage can result in delays and possible risk to cargo handlers, flight crews, emergency responders, and the general public. The requirements in this final rule for more stringent packaging for these materials, combined with the exceptions for transportation of these materials as MOTS or by private or contract carriers in dedicated vehicles will assure swift and efficient transportation. This final rule will also reduce the risks to transportation workers and the general public. Enhancements to packaging also reduce the risk of exposure for laboratory workers opening and handling packages at the point of receipt. The minimal level of regulation proposed for these materials enhances overall safety while imposing insignificant costs on the regulated industry.

Although we cannot assign definitive dollar amounts to these potential benefits, we believe the final rule adopts the least costly alternatives available for ensuring an acceptable level of transportation safety, and the potential benefits to society exceed the potential costs associated with this final rule.

*B. Executive Order 13132*

This final rule has been analyzed in accordance with the principles and criteria contained in Executive Order 13132 (''Federalism''). This final rule preempts state, local, and Indian tribe requirements, but does not propose any regulation with substantial direct effects on the states, the relationship between the national government and the states, or the distribution of power and responsibilities among the various levels of government. Therefore, the consultation and funding requirements of Executive Order 13132 do not apply.

The Federal hazardous materials transportation law, 49 U.S.C. 5101–5127, contains an express preemption provision that preempts state, local, and Indian tribe requirements on certain covered subjects (49 U.S.C. 5125(b)). Covered subjects are:

(1) The designation, description, and classification of hazardous materials;

(2) The packing, repacking, handling, labeling, marking, and placarding of hazardous materials;

(3) The preparation, execution, and use of shipping documents related to hazardous materials and requirements

related to the number, contents, and placement of those documents;

(4) The written notification, recording, and reporting of the unintentional release in transportation of hazardous material; or

(5) The design, manufacture, fabrication, marking, maintenance, recondition, repair, or testing of a packaging or container represented, marked, certified, or sold as qualified for use in transporting hazardous material.

This final rule addresses covered subject items 1–5 above and preempts state, local, and Indian tribe requirements not meeting the ''substantively the same'' standard. This final rule is necessary to assure an acceptable level of safety for the transportation of infectious substances and facilitate international transportation of these materials.

Federal hazardous materials transportation law provides at § 5125(b)(2) that, if we issue a regulation concerning any of the covered subjects, we must determine and publish in the **Federal Register** the effective date of Federal preemption. The effective date may not be earlier than the 90th day following the date of issuance of the final rule and not later than two years after the date of issuance. The effective date of Federal preemption is one year from publication of this final rule in the **Federal Register**.

*C. Executive Order 13175*

This final rule has been analyzed in accordance with the principles and criteria contained in Executive Order 13175 (''Consultation and Coordination with Indian Tribal Governments''). This final rule does not have tribal implications, does not impose substantial direct compliance costs, and is not required by statute. Consequently, the funding and consultation requirements of Executive Order 13175 do not apply.

*D. Regulatory Flexibility Act*

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires an agency to review regulations to assess their impact on small entities unless the agency determines a rule is not expected to have a significant impact on a substantial number of small entities. Based on the assessment in the regulatory evaluation, I hereby certify that while this final rule applies to a substantial number of small entities, there will not be a significant economic impact on those small entities. This certification is based upon a consideration that the identified costs are randomly distributed to the more than 441,000 establishments (offices and clinics of doctors of medicine, dentists, doctors of osteopathy, chiropractors, optometrists, podiatrists, and health practitioners; nursing and personal care facilities; hospitals; and medical and dental laboratories) that comprise Standard Industrial Classification (SIC) Major Group 80 (Health Services). The annual costs attributed to this final rule are minimal, especially when compared to the $300 billion in receipts reported by the health services industry. We believe none of those costs will be disproportionately borne by any of the identified groups of small businesses.

*E. Paperwork Reduction Act*

RSPA has current information collection approvals under OMB No. 2137–0039, Hazardous Materials Incident Reports, which expires May 31, 2004, with 34,441 burden hours and $825,621.66 annual costs; and OMB No. 2137–0557, Approvals for Hazardous Materials, which expires May 31, 2004, with 18,405 burden hours and $415,237.40 annual costs. This final rule will result in small increases in annual burden hours and costs.

Section 1320.8(d), Title 5, Code of Federal Regulations requires RSPA to provide interested members of the public and affected agencies an opportunity to comment on information collection and record keeping requests. The NPRM identified and requested comment on revised information collections submitted to OMB for approval. We estimated the total information collection and record keeping burden as proposed in the NPRM would be revised as follows:

*OMB No. 2137–0039:*
*Number of Respondents:* 1,536.
*Total Annual Responses:* 22,900.
*Total Annual Burden Hours:* 34,441.
*Total Annual Burden Cost:* $825,621.66.

*OMB No. 2137–0557:*
*Number of Respondents:* 3,523.
*Total Annual Responses:* 3,875.
*Total Annual Burden Hours:* 18,405.
*Total Annual Burden Cost:* $415,237.40.

We received no comments on these revised information collections. Under the Paperwork Reduction Act of 1995, no person is required to respond to an information collection unless it displays a valid OMB control number. OMB approved the revised information collections proposed in the NPRM on May 4, 2001, and May 9, 2001.

*F. Regulation Identifier Number (RIN)*

A regulation identifier number (RIN) is assigned to each regulatory action listed in the Unified Agenda of Federal Regulations. The Regulatory Information Service Center publishes the Unified Agenda in April and October of each year. The RIN contained in the heading of this document can be used to cross-reference this action with the Unified Agenda.

*G. Unfunded Mandates Reform Act*

This final rule imposes no mandates and thus does not impose unfunded mandates under the Unfunded Mandates Reform Act of 1995.

*H. Environmental Assessment*

We find there are no significant environmental impacts associated with this final rule. An environmental assessment is in the public docket for this rulemaking.

**List of Subjects**

*49 CFR Part 171*

Exports, Hazardous materials transportation, Hazardous waste, Imports, Incorporation by reference, Reporting and recordkeeping requirements.

*49 CFR Part 172*

Education, Hazardous materials transportation, Hazardous waste, Labeling, Markings, Packaging and containers, Reporting and recordkeeping requirements.

*49 CFR Part 173*

Hazardous materials transportation, Packaging and containers, Radioactive materials, Reporting and recordkeeping requirements.

*49 CFR Part 177*

Hazardous materials transportation, Motor carriers, Radioactive materials, Reporting and recordkeeping requirements.

*49 CFR Part 178*

Hazardous materials transportation, Motor vehicle safety, Packaging and containers, Reporting and recordkeeping requirements.

In consideration of the foregoing, we are amending 49 CFR parts 171, 172, 173, 177, and 178 as follows:

## PART 171—GENERAL INFORMATION, REGULATIONS, AND DEFINITIONS

1. The authority citation for part 171 continues to read as follows:

**Authority:** 49 U.S.C. 5101–5127; 49 CFR part 1.

2. In § 171.7, in the table in paragraph (a)(3), two new entries are added in alphanumeric sequence under the American Society for Testing and

Materials, and three new entries are added in alphabetical order to the table in paragraph (b), to read as follows:

**§ 171.7— Reference material.**

(a) * * *

(3) *Table of material incorporated by reference.*

| Source and name of material | 49 CFR reference |
|---|---|
| * * * * * * * | |
| American Society for Testing and Materials * * * | |
| * * * * * * * | |
| ASTM D 1709–01 Standard Test Methods for Impact Resistance of Plastic Film by the Free-Falling Dart Method | 173.197 |
| * * * * * * * | |
| ASTM D 1922–00a Standard Test Method for Propagation Tear Resistance of Plastic Film and Thin Sheeting by Pendulum Method | 173.197 |
| * * * * * * * | |

* * * * * * *

(b) *List of informational materials not requiring incorporation by reference.* * * *

| Source and name of material | 49 CFR reference |
|---|---|
| *American Biological Safety Association* 1202 Allanson Road, Mundelein, IL 60060 | |
| Risk Group Classification for Infectious Agents, 1998 | 173.134 |
| * * * * * * * | |
| *Centers for Disease Control and Prevention* 1600 Clifton Road, Atlanta, GA 30333 | |
| Biosafety in Microbiological and Biomedical Laboratories, Fourth Edition, April 1999 | 173.134 |
| * * * * * * * | |
| *National Institutes of Health* Bethesda, MD 20892 | |
| NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines), January 2001, Appendix B | 173.134 |
| * * * * * * * | |

3. Section 171.8 is amended by adding the following definitions in alphabetical order to read as follows:

**§ 171.8 Definitions and abbreviations.**

* * * * *

*Biological product.* See § 173.134 of this subchapter.

* * * * *

*Cultures and stocks.* See § 173.134 of this subchapter.

* * * * *

*Diagnostic specimen.* See § 173.134 of this subchapter.

* * * * *

*Risk group.* See § 173.134 of this subchapter.

* * * * *

*Sharps.* See § 173.134 of this subchapter.

* * * * *

*Toxin.* See § 173.134 of this subchapter.

* * * * *

4. Section 171.14 is amended by adding paragraph (e) to read as follows:

**§ 171.14 Transitional provisions for implementing certain requirements.**

* * * * *

(e) A Division 6.2 label conforming to specifications in § 172.432 of this subchapter in effect on September 30, 2002, may be used until October 1, 2005.

**§ 171.15 [Amended]**

5. In § 171.15, the following changes are made:

a. Paragraph (a)(3) is amended by removing the term ''(etiologic agents)''.

b. Paragraph (b) introductory text is amended by removing the term ''etiologic agents'' and in its place adding the term ''infectious substances'', and by adding the wording ''; however, a written report is still required as stated in paragraph (c) of this section'' immediately after the number ''202–267–2675''.

## PART 172—HAZARDOUS MATERIALS TABLE, SPECIAL PROVISIONS, HAZARDOUS MATERIALS COMMUNICATIONS, EMERGENCY RESPONSE INFORMATION, AND TRAINING REQUIREMENTS

6. The authority citation for part 172 continues to read as follows:

**Authority:** 49 U.S.C. 5101–5127; 49 CFR 1.53.

7. In § 172.101, the following proper shipping names are added, in alphabetical order, or revised in the Hazardous Materials Table to read as follows:

**§ 172.101 Purpose and use of hazardous materials table.**

* * * * *

§ 172.101.—HAZARDOUS MATERIALS TABLE

| Symbols | Hazardous materials descriptions and proper shipping names | Hazard class or Division | Identification Numbers | PG | Label Codes | Special provisions | (8) Packaging (§ 173.***) | | | (9) Quantity limitations | | (10) Vessel stowage | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | Exceptions | Non-bulk | Bulk | Passenger aircraft/ rail | Cargo aircraft only | Location | Other |
| (1) | (2) | (3) | (4) | (5) | (6) | (7) | (8A) | (8B) | (8C) | (9A) | (9B) | (10A) | (10B) |
| | [Add]. | | | | | | | | | | | | |
| | * | * | | * | * | * | | * | | * | | | |
| | Diagnostic specimen ..... | 6.2 | ..... | ..... | ..... | A82 ..... | 134 ..... | 199 ..... | None ... | 4 L or 4kg. | 4L or 4 kg. | A ..... | 40 |
| | * | * | | * | * | * | | * | | * | | | |
| G ..... | Toxins, from living sources, liquid, n.o.s.. | 6.1 | UN3172 | I ..... | 6.1 ..... | 141 ..... | None ... | 201 ..... | 243 ..... | 1 L ..... | 30 L ..... | B ..... | 40 |
| | | | | II ..... | | 141 ..... | None ... | 202 ..... | 243 ..... | 5 L ..... | 60 L ..... | B ..... | 40 |
| | | | | III ..... | | 141 ..... | 153 ..... | 203 ..... | 241 ..... | 60 L ..... | 220L .... | A ..... | 40 |
| G ..... | Toxins, from living sources, solid, n.o.s.. | 6.1 | UN3172 | I ..... | 6.1 ..... | 141 ..... | None ... | 211 ..... | 243 ..... | 5 kg ..... | 50 kg ... | B ..... | |
| | | | | II ..... | | 141 ..... | None ... | 212 ..... | 243 ..... | 25 kg ... | 100 kg | B ..... | |
| | | | | III ..... | | 141 ..... | 153 ..... | 213 ..... | 241 ..... | 100 kg | 200 kg | A. | |
| | * | * | | * | * | * | | * | | * | | | |
| | [Revise]. | | | | | | | | | | | | |
| G ..... | Infectious substances, affecting animals *only*. | 6.2 | UN2900 | ..... | 6.2 ..... | A81, 82 | 134 ..... | 196 ..... | None ... | 50 mL or 50 g. | 4 L or 4 kg. | B ..... | 40 |
| G ..... | Infectious substances, affecting humans. | 6.2 | UN2814 | ..... | 6.2 ..... | A81, 82 | 134 ..... | 196 ..... | None ... | 50 mL or 50 g. | 4 L or 4 kg. | B ..... | 40 |
| | * | * | | * | * | * | | * | | * | | | |
| | Regulated medical waste .. | 6.2 | UN3291 | II ..... | 6.2 ..... | A13 ..... | 134, 197. | 197 ..... | 197 ..... | No Limit | No Limit | A ..... | 40 |
| | * | * | | * | * | * | | * | | * | | | |

8. In § 172.102, in paragraph (c)(1), Special provision 141 is added, and in paragraph (c)(2), Special Provision A13 is revised, Special provision A14 is removed, and Special Provisions A81 and A82 are added in alphanumeric order to read as follows:

**§ 172.102 Special provisions.**

* * * * *

(c) * * *

(1) * * *

*Code/Special Provisions*

* * * * *

141 A toxin obtained from a plant, animal, or bacterial source containing an infectious substance, or a toxin contained in an infectious substance, must be classed as Division 6.2, described as an infectious substance, and assigned to UN 2814 or UN 2900, as appropriate.

* * * * *

(2) * * *

*Code/Special Provisions*

* * * * *

A13 Bulk packagings are not authorized for transportation by aircraft.

* * * * *

A81 The quantity limits in columns (9A) and (9B) do not apply to body fluids known to contain or suspected of containing an infectious substance when transported in primary receptacles not exceeding 1,000 mL (34 ounces) and in outer packagings not exceeding 4 L (1 gallon) and packaged in accordance with § 173.196 of this subchapter.

A82 The quantity limits in columns (9A) and (9B) do not apply to human or animal body parts, whole organs or whole bodies known to contain or suspected of containing an infectious substance.

* * * * *

9. Section 172.323 is added to read as follows:

**§ 172.323 Infectious substances.**

(a) In addition to other requirements of this subpart, after September 30, 2003, a bulk packaging containing a regulated medical waste, as defined in § 173.134(a)(5) of this subchapter, must be marked with a BIOHAZARD marking conforming to 29 CFR 1910.1030(g)(1)(i)—

(1) On two opposing sides or two ends other than the bottom if the packaging has a capacity of less than 3,785 L (1,000 gallons). The BIOHAZARD marking must measure at least 152.4 mm (6 inches) on each side and must be visible from the direction it faces.

(2) On each end and each side if the packaging has a capacity of 3,785 L (1,000 gallons) or more. The BIOHAZARD marking must measure at least 152.4 mm (6 inches) on each side and must be visible from the direction it faces.

(b) For a bulk packaging contained in or on a transport vehicle or freight container, if the BIOHAZARD marking on the bulk packaging is not visible, the transport vehicle or freight container must be marked as required by paragraph (a) of this section on each side and each end.

(c) The background color for the BIOHAZARD marking required by paragraph (a) of this section must be orange and the symbol and letters must be black. Except for size the BIOHAZARD marking must appear as follows:


(d) The BIOHAZARD marking required by paragraph (a) of this section must be displayed on a background of contrasting color. It may be displayed on a plain white square-on-point configuration having the same outside dimensions as a placard, as specified in § 172.519(c) of this part.

10. In § 172.432, the illustration in paragraph (a) is revised to read as follows:

**§ 172.432 INFECTIOUS SUBSTANCE label.**

(a) * * *


* * * * *

11. In § 172.502, paragraph (b)(2) is revised to read as follows:

**§ 172.502 Prohibited and permissive placarding.**

* * * * *

(b) * * *

(2) The restrictions of paragraph (a) of this section do not apply to the display of a BIOHHAZARD marking, a ''HOT'' marking, or an identification number on a white square-on-point configuration in accordance with §§ 172.323(c), 172.325(c), or 172.336(b) of this part, respectively.

* * * * *

## PART 173—SHIPPERS—GENERAL REQUIREMENTS FOR SHIPMENTS AND PACKAGINGS

12. The authority citation for part 173 continues to read as follows:

**Authority:** 49 U.S.C. 5101–5127, 44701; 49 CFR 1.45, 1.53.

13. In § 173.6, paragraph (a)(4) is redesignated as paragraph (a)(5), and a new paragraph (a)(4) is added to read as follows:

**§ 173.6 Materials of trade exceptions.**

* * * * *

(a) * * *

(4) A Division 6.2 material, other than a Risk Group 4 material, that is a diagnostic specimen, biological product, or regulated medical waste. The material must be contained in a combination packaging. For liquids, the inner packaging must be leak tight, and the outer packaging must contain sufficient absorbent material to absorb the entire contents of the inner packaging. For sharps, the inner packaging must be constructed of a rigid material resistant to punctures and leaks. For all Division 6.2 materials, the outer packaging must be a strong, tight packaging securely closed and secured against movement.

(i) For a diagnostic specimen or biological product, combination packagings must conform to the following capacity limitations:

(A) One or more inner packagings where the gross mass or capacity of each inner packaging does not exceed 0.5 kg (1.1 pound), or 0.5 L (17 ounces), and an outer packaging having a gross mass or capacity not exceeding 4 kg (8.8 pounds) or 4 L (1 gallon); or

(B) A single inner packaging with a gross mass or capacity not exceeding 16 kg (35.2 pounds) or 16 L (4.2 gallons) in a single outer packaging.

(ii) For a regulated medical waste, a combination packaging must consist of one or more inner packagings having a gross mass or capacity not exceeding 4 kg (8.8 pounds) or 4 L (1 gallon), and an

outer packaging having a gross mass or capacity not exceeding 16 kg (35.2 pounds) or 16 L (4.2 gallons).

* * * * *

14. Section 173.28 is amended by adding paragraph (f) to read as follows:

**§ 173.28 Reuse, reconditioning and remanufacture of packagings.**

* * * * *

(f) A Division 6.2 packaging to be reused must be disinfected prior to reuse by any means effective for neutralizing the infectious substance the packaging previously contained. A secondary packaging or outer packaging conforming to the requirements of § 173.196 or § 173.199 need not be disinfected prior to reuse if no leakage from the primary receptacle has occurred.

15. Section 173.134 is revised to read as follows:

**§ 173.134 Class 6, Division 6.2—Definitions and exceptions.**

(a) *Definitions and classification criteria.* For purposes of this subchapter, the following definitions and classification criteria apply:

(1) *Division 6.2 (infectious substance)* means a material known to contain or suspected of containing a pathogen. A pathogen is a virus or micro-organism (including its viruses, plasmids, or other genetic elements, if any) or a proteinaceous infectious particle (prion) that has the potential to cause disease in humans or animals. A Division 6.2 material must be assigned to a risk group in accordance with this paragraph (a). Assignment to a risk group is based on known medical condition and history of the source patient or animal, endemic local conditions, symptoms of the source patient or animal, or professional judgement concerning individual circumstances of the source patient or animal. Infectious substances are subject to applicable requirements in 42 CFR Part 72—Interstate Shipment of Etiologic Agents.

(2) *Biological product* means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product used in the prevention, diagnosis, treatment, or cure of diseases in humans or animals. A *biological product* includes a material manufactured and distributed in accordance with one of the following provisions: 9 CFR part 102 (Licenses for Biological Products); 9 CFR part 103 (Experimental Products, Distribution, and Evaluation of Biological Products Prior to Licensing); 9 CFR part 104 (Permits for Biological Products); 21 CFR part 312 (Investigational New Drug Application); 21 CFR part 314 (Applications for FDA Approval to Market a New Drug); 21 CFR parts 600 to 680 (Biologics); or 21 CFR part 812 (Investigational Device Exemptions). A *biological product* known to contain or suspected of containing a pathogen in Risk Group 2, 3, or 4 must be classed as Division 6.2, described as an infectious substance, and assigned to UN 2814 or UN 2900, as appropriate, unless otherwise excepted.

(3) *Cultures and stocks* means a material prepared and maintained for growth and storage and containing a Risk Group 2, 3 or 4 infectious substance.

(4) *Diagnostic specimen* means any human or animal material, including excreta, secreta, blood and its components, tissue, and tissue fluids being transported for diagnostic or investigational purposes, but excluding live infected humans or animals. A *diagnostic specimen* is not assigned a UN identification number unless the source patient or animal has or may have a serious human or animal disease from a Risk Group 4 pathogen, in which case it must be classed as Division 6.2, described as an infectious substance, and assigned to UN 2814 or UN 2900, as appropriate. Assignment to UN 2814 or UN 2900 is based on known medical condition and history of the patient or animal, endemic local conditions, symptoms of the source patient or animal, or professional judgement concerning individual circumstances of the source patient or animal.

(5) *Regulated medical waste* means a waste or reusable material known to contain or suspected of containing an infectious substance in Risk Group 2 or 3 and generated in the diagnosis, treatment, or immunization of human beings or animals; research on the diagnosis, treatment or immunization of human beings or animals; or the production or testing of biological products. *Regulated medical waste* containing an infectious substance in Risk Group 4 must be classed as Division 6.2, described as an infectious substance, and assigned to UN 2814 or UN 2900, as appropriate.

(6) *Risk group* means a ranking of a micro-organism's ability to cause injury through disease. A *risk group* is defined by criteria developed by the World Health Organization (WHO) based on the severity of the disease caused by the organism, the mode and relative ease of transmission, the degree of risk to both an individual and a community, and the reversibility of the disease through the availability of known and effective preventative agents and treatment. There is no relationship between a *risk group* and a packing group. The criteria for each *risk group* according to the level of risk are as follows:

RISK GROUP TABLE

| Risk group | Pathogen | Risk to individuals | Risk to the community |
|---|---|---|---|
| 4 | A pathogen that usually causes serious human or animal disease and that can be readily transmitted from one individual to another, directly or indirectly, and for which effective treatments and preventive measures are not usually available. | High | High. |
| 3 | A pathogen that usually causes serious human or animal disease but does not ordinarily spread from one infected individual to another, and for which effective treatments and preventive measures are available. | High | Low. |
| 2 | A pathogen that can cause human or animal disease but is unlikely to be a serious hazard, and, while capable of causing serious infection on exposure, for which there are effective treatments and preventive measures available and the risk of spread of infection is limited. | Moderate | Low. |
| 1 | A micro-organism that is unlikely to cause human or animal disease. A material containing only such micro-organisms is not subject to the requirements of this subchapter. | None or very low | None or very low. |

(7) *Sharps* means any object contaminated with a pathogen or that may become contaminated with a pathogen through handling or during transportation and also capable of cutting or penetrating skin or a packaging material. *Sharps* includes needles, syringes, scalpels, broken glass, culture slides, culture dishes, broken capillary tubes, broken rigid plastic, and exposed ends of dental wires.

(8) *Toxin* means a Division 6.1 material from a plant, animal, or bacterial source. A *toxin* containing an infectious substance or a *toxin* contained in an infectious substance must be classed as Division 6.2, described as an infectious substance, and assigned to UN 2814 or UN 2900, as appropriate.

(9) *Used health care product* means a medical, diagnostic, or research device or piece of equipment, or a personal care product used by consumers, medical professionals, or pharmaceutical providers that does not meet the definition of a diagnostic specimen, biological product, or regulated medical waste, is contaminated with potentially infectious body fluids or materials, and is not decontaminated or disinfected to remove or mitigate the infectious hazard prior to transportation.

(b) *Exceptions.* The following are not subject to the requirements of this subchapter as Division 6.2 materials:

(1) A biological product known to contain or suspected of containing a micro-organism in Risk Group 1, or that does not contain a pathogen.

(2) A diagnostic specimen known to contain or suspected of containing a micro-organism in Risk Group 1, or that does not contain a pathogen, or a diagnostic specimen in which the pathogen has been neutralized or inactivated so it cannot cause disease when exposure to it occurs.

(3) A biological product, including an experimental product or component of a product, subject to Federal approval, permit, or licensing requirements, such as those required by the Food and Drug Administration of the Department of Health and Human Services or the U.S. Department of Agriculture.

(4) Blood collected for the purpose of blood transfusion or the preparation of blood products; blood products; tissues or organs intended for use in transplant operations; and human cell, tissues, and cellular and tissue-based products regulated under authority of the Public Health Service Act and/or the Food, Drug, and Cosmetic Act.

(5) Blood collected for the purpose of blood transfusion or the preparation of blood products and sent for testing as part of the collection process, except where the person collecting the blood has reason to believe it contains an infectious substance, in which case the test sample must be shipped in accordance with § 173.199.

(6) A diagnostic specimen or biological product when transported by a private or contract carrier in a motor vehicle used exclusively to transport diagnostic specimens or biological products. Medical or clinical equipment and laboratory products may be transported aboard the same vehicle provided they are properly packaged and secured against exposure or contamination. If a diagnostic specimen or biological product meets the definition of regulated medical waste in paragraph (a)(5) of this section, it must be offered for transportation and transported in conformance with the appropriate requirements for regulated medical waste.

(7) Laundry or medical equipment conforming to the regulations of the Occupational Safety and Health Administration of the Department of Labor in 29 CFR 1910.1030. This exception includes medical equipment intended for use, cleaning, or refurbishment, such as reusable surgical equipment, or equipment used for testing where the components within which the equipment is contained essentially function as packaging. This exception does not apply to medical equipment being transported for disposal.

(8) A material, including waste, that previously contained an infectious substance that has been treated by steam sterilization, chemical disinfection, or other appropriate method, so it no longer meets the definition of an infectious substance.

(9) A living person.

(10) Any waste or recyclable material, other than regulated medical waste, including—

(i) Garbage and trash derived from hotels, motels, and households, including but not limited to single and multiple residences;

(ii) Sanitary waste or sewage;

(iii) Sewage sludge or compost;

(iv) Animal waste generated in animal husbandry or food production; or

(v) Medical waste generated from households and transported in accordance with applicable state, local, or tribal requirements.

(11) Corpses, remains, and anatomical parts intended for interment, cremation, or medical research at a college, hospital, or laboratory.

(12) Forensic material transported on behalf of a U.S. Government, state, local or Indian tribal government agency, except that—

(i) Forensic material known or suspected to contain a Risk Group 2 or 3 infectious substance must be shipped in a packaging conforming to the provisions of § 173.24.

(ii) Forensic material known or suspected to contain a Risk Group 4 infectious substance or an infectious substance listed as a select agent in 42 CFR Part 72 must be transported in packaging capable of meeting the test standards in § 178.609 of this subchapter. The secondary packaging must be marked with a BIOHAZARD symbol conforming to specifications in 29 CFR 1910.1030(g)(1)(i). An itemized list of contents must be enclosed between the secondary packaging and the outer packaging.

(13) Environmental microbiological samples, such as a sample of dust from a ventilation system or mold from a wallboard, collected to evaluate occupational and residential exposure risks.

(14) Agricultural products and food as defined in the Federal Food, Drug, and Cosmetics Act.

(c) *Exceptions for regulated medical waste.* The following provisions apply to the transportation of regulated medical waste:

(1) A regulated medical waste transported by a private or contract carrier is excepted from—

(i) The requirement for an ''INFECTIOUS SUBSTANCE'' label if the outer packaging is marked with a ''BIOHAZARD'' marking in accordance with 29 CFR 1910.1030; and

(ii) For other than a waste culture or stock of an infectious substance, the specific packaging requirements of this section if packaged in a rigid non-bulk packaging conforming to the general packaging requirements of §§ 173.24 and 173.24a and packaging requirements specified in 29 CFR 1910.1030.

(2) A waste culture or stock of a Risk Group 2 or 3 infectious substance may be offered for transportation and transported as a regulated medical waste when it is packaged in a rigid non-bulk packaging conforming to the general packaging requirements of §§ 173.24 and 173.24a and packaging requirements specified in 29 CFR 1910.1030 and transported by a private or contract carrier using a vehicle dedicated to the transportation of regulated medical waste. Medical or clinical equipment and laboratory products may be transported aboard the same vehicle provided they are properly packaged and secured against exposure or contamination.

(d) If an item listed in paragraph (b) or (c) of this section meets the definition of another hazard class or if it is a hazardous substance, hazardous waste, or marine pollutant, it must be offered for transportation and transported in accordance with applicable requirements of this subchapter.

16. Section 173.196 is revised to read as follows:

**§ 173.196 Infectious substances.**

(a) *Division 6.2 packaging.* A Division 6.2 packaging must meet the test standards of § 178.609 of this subchapter and must be marked in conformance with § 178.503(f) of this subchapter. Division 6.2 packaging is a triple packaging consisting of the following components:

(1) A watertight primary receptacle.

(2) A watertight secondary packaging. If multiple fragile primary receptacles are placed in a single secondary packaging, they must be wrapped individually to prevent contact between them.

(3) An outer packaging of adequate strength for its capacity, mass and intended use. The outer packaging must measure at least 100 mm (3.9 inches) at its smallest overall external dimension.

(4) For a liquid infectious substance, an absorbent material placed between the primary receptacle and the secondary packaging. The absorbent material must be sufficient to absorb the entire contents of all primary receptacles.

(5) An itemized list of contents enclosed between the secondary packaging and the outer packaging.

(6) The primary receptacle or secondary packaging used for infectious substances must be capable of withstanding, without leakage, an internal pressure producing a pressure differential of not less than 95 kPa (0.95 bar, 14 psi).

(7) The primary receptacle or secondary packaging used for infectious substances must be capable of withstanding without leakage temperatures in the range of −40°C to +55°C (−40°F to +131°F).

(b) *Additional requirements for packaging infectious substances.* Infectious substances must be packaged according to the following requirements depending on the physical state and other characteristics of the material:

(1) *Infectious lyophilized (freeze-dried) substances.* Primary receptacles must be flame-sealed glass ampules or rubber-stopped glass vials fitted with metal seals.

(2) *Liquid or solid infectious substances—*

(i) *Infectious substances shipped at ambient temperatures or higher.* Authorized primary receptacles are those of glass, metal, or plastic. Positive means of ensuring a leakproof seal must be provided, such as heat seal, skirted stopper, or metal crimp seal. If screw caps are used, they must be secured by positive means, such as with adhesive tape.

(ii) *Infectious substances shipped refrigerated or frozen (ice, pre-frozen packs, dry ice).* Ice or dry ice must be placed outside the secondary packagings or in an overpack with one or more complete packages marked in accordance with § 178.503 of this subchapter. Interior supports must be provided to secure the secondary packagings in the original position after the ice or dry ice has dissipated. If ice is used, the outside packaging must be leakproof. If dry ice is used, the outside packaging must permit the release of carbon dioxide gas and otherwise meet the provisions in § 173.217. The primary receptacle and the secondary packaging must maintain their integrity at the temperature of the refrigerant used as well as the temperatures and pressures of air transport to which they could be subjected if refrigeration were lost.

(iii) *Infectious substances shipped in liquid nitrogen.* Primary receptacles capable of withstanding very low temperatures must be used. Secondary packaging must withstand very low temperatures and in most cases will need to be fitted over individual primary receptacles. The primary receptacle and the secondary packaging must maintain their integrity at the temperature of the liquid nitrogen as well as the temperatures and pressures of air transport to which they could be subjected if refrigeration were to be lost. Refrigerated liquid nitrogen packagings must be metal vacuum insulated vessels or flasks (also called ''dry shippers'') vented to the atmosphere to prevent any increase in pressure within the packaging. The use of safety relief valves, check valves, frangible discs, or similar devices in the vent lines is prohibited. Fill and discharge openings must be protected against the entry of foreign materials that might cause an increase in the internal pressure. The package orientation markings specified in § 172.312(a) of this subchapter must be marked on the packaging. The packaging must be designed to prevent the release of any refrigerated liquid nitrogen irrespective of the packaging orientation.

(c) Live animals may not be used to transport infectious substances unless such substances cannot be sent by any other means. An animal containing or contaminated with an infectious substance must be transported under terms and conditions approved by the Associate Administrator for Hazardous Materials Safety.

(d) Body parts, organs or whole bodies meeting the definition of Division 6.2 material must be packaged as follows:

(1) In Division 6.2 packaging, as specified in paragraphs (a) and (b) of this section; or

(2) In packaging meeting the requirements of § 173.197.

17. Section 173.197 is revised to read as follows:

**§ 173.197 Regulated medical waste.**

(a) *General provisions.* Non-bulk packagings, large packagings, and bulk outer packagings used for the transportation of regulated medical waste must be rigid containers meeting the provisions of subpart B of this part.

(b) *Non-bulk packagings.* Except as otherwise provided in § 173.134 of this subpart, non-bulk packagings for regulated medical waste must be DOT specification packagings conforming to the requirements of Part 178 of this subchapter at the Packing Group II performance level. A non-bulk packaging must be puncture-resistant for sharps and sharps with residual fluid as demonstrated by conducting the performance tests in Part 178, Subpart M, of this subchapter on packagings containing materials representative of the sharps and fluids (such as sterile sharps) intended to be transported in the packagings.

(c) *Large Packagings.* Large Packagings constructed, tested, and marked in accordance with the requirements of the UN Recommendations and conforming to other requirements of this paragraph (c) may be used for the transportation of regulated medical waste, provided the waste is contained in inner packagings conforming to the requirements of paragraph (e) of this section. Each Large Packaging design must be capable of meeting the vibration test specified in § 178.819 of this subchapter. Each Large Packaging is subject to the periodic design requalification requirements for intermediate bulk containers in § 178.801(e) of this subchapter and to the proof of compliance requirements of § 178.801(j) and record retention requirements of § 178.801(l) of this subchapter. Inner packagings used for liquids must be rigid.

(1) *Authorized packagings.* Only the following Large Packagings are authorized for the transportation of liquid or solid regulated medical waste:

(i) Metal: 50A, 50B, or 50N.

(ii) Rigid plastic: 50H.

(2) *Additional requirements.* Each Large Packaging used to transport liquid regulated medical waste must contain absorbent material in sufficient quantity and appropriate location to absorb the entire amount of liquid present in the event of an unintentional release of contents. Each Large Packaging design intended for the transportation of sharps containers must be puncture resistant and capable of retaining liquids. The design must also be tested and certified as meeting the performance tests specified for intermediate bulk containers intended for the transportation of liquids in subpart O of part 178 of this subchapter.

(d) *Non-specification bulk packaging.* A wheeled cart (Cart) or bulk outer packaging (BOP) is authorized as an outer packaging for the transportation of regulated medical waste in accordance with the provisions of this paragraph (d).

(1) *General requirements.* The following requirements apply to the transportation of regulated medical waste in Carts or BOPs:

(i) Regulated medical waste in each Cart or BOP must be contained in non-bulk inner packagings conforming to paragraph (e) of this section.

(ii) Each Cart or BOP must have smooth, non-porous interior surfaces free of cracks, crevices, and other defects that could damage plastic film inner packagings or impede disinfection operations.

(iii) Except as otherwise provided in this paragraph (d), each Cart or BOP must be used exclusively for the transportation of regulated medical waste. Prior to reuse, each Cart or BOP must be disinfected by any means effective for neutralizing the infectious substance the packaging previously contained.

(iv) Untreated cultures and stocks of infectious substances containing Risk Group 4 materials may not be transported in a Cart or BOP.

(v) Division 6.1 toxic waste or Class 7 radioactive waste, with the exception of chemotherapeutic waste, may not be transported in a Cart or BOP.

(vi) Division 6.1 or Class 7 chemotherapeutic waste; untreated stocks and cultures of infectious substances containing Risk Group 2 or 3 pathogenic organisms; unabsorbed liquids; and sharps containers may be transported in a Cart or BOP only if packaged in rigid non-bulk packagings conforming to paragraph (a) of this section.

(2) *Wheeled cart (Cart).* A Cart is authorized as an outer packaging for the transportation of regulated medical waste if it conforms to the following requirements:

(i) Each Cart must consist of a solid, one-piece body with a nominal volume not exceeding 1,655 L (437 gallons).

(ii) Each Cart must be constructed of metal, rigid plastic, or fiberglass fitted with a lid to prevent leakage during transport.

(iii) Each Cart must be capable of meeting the requirements of § 178.603 (drop test), as specified for solids at the Packing Group II performance level.

(iv) Inner packagings must be placed into a Cart and restrained in such a manner as to minimize the risk of breakage.

(3) *Bulk outer packaging (BOP).* A BOP is authorized as an outer packaging for regulated medical waste if it conforms to the following requirements:

(i) Each BOP must be constructed of metal or fiberglass and have a capacity of at least 3.5 cubic meters (123.6 cubic feet) and not more than 45 cubic meters (1,590 cubic feet).

(ii) Each BOP must have bottom and side joints of fully welded or seamless construction and a rigid, weatherproof top to prevent the intrusion of water (*e.g.,* rain or snow).

(iii) Each opening in a BOP must be fitted with a closure to prevent the intrusion of water or the release of any liquid during all loading, unloading, and transportation operations.

(iv) In the upright position, each BOP must be leakproof and able to contain a liquid quantity of at least 300 liters (79.2 gallons) with closures open.

(v) Inner packagings must be placed in a BOP in such a manner as to minimize the risk of breakage. Rigid inner packagings may not be placed in the same BOP with plastic film bag inner packagings unless separated from each other by rigid barriers or dividers to prevent damage to the packagings caused by load shifting during normal conditions of transportation.

(vi) Division 6.1 or Class 7 chemotherapeutic waste, untreated cultures and stocks of infectious substances containing Risk Group 2 or 3 pathogenic organisms, unabsorbed liquids, and sharps may be transported in a BOP only if separated and secured as provided by paragraph (d)(3)(v) of this section.

(e) *Inner packagings authorized for Large Packagings, Carts, and BOPs.* After September 30, 2003, inner packagings must be durably marked or tagged with the name and location (city and state) of the offeror, except when the entire contents of the Large Packaging, Cart, or BOP originates at a single location and is delivered to a single location.

(1) *Solids.* A plastic film bag is authorized as an inner packaging for solid regulated medical waste transported in a Cart, Large Packaging, or BOP. Waste material containing absorbed liquid may be packaged as a solid in a plastic film bag if the bag contains sufficient absorbent material to absorb and retain all liquid during transportation.

(i) The film bag may not exceed a volume of 175 L (46 gallons). The film bag must be marked and certified by its manufacturer as having passed the tests prescribed for tear resistance in ASTM D 1709–01, *Standard Test Methods for Impact Resistance of Plastic Film by the Free-Falling Dart Method* (see § 171.7 of this subchapter), and for impact resistance in ASTM D 1922–00a, *Standard Test Method for Propagation Tear Resistance of Plastic Film and Thin Sheeting by Pendulum Method* (see § 171.7 of this subchapter). The film bag must meet an impact resistance of 165 grams and a tearing resistance of 480 grams in both the parallel and perpendicular planes with respect to the length of the bag.

(ii) The plastic film bag must be closed with a minimum of entrapped air to prevent leakage in transportation. The bag must be capable of being held in an inverted position with the closed end at the bottom for a period of 5 minutes without leakage.

(iii) When used as an inner packaging for Carts or BOPs, a plastic film bag may not weigh more than 10 kg (22 lbs.) when filled.

(2) *Liquids.* Liquid regulated medical waste transported in a Large Packaging, Cart, or BOP must be packaged in a rigid inner packaging conforming to the requirements of paragraph (a) of this section. Liquid materials are not authorized for transportation in inner packagings having a capacity greater than 19 L (5 gallons).

(3) *Sharps.* Sharps transported in a Large Packaging, Cart, or BOP must be packaged in a puncture-resistant inner packaging (sharps container). Each sharps container exceeding 76 L (20 gallons) in volume must be capable of passing the performance tests in § 178.601 of this subchapter at the Packing Group II performance level. A sharps container may be reused only if it conforms to the following criteria:

(i) The sharps container is specifically approved and certified by the U.S. Food and Drug Administration as a medical device for reuse.

(ii) The sharps container must be permanently marked for reuse.

(iii) The sharps container must be disinfected prior to reuse by any means

effective for the infectious substance the container previously contained.

(iv) The sharps container must have a capacity greater than 7.57 L (2 gallons) and not greater than 151.42 L (40 gallons) in volume.

18. A new § 173.199 is added to read as follows:

**§ 173.199 Diagnostic specimens and used health care products.**

(a) *Diagnostic specimens.* Except as provided in this paragraph (a), diagnostic specimens are excepted from all other requirements of this subchapter when offered for transportation or transported in accordance with this section. Diagnostic specimens offered for transportation or transported by aircraft under the provisions of this section are subject to the incident reporting requirements in §§ 171.15 and 171.16 of this subchapter. A diagnostic specimen meeting the definition of a hazard class other than Division 6.2 must be offered for transportation or transported in accordance with applicable requirements of this subchapter.

(1) Diagnostic specimens must be packaged in a triple packaging, consisting of a primary receptacle, a secondary packaging, and an outer packaging.

(2) Primary receptacles must be packed in secondary packaging in such a way that, under normal conditions of transport, they cannot break, be punctured, or leak their contents into the secondary packaging.

(3) Secondary packagings must be secured in outer packagings with suitable cushioning material such that any leakage of the contents will not impair the protective properties of the cushioning material or the outer packaging.

(4) The completed package must be capable of successfully passing the drop test in § 178.603 of this subchapter at a drop height of at least 1.2 meters (3.9 feet). The outer packaging must be clearly and durably marked with the words ''Diagnostic Specimen.''

(b) *Liquid diagnostic specimens.* Liquid diagnostic specimens must be packaged in conformance with the following provisions:

(1) The primary receptacle must be leakproof with a volumetric capacity of not more than 500 mL (16.9 ounces).

(2) Absorbent material must be placed between the primary receptacle and secondary packaging. If several fragile primary receptacles are placed in a single secondary packaging, they must be individually wrapped or separated so as to prevent contact between them. The absorbent material must be of sufficient quantity to absorb the entire contents of the primary receptacles.

(3) The secondary packaging must be leakproof.

(4) For shipments by aircraft, the primary receptacle or the secondary packaging must be capable of withstanding without leakage an internal pressure producing a pressure differential of not less than 95 kPa (0.95 bar, 14 psi).

(5) The outer packaging may not exceed 4 L (1 gallon) capacity.

(c) *Solid diagnostic specimens.* Solid diagnostic specimens must be packaged in a triple packaging, consisting of a primary receptacle, secondary packaging, and outer packaging, conforming to the following provisions:

(1) The primary receptacle must be siftproof with a capacity of not more than 500 g (1.1 pounds).

(2) If several fragile primary receptacles are placed in a single secondary packaging, they must be individually wrapped or separated so as to prevent contact between them.

(3) The secondary packaging must be leakproof.

(4) The outer packaging may not exceed 4 kg (8.8 pounds) capacity.

(d) *Used health care products.* A used health care product being returned to the manufacturer or the manufacturer's designee is excepted from the requirements of this subchapter when offered for transportation or transported in accordance with this section. For purposes of this section, a health care product is used when it has been removed from its original inner packaging. Used health care products contaminated with or suspected of contamination with a Risk Group 4 infectious substance may not be transported under the provisions of this section.

(1) Each used health care product must be drained of free liquid to the extent practicable and placed in a watertight primary container designed and constructed to assure that it remains intact under conditions normally incident to transportation. For a used health care product capable of cutting or penetrating skin or packaging material, the primary container must be capable of retaining the product without puncture of the packaging under normal conditions of transport. Each primary container must be marked with a BIOHAZARD marking conforming to 29 CFR 1910.1030(g)(1)(i).

(2) Each primary container must be placed inside a watertight secondary container designed and constructed to assure that it remains intact under conditions normally incident to transportation. The secondary container must be marked with a BIOHAZARD marking conforming to 29 CFR 1910.1030(g)(1)(i).

(3) The secondary container must be placed inside an outer packaging with sufficient cushioning material to prevent movement between the secondary container and the outer packaging. An itemized list of the contents of the primary container and information concerning possible contamination with a Division 6.2 material, including its possible location on the product, must be placed between the secondary container and the outside packaging.

(e) *Training.* Each person who offers or transports a diagnostic specimen or used health care product under the provisions of this section must know about the requirements of this section.

## PART 177—CARRIAGE BY PUBLIC HIGHWAY

19. The authority citation for part 177 continues to read as follows:

**Authority:** 49 U.S.C. 5101–5127; 49 CFR 1.53.

20. In § 177.834, paragraphs (a) and (g) are revised to read as follows:

**§ 177.834 General requirements.**

(a) *Packages secured in a vehicle.* Any tank, barrel, drum, cylinder, or other packaging not permanently attached to a motor vehicle and containing any Class 2 (gases), Class 3 (flammable liquid), Division 6.1 (poisonous), Division 6.2 (infectious substance), Class 7 (radioactive), or Class 8 (corrosive) material must be secured against movement within the vehicle on which it is being transported, under conditions normally incident to transportation.

* * * * *

(g) *Prevent relative motion between containers.* Containers of Class 1 (explosive), Class 2 (gases), Class 3 (flammable liquid), Class 4 (flammable solid), Class 5 (oxidizing), Division 6.1 (poisonous), Division 6.2 (infectious substance), or Class 8 (corrosive) materials must be so braced as to prevent motion thereof relative to the vehicle while in transit. Containers having valves or other fittings must be loaded to minimize the likelihood of damage thereto during transportation.

* * * * *

21. In § 177.843, paragraph (d) is added to read as follows:

**§ 177.843 Contamination of vehicles.**

* * * * *

(d) Each transport vehicle used to transport Division 6.2 materials must be

disinfected prior to reuse if a Division 6.2 material is released from its packaging during transportation. Disinfection may be by any means effective for neutralizing the material released.

## PART 178—SPECIFICATIONS FOR PACKAGINGS

22. The authority citation for part 178 continues to read as follows:

**Authority:** 49 U.S.C. 5101–5127; 49 CFR 1.53.

23. In § 178.503, paragraph (f) is added to read as follows:

### § 178.503 Marking of packagings.

* * * * *

(f) A manufacturer must mark every UN specification package represented as manufactured to meet the requirements of § 178.609 for packaging of infectious substances with the marks specified in this section. The markings must be durable, legible, and must be readily visible, as specified in § 178.3(a). An infectious substance packaging that successfully passes the tests conforming to the UN standard must be marked as follows:

(1) The United Nations symbol as illustrated in paragraph (e) of this section.

(2) The code designating the type of packaging and material of construction according to the identification codes for packagings specified in § 178.502.

(3) The text ''CLASS 6.2''.

(4) The last two digits of the year of manufacture of the packaging.

(5) The country authorizing the allocation of the mark. The letters ''USA'' indicate the packaging is manufactured and marked in the United States in compliance with the provisions of this subchapter.

(6) The name and address or symbol of the manufacturer or the approval agency certifying compliance with subparts L and M of this part. Symbols, if used, must be registered with the Associate Administrator for Hazardous Materials Safety.

(7) For packagings meeting the requirements of § 178.609(i)(3), the letter ''U'' must be inserted immediately following the marking designating the type of packaging and material required in paragraph (f)(2) of this section.

24. In § 178.601, paragraphs (c)(1), (c)(2), and (e) are revised to read as follows:

### § 178.601 General requirements.

* * * * *

(c) * * *

(1) *Design qualification testing* is the performance of the tests prescribed in § 178.603, § 178.604, § 178.605, § 178.606, § 178.607, § 178.608, or § 178.609, as applicable, for each new or different packaging, at the start of production of that packaging.

(2) *Periodic retesting* is the performance of the drop, leakproofness, hydrostatic pressure, and stacking tests, as applicable, as prescribed in § 178.603, § 178.604, § 178.605, or § 178.606, respectively, at the frequency specified in paragraph (e) of this section. For infectious substances packagings required to meet the requirements of § 178.609, periodic retesting is the performance of the tests specified in § 178.609 at the frequency specified in paragraph (e) of this section.

* * * * *

(e) *Periodic retesting.* The packaging manufacturer must achieve successful test results for the periodic retesting at intervals established by the manufacturer of sufficient frequency to ensure that each packaging produced by the manufacturer is capable of passing the design qualification tests. Changes in retest frequency are subject to the approval of the Associate Administrator for Hazardous Materials Safety. For single or composite packagings, the periodic retests must be conducted at least once every 12 months. For combination packagings, the periodic retests must be conducted at least once every 24 months. For infectious substances packagings, the periodic retests must be conducted at least once every 24 months.

* * * * *

25. In § 178.609, the section heading, the text of paragraph (c) preceding the table, the introductory text of paragraph (d)(1), paragraphs (d)(1)(i), (d)(1)(iii), (d)(1)(iv), (e), (h)(1), (h)(2), and (i) are revised to read as follows:

### § 178.609 Test requirements for packagings for infectious substances.

* * * * *

(c) Packagings prepared as for transport must be subjected to the tests in Table I of this paragraph (c), which, for test purposes, categorizes packagings according to their material characteristics. For outer packagings, the headings in Table I relate to fiberboard or similar materials whose performance may be rapidly affected by moisture; plastics that may embrittle at low temperature; and other materials, such as metal, for which performance is not significantly affected by moisture or temperature. Where a primary receptacle and a secondary packaging of an inner packaging are made of different materials, the material of the primary receptacle determines the appropriate test. In instances where a primary receptacle is made of more than one material, the material most likely to be damaged determines the appropriate test.

* * * * *

(d) * * *

(1) Where the samples are in the shape of a box, five must be dropped in sequence:

(i) Flat on the base;

* * * * *

(iii) Flat on the longest side;

(iv) Flat on the shortest side; and

* * * * *

(e) The samples must be subjected to a water spray to simulate exposure to rainfall of approximately 50 mm (2 inches) per hour for at least one hour. They must then be subjected to the test described in paragraph (d) of this section.

* * * * *

(h) * * *

(1) Samples must be placed on a level, hard surface. A cylindrical steel rod with a mass of at least 7 kg (15 pounds), a diameter not exceeding 38 mm (1.5 inches), and, at the impact end edges, a radius not exceeding 6 mm (0.2 inches), must be dropped in a vertical free fall from a height of 1 m (3 feet), measured from the impact end of the sample's impact surface. One sample must be placed on its base. A second sample must be placed in an orientation perpendicular to that used for the first. In each instance, the steel rod must be aimed to impact the primary receptacle(s). For a successful test, there must be no leakage from the primary receptacle(s) following each impact.

(2) Samples must be dropped onto the end of a cylindrical steel rod. The rod must be set vertically in a level, hard surface. It must have a diameter of 38 mm (1.5 inches) and a radius not exceeding 6 mm (0.2 inches) at the edges of the upper end. The rod must protrude from the surface a distance at least equal to that between the primary receptacle(s) and the outer surface of the outer packaging with a minimum of 200 mm (7.9 inches). One sample must be dropped in a vertical free fall from a height of 1 m (3 feet), measured from the top of the steel rod. A second sample must be dropped from the same height in an orientation perpendicular to that used for the first. In each instance, the packaging must be oriented so the steel rod will impact the primary receptacle(s). For a successful test, there must be no leakage from the primary receptacle(s) following each impact.

(i) *Variations.* The following variations in the primary receptacles placed within the secondary packaging

are allowed without additional testing of the completed package. An equivalent level of performance must be maintained.

(1) *Variation 1.* Primary receptacles of equivalent or smaller size as compared to the tested primary receptacles may be used provided they meet all of the following conditions:

(i) The primary receptacles are of similar design to the tested primary receptacle (*e.g.,* shape: round, rectangular, *etc.*).

(ii) The material of construction of the primary receptacle (glass, plastics, metal, *etc.*) offers resistance to impact and a stacking force equal to or greater than that of the originally tested primary receptacle.

(iii) The primary receptacles have the same or smaller openings and the closure is of similar design (*e.g.,* screw cap, friction lid, *etc.*).

(iv) Sufficient additional cushioning material is used to fill void spaces and to prevent significant movement of the primary receptacles.

(v) Primary receptacles are oriented within the intermediate packaging in the same manner as in the tested package.

(2) *Variation 2.* A lesser number of the tested primary receptacles, or of the alternative types of primary receptacles identified in paragraph (i)(1) of this section, may be used provided sufficient cushioning is added to fill the void space(s) and to prevent significant movement of the primary receptacles.

(3) *Variation 3.* Primary receptacles of any type may be placed within a secondary packaging and shipped without testing in the outer packaging provided all of the following conditions are met:

(i) The secondary and outer packaging combination must be successfully tested in accordance with paragraphs (a) through (h) of this section with fragile (*e.g.,* glass) inner receptacles.

(ii) The total combined gross weight of inner receptacles may not exceed one-half the gross weight of inner receptacles used for the drop test in paragraph (d) of this section.

(iii) The thickness of cushioning material between inner receptacles and between inner receptacles and the outside of the secondary packaging may not be reduced below the corresponding thicknesses in the originally tested packaging. If a single inner receptacle was used in the original test, the thickness of cushioning between the inner receptacles must be no less than the thickness of cushioning between the outside of the secondary packaging and the inner receptacle in the original test. When either fewer or smaller inner receptacles are used (as compared to the inner receptacles used in the drop test), sufficient additional cushioning material must be used to fill the void.

(iv) The outer packaging must pass the stacking test in § 178.606 while empty. The total weight of identical packages must be based on the combined mass of inner receptacles used in the drop test in paragraph (d) of this section.

(v) For inner receptacles containing liquids, an adequate quantity of absorbent material must be present to absorb the entire liquid contents of the inner receptacles.

(vi) If the outer packaging is intended to contain inner receptacles for liquids and is not leakproof, or is intended to contain inner receptacles for solids and is not sift proof, a means of containing any liquid or solid contents in the event of leakage must be provided. This can be a leakproof liner, plastic bag, or other equally effective means of containment.

(vii) In addition, the marking required in § 178.503(f) of this subchapter must be followed by the letter ''U''.

Issued in Washington, DC, on August 2, 2002, under authority delegated in 49 CFR part 106.

**Ellen G. Engleman,**

*Administrator, Research and Special Programs Administration.*

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**Part IV**

# Commodity Futures Trading Commission

**17 CFR Part 41**

# Securities and Exchange Commission

**17 CFR Part 242**

**Customer Margin Rules Relating to Security Futures; Joint Final Rules**

**COMMODITY FUTURES TRADING COMMISSION**

**17 CFR Part 41**

**RIN 3038–AB71**

**SECURITIES AND EXCHANGE COMMISSION**

**17 CFR Part 242**

**[Release No. 34–46292; File No. S7–16–01]**

**RIN 3235–AI22**

## Customer Margin Rules Relating to Security Futures

**AGENCIES:** Commodity Futures Trading Commission and Securities and Exchange Commission.

**ACTION:** Joint final rules.

**SUMMARY:** The Commodity Futures Trading Commission (''CFTC'') and the Securities and Exchange Commission (''SEC'') (collectively, ''Commissions'') are adopting rules to establish margin requirements for security futures. The final rules preserve the financial integrity of markets trading security futures, prevent systemic risk, and require that the margin requirements for security futures be consistent with the margin requirements for comparable exchange-traded option contracts.

**EFFECTIVE DATE:** September 13, 2002.

**FOR FURTHER INFORMATION CONTACT:**

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*SEC:* Onnig Dombalagian, Attorney Fellow, at (202) 942–0737; Theodore R. Lazo, Senior Special Counsel, at (202) 942–0745; Hong-anh Tran, Special Counsel, at (202) 942–0088; and Lisa Jones, Attorney, at (202) 942–0063, Division of Market Regulation, Securities and Exchange Commission, 450 Fifth Street, NW, Washington, DC 20549–1001.

**SUPPLEMENTARY INFORMATION:** The CFTC is adopting Rules 41.42 through 41.49, 17 CFR 41.42 through 41.49, and the SEC is adopting Rules 400 through 406, 17 CFR 242.400 through 242.406, (the ''Final Rules'') under authority delegated by the Federal Reserve Board pursuant to the Securities Exchange Act of 1934 (''Exchange Act'').



## I. Background

### *A. Statutory Provisions*

The Commodity Futures Modernization Act of 2000 (''CFMA''),[1] which became law on December 21, 2000, lifted the ban on single stock and narrow-based stock index futures (''security futures''). In addition, the CFMA established a framework for the joint regulation of security futures by the CFTC and the SEC.

As part of the statutory scheme for the regulation of security futures, the CFMA provided for the issuance of rules governing customer margin for transactions in security futures. Specifically, the CFMA added a new subsection (2) to section 7(c) of the Exchange Act,[2] which directs the Board of Governors of the Federal Reserve System (''Federal Reserve Board'') to prescribe rules establishing initial and maintenance customer margin requirements imposed by brokers, dealers, and members of national securities exchanges for security futures products. In addition, section 7(c)(2)(B) provides that the Federal Reserve Board may delegate this rulemaking authority jointly to the Commissions. On March 6, 2001, the Federal Reserve Board delegated its authority under Section 7(c)(2)(B) to the Commissions.[3] Pursuant to that authority, the SEC and the CFTC have adopted customer

[1] Appendix E of Pub. L. No. 106–554, 114 Stat. 2763 (2000).

[2] 15 U.S.C. 78g(c)(2).

[3] Letter from Jennifer J. Johnson, Secretary of the Board, Federal Reserve Board, to James E. Newsome, Acting Chairman, CFTC, and Laura S. Unger, Acting Chairman, SEC (March 6, 2001) (''FRB Letter'').

margin requirements for security futures.[4]

Section 7(c)(2) provides that the customer margin requirements for security futures must satisfy four requirements. First, they must preserve the financial integrity of markets trading security futures products. Second, they must prevent systemic risk. Third, they must (a) be consistent with the margin requirements for comparable option contracts traded on any exchange registered pursuant to section 6(a) of the Exchange Act; and (b) provide for initial and maintenance margin levels that are not lower than the lowest level of margin, exclusive of premium, required for comparable exchange-traded options. Fourth, they must be and remain consistent with the margin requirements established by the Federal Reserve Board under Regulation T.[5]

*B. Proposed Rules*

On September 26, 2001, the CFTC and the SEC issued for public comment proposed rules (the ''Proposed Rules'') relating to customer margin requirements for security futures.[6] In response to a joint request from the Futures Industry Association (''FIA'') and the Securities Industry Association (''SIA'') for an extension of the public comment period, the Commissions granted a 30-day extension until December 5, 2001.[7]

*C. Overview of the Comment Letters*

The Commissions received a total of 19 comment letters from securities and futures industry associations,[8] exchanges,[9] a clearing organization,[10] financial services firms,[11] systems vendors,[12] a member of the academic community,[13] and two members of the public.[14] In general, the comment letters focused on three major issues raised by the Proposed Rules: the applicability of Regulation T and the desirability of an account-specific margin regime; the appropriateness of the proposed 20% margin level; and the permissibility of portfolio margining.

The majority of commenters expressed the view that Regulation T should not be applied to futures accounts. They stated their concern that application of Regulation T to security futures carried in futures accounts would impose heavy costs on carrying firms in the form of reprogramming of systems and training of staff. Some believed that it would discourage futures commission merchants (''FCMs'') from trading security futures. One commenter, however, supported the application of Regulation T to security futures, regardless of the type of account in which they are carried. Several commenters identified specific provisions of Regulation T that would have to be addressed in order to accommodate carrying security futures in a securities account, *e.g.,* rules for variation margin payments.

Ten of the commenters specifically endorsed the concept that the margin rules should build on the existing regulatory infrastructure and that, to the extent possible, the rules applicable to security futures should be determined by the type of account in which the security futures are carried. Under this ''account-specific'' approach, for example, rules relating to acceptable collateral, collateral haircuts, timing for collection of margin, and calculations of current market value would be determined in accordance with the rules otherwise applicable to a securities account or futures account, respectively. Several commenters observed that this would be consistent with the Commissions' proposed customer funds rules [15] and would be the most prudent and cost effective approach.

Most commenters found the proposed 20% minimum margin level to be acceptable, although some thought the minimum should instead be 25%. The SIA/FIA Letter noted that ''members of the Associations are divided'' as to whether the minimum level of initial and maintenance margin should be 20% or 25%. Another commenter expressed the view that the 20% level could be either too high or too low depending on the circumstances, and that for certain positions 50% initial margin would be appropriate.

Eleven commenters supported the implementation of full portfolio margining for security futures, as soon as possible. Two other commenters emphasized the need for experience with a proposed pilot program.[16] One commenter supported portfolio margining only for sophisticated customers, with another commenter joining in the view that portfolio margining might not be appropriate for all customers.

After carefully considering the public comments, the Commissions have adopted Final Rules that reflect modifications to the Proposed Rules in response to the views and concerns expressed by the commenters. The Commissions believe that the Final Rules fulfill the statutory requirements and that the changes made to the

[4] Because section 6(h)(6) of the Exchange Act (15 U.S.C. 78f(h)(6)) provides that options on security futures may not be traded for at least three years after the enactment of the CFMA, the margin requirements do not address options on security futures.

[5] 12 CFR 220 *et seq.*

[6] Securities Exchange Act Release No. 44853 (September 26, 2001), 66 FR 50720 (October 4, 2001). The FRB Letter was attached as Appendix B. *See id.* at 50741.

[7] *See* Securities Exchange Act Release No. 44996 (October 29, 2001), 66 FR 55608 (November 2, 2001).

[8] *See* letters from Mark E. Lackritz, President, SIA, and John M. Damgard, President, FIA, dated December 5, 2001 (''SIA/FIA Letter''); George Ruth, Chairman, Rules and Regulations Committee, Securities Industry Association Credit Division, dated December 4, 2001 (''SIA Credit Division Letter''); Thomas W. Sexton, Vice President and General Counsel, National Futures Association, dated December 5, 2001 (''NFA Letter''); and John G. Gaine, President, Managed Funds Association, dated January 11, 2002 (''Manager Funds Letter'').

[9] *See* letters from James J. McNulty, Chicago Mercantile Exchange Inc., and David J. Vitale, Board of Trade of the City of Chicago, Inc., dated December 4, 2001 (''CME/CBOT Letter''); the American Stock Exchange, Chicago Board Options Exchange, The Options Clearing Corporation, International Securities Exchange, Pacific Exchange, and Philadelphia Stock Exchange, dated December 5, 2001 (''Options Exchanges Letter''); Kathleen M. Hamm, Director of Market Regulation, Senior Vice President Regulation and Compliance, Nasdaq Liffe Markets, LLC, dated December 5, 2001 (''Nasdaq Liffe Letter''); Kenneth M. Rosenzweig, on behalf of OneChicago, LLC, dated December 6, 2001 (''OneChicago Letter''); Michael J. Ryan, Jr., Executive Vice President and General Counsel, American Stock Exchange, dated December 7, 2001 (''Amex Letter''); and William J. Brodsky, Chairman and Chief Executive Officer, Chicago Board Options Exchange, dated December 7, 2001 (''CBOE Letter''). The CBOE also joined in the Options Exchanges Letter.

[10] *See* letter from Susan Milligan, The Options Clearing Corporation, dated December 14, 2001 (''OCC Letter''). The OCC also joined in the Options Exchanges Letter.

[11] *See* letters from John P. Davidson III, Managing Director, Morgan Stanley, dated December 5, 2001 (''Morgan Stanley Letter''); James A. Gary, Executive Vice President, ABN AMRO Incorporated, dated December 5, 2001 (''ABN AMRO Letter''); and Russell R. Wasendorf, Sr., Chairman and Chief Executive Officer, Peregrine Financial Group, Inc., dated December 5, 2001 (''Peregrine Letter'').

[12] *See* letters from John Munro, Senior Vice President, Product Design, Rolfe and Nolan Systems Inc (''Rolfe and Nolan Letter''); and Stephen P. Auerbach, Chief Operating Officer, SunGard Futures Systems, dated December 5, 2001 (''SunGard Letter'').

[13] *See* letter from Frank Partnoy, Professor of Law, University of San Diego School of Law, dated October 29, 2001 (''Partnoy Letter'').

[14] *See* letter from Robert Drinkard, dated September 28, 2001 (''Drinkard Letter''); and letter from Bernard E. Klein, dated December 18, 2001 (''Klein Letter'').

[15] *See* Securities Exchange Act Release No. 44854 (September 26, 2001), 66 FR 50768 (October 4, 2001).

[16] *See* Securities Exchange Act Release No. 45630 (March 22, 2002), 67 FR 15263 (March 29, 2002) (notice of rules proposed by the CBOE related to customer portfolio and cross-margining requirements).

Proposed Rules will more effectively promote market efficiency and liquidity.

*D. Overview of the Final Rules*

The Commissions have carefully considered the commenters' views, and have modified the Proposed Rules in various respects. The Final Rules, among other things:

- Establish stand-alone requirements that are consistent with Regulation T, but do not apply Regulation T in its entirety to futures accounts.
- Establish minimum initial and maintenance margin levels for unhedged positions in security futures at 20% of their ''current market value.''
- Permit self-regulatory authorities to set margin levels lower than 20% of current market value for customers with certain strategy-based offset positions involving security futures and one or more related securities or futures.
- Identify the types of collateral acceptable as margin deposits and establish standards for the valuation of such collateral and other components of equity.
- Establish standards for the withdrawal of margin by customers and security futures intermediaries.
- Set forth procedures applicable to undermargined accounts.
- Set forth procedures for filing proposed rule changes with the CFTC.

## II. Discussion of the Final Rules

*A. Who Is Covered by the Final Rules*

The Commissions are adopting the Final Rules under the authority delegated to them by the Federal Reserve Board under section 7(c)(2) of the Exchange Act, which applies to brokers, dealers, and members of national securities exchanges extending credit to or for customers, or collecting margin from customers, in connection with security futures. In the Proposed Rules, the Commissions used the term ''creditor,'' as defined in Regulation T, to delineate those persons who would be subject to the margin rules.[17] Because FCMs that effect transactions in security future products are broker-dealers,[18] they were included in the definition of ''creditor'' under the Proposed Rules.

To avoid characterizing the collection of margin for a security futures contract as involving an extension of credit, the Final Rules use the term ''security futures intermediary'' instead of the term ''creditor.'' [19] The term ''security futures intermediary'' is intended to include the same persons as are included in the Regulation T definition of ''creditor,'' but solely with respect to their financial relations involving security futures. SEC Rule 401(a)(29) defines security futures intermediary by reference to the term creditor. For the sole purpose of clarifying the scope of the Final Rules for market participants that are not subject to Regulation T, the definition of security futures intermediary in CFTC Rule 41.43(a)(29) specifies that the term includes FCMs and enumerated affiliated persons.[20]

The Commissions believe that the term security futures intermediary is defined identically for all substantive purposes, and emphasize that the difference in the language used in the two rules to define a security futures intermediary is not intended to mean that the scope of the two rules is different.

In addition, the term ''customer'' is defined under the Final Rules as any person or persons acting jointly on whose behalf a security futures intermediary effects a security futures transaction or carries a security futures position, or who would be considered a customer of the security futures intermediary according to the ordinary usage of the trade.[21] The definition of customer further includes (i) any partner in a security futures intermediary that is organized as a partnership who would be considered a customer of the security futures intermediary absent the partnership relationship, and (ii) any joint venture in which a security futures intermediary participates and which would be considered a customer of the security futures intermediary if the security futures intermediary were not a participant.[22] This definition is derived from the Regulation T definition of customer.[23]

*B. Exclusions From Coverage*

The Final Rules include specific exclusions for certain categories of financial relations, substantially as proposed. The exclusions are described below.

1. Financial Relations between a Customer and a Security Futures Intermediary Under a Portfolio Margining System

The Proposed Rules provided an exclusion for margin calculated by a portfolio margining system that has been approved by the SEC and, as applicable, the CFTC.[24] The Commissions are adopting this exclusion substantially as proposed.[25] The Final Rules add a provision requiring that the portfolio margining system meet the criteria set forth in section 7(c)(2)(B) of the Exchange Act.[26] This addition is intended to clarify that the portfolio margining system must be consistent with a risk-based system used for comparable exchange-traded options. This requirement does not preclude the use of an existing portfolio margining system that interfaces with an FCM's bookkeeping system, so long as the portfolio margining system is modified to produce results that comply with the Final Rules.[27]

Portfolio margining establishes margin levels by assessing the market risk of a ''portfolio'' of positions in securities or commodities. Under a portfolio margining system, the amount of required margin is determined by analyzing the risk of each component position in a customer account (*e.g.,* a class of option with the same expiration date) and by recognizing any risk offsets in an overall portfolio of positions (*e.g.,* across options and futures on the same underlying instrument). So that adequate margin is deposited to cover extraordinary market events, one or more additional adjustments may be applied in calculating a customer's required margin. A portfolio margining system may also be used in conjunction with a risk-based margining system,

[17] Under Section 220.2 of Regulation T (17 CFR 220.2), the term ''creditor'' means any broker or dealer, member of a national securities exchange, or any person associated with a broker or dealer other than business entities controlling or under common control with the broker-dealer.

[18] *See* sections 3(a)(4) and 3(a)(5) of the Exchange Act, 15 U.S.C. 78c(a)(4) and 78c(a)(5).

[19] For the same reason, the Final Rules do not use the term ''borrower'' to refer to persons who deposit margin in connection with security futures transactions.

[20] *See* CFTC Rule 41.43(a)(29); SEC Rule 401(a)(29).

[21] *See* CFTC Rule 41.43(a)(5)(i); SEC Rule 401(a)(5)(i).

[22] *See* CFTC Rule 41.43(a)(5)(ii) and (iii); SEC Rule 401(a)(5)(ii) and (iii).

[23] *See* 12 CFR 220.2.

[24] *See* Proposed CFTC Rule 41.43(b)(3)(i); Proposed SEC Rule 400(b)(3)(i).

[25] *See* CFTC Rule 41.42(c)(2)(i); SEC Rule 400(c)(2)(i).

[26] *See* CFTC Rule 41.42(c)(2)(i); SEC Rule 400(c)(2)(i). Section 7(c)(2)(B) requires that the margin requirements for security futures (i) be consistent with the margin requirements for comparable exchange-traded security options (and that margin levels for security futures not be lower than the levels of margin required for comparable exchange-traded options), and (ii) be and remain consistent with Regulation T of the Federal Reserve Board. 15 U.S.C. 78g(c)(2)(B).

[27] Under the Final Rules, a portfolio margining system can be used to compute required initial or maintenance margin that results in margin levels that are equal to or higher than the margin levels required by the Final Rules. In this regard, for example, the minimum margin requirement for unhedged security futures positions must be 20%, and the system cannot recognize any offset for combination positions that is not permitted under self-regulatory authority rules, as provided in CFTC Rule 41.45(b)(2) and SEC Rule 403(b)(2). See discussion of margin offsets, Section II.G.3. below.

which assesses margin based on the historical performance of individual instruments, rather than as a fixed percentage of current market value. Depending upon the risks attributable to one or more positions, the amount of required margin in a portfolio margining system may be greater than or less than the margin levels currently required for securities positions in a fixed-percentage, strategy-based margining system.

The Commissions received 14 comment letters that addressed the issue of portfolio margining, all of which supported the concept of portfolio margining for security futures.[28] Ten of the commenters strongly supported the implementation of full portfolio margining for security futures as soon as possible.[29]

Five commenters observed that portfolio margining recognizes the market risk associated with a specific position more accurately than a fixed-percentage margin scheme.[30] One commenter criticized the Proposed Rules for limiting customers to an ''archaic strategy-based system.'' [31]

One commenter stated its opinion that portfolio margining should be allowed immediately for security futures, and that the higher margin levels collected under a strategy-based approach would make it difficult for U.S. markets to attract liquidity in security futures.[32] This commenter raised concerns that strategy-based margining would disadvantage U.S. markets and would encourage investors to seek foreign markets.[33] Another commenter supported portfolio margining for security futures, securities, and securities options to promote global competitiveness.[34] It observed that portfolio margining has become the international standard for major futures markets and without it, the U.S. markets will be at a disadvantage.[35]

One commenter expressed the view that portfolio margining should not be approved for security futures before it is approved for options, and stated that it was critical that any portfolio margining system applicable to security futures apply to all related products, including options and the underlying securities.[36] Another commenter supported implementation of a portfolio margining framework under which the margin requirements for portfolios comprised of securities and security futures would be determined through a risk-based analysis.[37]

Two other commenters, while strongly supporting the concept of portfolio margining, expressed the opinion that portfolio margining was not necessarily appropriate for all investors, and that it might be appropriate to limit the use of portfolio margining for security futures to sophisticated investors.[38]

The SEC and the CFTC have approved the use of portfolio margining systems for certain purposes. The CFTC has approved portfolio margining using the SPAN system for all currently traded futures contracts, at both the clearing level and the customer level.[39] The SEC has approved portfolio margining using The Options Clearing Corporation's (''The OCC'') Theoretical Intermarket Margin System (''TIMS'') for margin collected by The OCC for the options positions of its clearing members.[40] The SEC and CFTC also have approved self-regulatory organization (''SRO'') rules that permit the use of SPAN and TIMS in connection with certain cross-margining arrangements involving futures and securities.[41] In addition, as noted previously, on March 22, 2002, the SEC published notice of a proposed rule change filed by the CBOE to implement a portfolio margining system on a pilot basis for certain customers.[42]

Section 7(c)(2)(B)(iii) of the Exchange Act[43] provides that the margin requirements for security futures must be consistent with the margin requirements for comparable exchange-traded options, and that the initial and maintenance margin levels for security futures may not be lower than the lowest level of margin, exclusive of premium, required for any comparable exchange-traded option. After considerable deliberation about the application of this standard to security futures margin, the Commissions have determined that risk-based portfolio margining for security futures will not be permitted until a similar methodology is introduced for comparable exchange-traded options.

Three commenters expressed opinions regarding the future selection and use of SPAN or TIMS as a portfolio margining system.[44] The Commissions will consider issues related to the use of any particular portfolio margining system at such time as the Commissions consider the actual implementation of portfolio margining for security futures.

The Commissions strongly encourage the efforts of market participants to develop a portfolio margining proposal for security futures, and are committed to working with these participants to resolve any outstanding issues as quickly as feasible. Such a portfolio margining system would be in keeping with current practices in the futures industry and would be responsive to the Federal Reserve Board's desire to encourage the development of more risk-sensitive, portfolio-based approaches to margining security futures products.[45]

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[28] *See* SIA Credit Division Letter; Options Exchanges Letter; CME/CBOT Letter; SunGard Letter; SIA/FIA Letter; OCC Letter; Peregrine Letter; Nasdaq Liffe Letter; NFA Letter; Morgan Stanley Letter; OneChicago Letter; ABN AMRO Letter; Rolfe and Nolan Letter; and Managed Funds Letter.

[29] *See* CME/CBOT Letter; SunGard Letter; SIA/FIA Letter; Peregrine Letter; Nasdaq Liffe Letter; NFA Letter; OneChicago Letter; ABN AMRO Letter; Rolfe and Nolan Letter; and Managed Funds Letter.

[30] *See* SIA/FIA Letter at 2; Morgan Stanley Letter at 3; OneChicago Letter at 7–8; NFA Letter at 4–5; and Nasdaq Liffe Letter at 4.

[31] CME/CBOT Letter at 5.

[32] SunGard Letter at 2.

[33] *Id.*

[34] Nasdaq Liffe Letter at 5–6.

[35] *Id.*

[36] Options Exchanges Letter at 4.

[37] SIA/FIA Letter at 11. This commenter also recommended that the Commissions permit FCMs to use the Standard Portfolio Analysis of Risk (''SPAN'') system for establishing the initial and maintenance margin requirements for security futures maintained in a futures account as long as the resulting margin levels are consistent with the margin requirements for security futures held in a securities account. *Id.* at 12.

[38] *See* SIA Credit Division Letter at 2; Morgan Stanley Letter at 4.

[39] The CFTC also has approved SPAN margining for all options on futures contracts.

[40] *See* Securities Exchange Act Release No. 28928 (March 1, 1991), 56 FR 9995 (March 8, 1991); Securities Exchange Act Release No. 23167 (April 22, 1986), 51 FR 16127 (April 30, 1986).

[41] To date, the Commissions have approved cross-margining programs between The OCC and the following futures clearing organizations: The Intermarket Clearing Corporation (1988); Chicago Mercantile Exchange (''CME'') (1989); Board of Trade Clearing Corporation (''BOTCC'') (1991); Kansas City Board of Trade Clearing Corporation (1992); and Comex Clearing Association (1992). The Commissions also have approved cross-margining programs between the Government Securities Clearing Corporation and the following futures clearing organizations: the New York Clearing Corporation (1999); BOTCC (2001); and CME (2001).

[42] *See supra* note 16 and accompanying text.

[43] 15 U.S.C. 78g(c)(2)(B)(iii).

[44] *See* CME/CBOT Letter at 5; SIA/FIA Letter at 12–13 and Appendix I, Q 15; OCC Letter.

[45] In its delegation letter, the Federal Reserve Board requested that ''the Commissions provide an assessment of progress toward adopting more risk-sensitive, portfolio-based approaches to margining security futures products.'' The Federal Reserve Board further stated that ''[t]he Board has encouraged the development of such approaches by, for example, amending its Regulation T so that portfolio margining systems approved by the [SEC] can be used in lieu of the strategy-based system embodied in the Board's regulation. The Board anticipates that the creation of security future products will provide another opportunity to develop more risk-sensitive, portfolio based approaches for all securities, including security options and security futures products.'' FRB Letter at 2.

2. Financial Relations Between a Security Futures Intermediary and a Foreign Person

The Proposed Rules provided an exclusion from the margin requirements for financial relations between a foreign branch of a creditor and a foreign person involving foreign security futures.[46] This exclusion was intended to be consistent with the way Regulation T treats financial relations between a foreign branch of a creditor and a foreign person involving foreign securities.[47] The Commissions are adopting this exclusion with two modifications.[48]

First, in response to concerns raised by a commenter,[49] the scope of the exclusion is being expanded so that it applies to the U.S. offices as well as foreign branch offices of a security futures intermediary. This commenter expressed the view that the exclusion, as proposed, would create a competitive disadvantage for U.S. firms whose existing foreign futures customers would likely migrate to foreign offices or competing foreign firms to obtain the margin levels available on the foreign exchange. After considering the commenter's view, the Commissions have concluded that expanding the exclusion is appropriate and, in light of the potential competitive issues, is not inconsistent with Regulation T.

The second modification clarifies the scope of this exclusion. Because the Proposed Rules did not define the term ''foreign security future,'' the Final Rules provide that the exclusion applies to financial relations between a security futures intermediary and a foreign person involving ''security futures traded on or subject to the rules of a foreign board of trade.'' Thus, the exclusion applies regardless of whether the underlying security is issued in the United States or a foreign country.[50]

3. Margin Requirements Imposed by Clearing Agencies or Derivatives Clearing Organizations

The Proposed Rules provided an exclusion from the margin requirements for margin collected by registered clearing agencies from their members.[51] The Commissions received no comments relating to this provision. The text of the proposed exclusion has been revised to specify that the Final Rules exclude clearing agencies registered under section 17A of the Exchange Act and derivatives clearing organizations registered under Section 5b of the CEA.[52] These textual changes do not affect the meaning of the provision and, therefore, the Commissions have effectively adopted the provision as proposed.

Section 7(c)(2) of the Exchange Act directs the Federal Reserve Board to prescribe rules regarding customer margin for security futures products, but it does not confer authority over margin requirements for clearing agencies and derivatives clearing organizations. Accordingly, the Federal Reserve Board stated in its delegation letter that ''[t]he authority delegated by the Board is limited to customer margin requirements imposed by brokers, dealers, and members of national securities exchanges. It does not cover margin requirements imposed by clearing agencies on their members.'' The margin rules of clearing agencies registered with the SEC are approved by the SEC pursuant to section 19(b)(2) of the Exchange Act.[53] The CFTC has authority to ensure compliance with core principles for derivatives clearing organizations registered with the CFTC under Sections 5b and 5c of the CEA.[54] This exclusion clarifies that margin requirements that clearing agencies registered with the SEC or derivatives clearing organizations registered with the CFTC impose on their members are not subject to the Final Rules.

4. Financial Relations Between Security Futures Intermediaries and Broker-Dealers, and Certain Members of National Securities Exchanges

a. *Financial Relations with an Exempted Person.* The Proposed Rules provided an exclusion from the margin requirements for credit arrangements between a creditor and a borrower that is a member of a national securities exchange or is a registered broker-dealer (including an FCM registered as a broker-dealer under section 15(b)(11) of the Exchange Act) if the creditor made a good faith determination that the borrower was an ''exempted borrower'' under Regulation T.[55] The Regulation T criteria for an ''exempted borrower'' establish standards for the exception from federal margin regulation for exchange members and registered brokers and dealers, a substantial portion of whose business consists of transactions with persons other than brokers or dealers.[56] In addition, the Proposed Rules provided that a person that ceased to qualify for the exempted borrower exclusion would be required to notify the creditor of this fact before establishing any new security futures positions.[57] Any security futures positions subsequently established by that person would be subject to the Commissions' customer margin requirements.

One commenter addressed the exclusion, asserting that an FCM or floor broker whose only securities business consists of trading security futures would not likely qualify as an exempted borrower under Regulation T.[58] The commenter asked the Commissions to clarify that the scope of the exclusion includes FCMs or floor brokers that do not have a substantial securities or security futures business, as long as they have a substantial customer futures business.

After considering the commenter's view, the Commissions have adopted the exclusion with several modifications to clarify the application of the exclusion.[59] As a preliminary matter, the Commissions are replacing the term ''exempted borrower'' with the new term, ''exempted person,'' to avoid characterizing the collection of margin for a security futures contract as involving an extension of credit.

Consequently, the Commissions are also adding to the Final Rules a definition of ''exempted person.'' The Commissions believe that the definition of exempted person is consistent with

[46] *See* Proposed CFTC Rule 41.43(b)(3)(ii); Proposed SEC Rule 400(b)(3)(ii).

[47] *See* 12 CFR 220.1(b)(3)(iv).

[48] *See* CFTC Rule 41.42(c)(2)(ii); SEC Rule 400(c)(2)(ii).

[49] Meeting between SEC and CFTC staff and representatives of SIA/FIA (February 6, 2000).

[50] This exclusion does not address the application of Section 6(h)(1) of the Exchange Act (15 U.S.C. 78f(h)(1)) to transactions in security futures that are traded on or subject to the rules of a foreign board of trade.

[51] *See* Proposed CFTC Rule 41.43(b)(3)(iii); Proposed SEC Rule 400(b)(3)(iii).

[52] *See* CFTC Rule 41.42(c)(2)(iii); SEC Rule 400(c)(2)(iii).

[53] 15 U.S.C. 78s(b)(2).

[54] 7 U.S.C. 7a–1; 7 U.S.C. 7a–2.

[55] *See* Proposed CFTC Rule 41.43(b)(3)(iv)(A); Proposed SEC Rule 400(b)(3)(iv)(A).

[56] The term ''exempted borrower'' is defined in Section 220.2 of Regulation T as a member of a national securities exchange or a registered broker or dealer, a substantial portion of whose business consists of transactions with persons other than brokers or dealers, and includes a borrower who: (1) Maintains at least 1,000 active accounts on an annual basis for persons other than brokers, dealers, and persons associated with a broker or dealer; (2) earns at least $10 million in gross revenues on an annual basis from transactions with persons other than brokers, dealers, and persons associated with a broker or dealer; or (3) earns at least 10% of its gross revenues on an annual basis from transactions with persons other than brokers, dealers, and persons associated with a broker or dealer. 12 CFR 220.2. section 7(c)(3)(A) of the Exchange Act (15 U.S.C. 78g(c)(3)(A)) provides an exception from federal margin regulation for members of national securities exchanges and registered broker-dealers, ''a substantial portion of whose business consists of transactions with persons other than brokers or dealers.''

[57] *See* Proposed CFTC Rule 41.45(e); Proposed SEC Rule 402(e).

[58] OneChicago Letter at 8–9.

[59] *See* CFTC Rule 41.42(c)(2)(iv); SEC Rule 400(c)(2)(iv).

the definition of exempted borrower in Regulation T. More specifically, the Final Rules define an exempted person as a member of a national securities exchange, a registered broker or dealer, or a registered futures commission merchant, a substantial portion of whose business consists of transactions in securities, commodity futures, or commodity options with persons other than brokers, dealers, futures commission merchants, floor brokers, or floor traders, including a person who:

- Maintains at least 1000 active accounts on an annual basis for persons other than brokers, dealers, persons associated with a broker or dealer, futures commission merchants, floor brokers, floor traders, and persons affiliated with a futures commission merchant, floor broker, or floor trader that are effecting transactions in securities, commodity futures, or commodity options;
- Earns at least $10 million in gross revenues on an annual basis from transactions in securities, commodity futures, or commodity options with persons other than brokers, dealers, persons associated with a broker or dealer, futures commission merchants, floor brokers, floor traders, and persons affiliated with a futures commission merchant, floor broker, or floor trader; or
- Earns at least 10 percent of its gross revenues on an annual basis from transactions in securities, commodity futures, or commodity options with persons other than brokers, dealers, persons associated with a broker or dealer, futures commission merchants, floor brokers, floor traders, and persons affiliated with a futures commission merchant, floor broker, or floor trader.[60]

Although the commenter recommended that floor brokers as well as FCMs be permitted to qualify as exempted borrowers, the Commissions have not included floor brokers in the definition of exempted person. This is because the exemption cannot readily be applied to floor brokers given that they do not carry the type of customer accounts contemplated by the Regulation T exempted borrower provision. The Commissions note that, although floor brokers are not included in the definition of exempted person, they may still qualify for an exclusion from the security futures margin requirements if they meet the criteria for a market maker under the Final Rules, as discussed below.[61]

The Final Rules also set forth an express definition of ''persons affiliated with'' a futures commission merchant, floor broker, or floor trader,[62] which parallels the definition in the Exchange Act of ''person associated with a broker or dealer.'' [63] The purpose of this definition is to establish consistency with the Regulation T definition of exempted borrower, which excludes transactions with ''persons associated with a broker or dealer,'' as that term is defined in section 3(a)(18) of the Exchange Act.[64] The phrase ''persons affiliated with'' has been used in the definition with respect to transactions with FCMs, floor brokers and floor traders, and the phrase ''persons associated with'' has been used with respect to transactions with brokers and dealers. This is not intended to create a substantive difference in the provisions applicable to the securities and futures industries. Rather, it is intended to avoid confusion insofar as the CFTC's definition of ''affiliated person'' (which includes corporate affiliates) [65] more closely matches the Exchange Act definition of ''persons associated with a broker or dealer,'' than does the CFTC definition of ''associated person,'' which is a registration category.[66]

The Final Rules clarify that a person may qualify as an exempted person based on transactions in commodity futures and commodity options, as well as securities. For purposes of the ''1000 active accounts'' threshold, an FCM or broker or dealer that clears a bona fide customer omnibus account for another FCM or broker or dealer may treat that account as a single customer account. For purposes of the $10 million and 10% thresholds, the gross revenues from transactions for bona fide customer omnibus accounts may be included in the computation. An omnibus account will not be considered a bona fide customer account if it is used to clear transactions for market professionals that would otherwise be excluded from the exempted person computation. A fully disclosed customer account will be considered a single customer account of the clearing firm, as well as the introducing firm.

The exempted person provision further states that a member of a national securities exchange or a registered broker, dealer, or futures commission merchant that has been in existence for less than one year may meet the definition of exempted person based on a six-month period.[67] This incorporates the standard set forth in Regulation T.[68]

In response to one commenter's suggestion,[69] the Commissions are also defining the term ''good faith,'' consistent with the definition of that term in Regulation T,[70] for the purposes of determining what steps a security futures intermediary must take to assure itself that a person is an exempted person.[71] The Final Rules further provide that a person who ceases to qualify as an exempted person must notify the security futures intermediary of that fact, and become subject to the provisions of the Final Rules, but only before entering into any new security futures transaction or related transaction that would require additional margin to be deposited.[72] This would permit a person to enter into new offsetting transactions that reduce the required margin in an account without triggering higher margin requirements.

b. *Margin Arrangements with a Borrower Otherwise Excluded Pursuant to section 7(c)(3) of the Exchange Act.* The Proposed Rules included an exclusion for credit extended, maintained, or arranged by a creditor to or for a registered broker-dealer, or member of a national securities exchange (including an FCM registered as a broker-dealer under section 15(b)(11) of the Exchange Act) that is otherwise excluded under section 7(c)(3) of the Exchange Act.[73] The Commissions have decided not to adopt this exclusion.

Under section 7(c)(3)(B) of the Exchange Act,[74] the financing of the market making or underwriting activities of a member of a national securities exchange or a registered broker-dealer is excluded from the scope of federal margin regulation. The Federal Reserve Board has expressed the view that floor traders on open-outcry futures exchanges act as market makers and therefore would be excluded from the margin requirements for security futures pursuant to Section 7(c)(3)(B).[75]

[60] *See* CFTC Rule 41.43(a)(9); SEC Rule 401(a)(9).

[61] *See* CFTC Rule 41.42(c)(2)(v); SEC Rule 400(c)(2)(v).

[62] *See* CFTC Rule 41.43(a)(9)(ii); SEC Rule 401(a)(9)(ii).

[63] *See* CFTC Rule 41.43(a)(23); SEC Rule 401(a)(23).

[64] 15 U.S.C. 78c(a)(18).

[65] *See* 17 CFR 155.1; Section 4f(c)(1)(i) of the CEA, 7 U.S.C. 6f(c)(1)(i).

[66] *See* 17 CFR 1.3(aa).

[67] *See* CFTC Rule 41.43(a)(9)(iii); SEC Rule 401(a)(9)(iii).

[68] *See* 12 CFR 220.3(j)(1).

[69] Meeting between SEC and CFTC staff and representatives of SIA/FIA (February 6, 2002).

[70] *See* 12 CFR 220.2.

[71] *See* CFTC Rule 41.43(a)(15); SEC Rule 401(a)(15).

[72] *See* CFTC Rule 41.44(f); SEC Rule 402(f).

[73] *See* Proposed CFTC Rule 41.43(b)(3)(iv)(B); Proposed SEC Rule 400(b)(3)(iv)(B).

[74] 15 U.S.C. 78g(c)(3)(B).

[75] In its delegation letter, the Federal Reserve Board stated that ''[i]n the current open-outcry

Continued

The proposed exclusion was intended to codify this view.

One commenter addressed this exclusion and maintained that the exclusion was confusing because the Commissions did not provide any guidance as to the factors under which a broker-dealer would qualify for the exclusion.[76] The commenter asked the Commissions to clarify the circumstances under which a floor trader on an open outcry exchange qualifies for the market maker exclusion.

The Commissions have not adopted the proposed exclusion. As noted above, the Federal Reserve Board has taken the position that floor traders on open-outcry futures exchanges qualify for the statutory market maker exception. However, any further interpretation of section 7(c)(3) of the Exchange Act is within the purview of the Federal Reserve Board. As a result, the Commissions would not be able to provide specific guidance as requested by the commenter as to the circumstances under which Section 7(c)(3) applies to floor traders on an open-outcry futures exchange. The Commissions emphasize that any person excluded from federal margin regulation under section 7(c)(3) of the Exchange Act is not subject to the rules adopted by the Commissions today. The Commissions encourage market participants to seek interpretive guidance from the Federal Reserve Board regarding the circumstances in which the exception under section 7(c)(3) of the Exchange Act applies.

c. *Financial Relations between a Security Futures Intermediary and a Member of a National Securities Exchange or Association in Connection with Market Making Activities.* The Commissions proposed to exclude from the scope of the margin requirements credit extended, maintained, or arranged to or for members of a national securities exchange or a national securities association in connection with market making activities.[77] As proposed, the exclusion had two conditions. First, the borrower could not directly or indirectly accept or solicit customer orders or provide advice to any customer in connection with the trading of security futures. Second, the borrower had to be registered with the exchange or association as a security futures dealer, pursuant to regulatory authority rules that require the borrower: (a) To be registered as a floor trader or floor broker with the CFTC, or as a dealer with the SEC; (b) to comply with applicable SEC or CFTC net capital requirements; (c) to maintain records sufficient to demonstrate compliance with the exclusion and the rules of the exchange or association; (d) to hold itself out as willing to buy and sell security futures for its own account on a regular or continuous basis; and (e) to be subject to disciplinary action if it failed to comply with the Commissions' margin rules or the rules of the exchange or association.[78] The Commissions are adopting this exclusion with modifications in light of commenters' views.[79]

The Commissions received four comments on the exclusion.[80] These comments generally supported the proposed exclusion, but suggested that the Commissions clarify certain aspects of the conditions.

One commenter expressed the view that a person is a market maker in security futures if it provides liquidity on a regular basis, even if it is not under an affirmative obligation to do so.[81] Based on that view, the commenter suggested two alternatives to the Commissions' proposal to determine whether a trader is a liquidity provider. First, the commenter recommended that the Commissions consider a person to be a liquidity provider solely because that person is registered with either the SEC or the CFTC as a trading professional (*e.g.,* as a broker-dealer or FCM) and is a member of an exchange. In the alternative, the commenter recommended that the Commissions consider a trader to be a liquidity provider if that person can demonstrate through its business activity that it is a professional liquidity provider, regardless of its regulatory status or membership in an exchange.[82] This commenter further stated that the net capital requirements for persons acting as market makers in security futures should be uniform in order to prevent security futures market makers subject to CFTC financial responsibility rules from obtaining an unfair competitive advantage over security futures market makers (or security options market makers) subject to SEC financial responsibility rules.[83]

Another commenter asked the Commissions to modify the condition to the exclusion for exchange members that requires that the member ''hold itself out as being willing to buy and sell security futures for its own account on a regular or continuous basis.'' [84] The commenter maintained that market makers on a screen-based trading system either should have an enforceable obligation to provide liquidity or should meet an objective standard for supplying liquidity.[85] Specifically, the commenter suggested that the condition be narrowed further with respect to members of screen-based trading systems so that it would apply only to members of such systems that: (1) have a continuous, affirmative obligation to quote a two-sided market; or (2) effect more than two-thirds of their security futures trades on that exchange with persons other than registered market makers on that exchange.[86]

A third commenter asked the Commissions to eliminate the condition to the exclusion for exchange members that requires that the member not ''directly or indirectly accept or solicit orders from any customer or provide advice to any customer in connection with the trading of security futures.'' [87] The commenter maintained that a broker-dealer acting as a market maker should not be precluded from also carrying out a customer securities business.

The fourth commenter asked the Commissions to confirm that registered floor brokers and floor traders would qualify for the exclusion even if they are not subject to a net capital requirement under CFTC rules.[88] In support of this request, the commenter stated that market makers in options are exempt from the SEC's net capital rule.[89]

After considering the commenters' views, the Commissions have adopted the exclusion with certain modifications. First, the Commissions are clarifying that the provision relating

environment, the Board believes that floor traders act as market makers and therefore would be exempt [under section 7(c)(3) of the Exchange Act].'' FRB Letter at 2.

[76] CBOE Letter.

[77] *See* Proposed CFTC Rule 41.43(b)(3)(iv)(C); Proposed SEC Rule 400(b)(3)(iv)(C).

[78] *Id.*

[79] *See* CFTC Rule 41.42(c)(2)(v); SEC Rule 400(c)(2)(v). The Commissions note that the Final Rules include a definition of the term ''member,'' which clarifies the applicability of that term to persons with trading privileges on an exchange, even if that exchange does not have a ''membership'' structure. More specifically, the term ''member'' has the meaning provided in section 3(a)(3) of the Exchange Act and includes persons registered under section 15(b)(11) of the Exchange Act that are permitted to effect transactions on a national securities exchange without the services of another person acting as executing broker. *See* CFTC Rule 41.43(a)(21); SEC Rule 401(a)(21).

[80] *See* Amex Letter; CBOE Letter; OneChicago Letter; SIA/FIA Letter. In addition, the ABN AMRO Letter endorsed the comments in the SIA/FIA Letter.

[81] CBOE Letter at 2–3.

[82] *Id.* at 4.

[83] *Id.* at 5–6.

[84] Amex Letter.

[85] *Id.* at 2, 4.

[86] *Id.* at 4.

[87] SIA/FIA Letter at 14, n.25; Appendix I, Q 17(a).

[88] OneChicago Letter at 9.

[89] *Id.*

to accepting or soliciting customer orders was not intended to bar a member from engaging in such activities. That provision was intended to limit the exclusion from the margin requirements to circumstances where the member was trading for its own account, not for the account of others. Accordingly, the rule has been modified to make clear that the exclusion is available to a member only with respect to trading activity for its own account.[90] Thus, the member may conduct a customer business and still qualify for the exclusion from the Commissions' margin requirements for security futures with regard to its market making activity.

The Commissions have also decided that it is unnecessary to restate the applicability of existing net capital requirements under CFTC and SEC rules, or to impose additional net capital requirements, as a condition of the exclusion for persons acting as market makers. Firms will continue to be subject to applicable CFTC or SEC net capital requirements. Further, even if a member is not subject to net capital requirements, the member's carrying firm will be subject to the treatment provided in existing SEC or CFTC net capital rules, whichever are applicable, with respect to the member's security futures transactions.

As noted above, the Commissions received several comments regarding the circumstances under which an exchange member should be considered a market maker for purposes of the margin rules, other than in circumstances that fall within the exception in Section 7(c)(3) of the Exchange Act. These comments largely refer to the requirement that the exchange member ''hold itself out as being willing to buy and sell security futures for its own account on a regular or continuous basis' in order to qualify for the exclusion. The Commissions do not believe that registration with the SEC or CFTC is, by itself, sufficient to show that a market participant is holding itself out as willing to buy and sell security futures. However, the Commissions believe that there are a number of different ways that an exchange member could satisfy this condition. For example, an exchange's or association's rules could require the member to effect a certain percentage of its security futures trades on that exchange or association with persons other than registered market makers on that exchange or association.[91]

Alternatively, such rules could require that a large majority of such exchange member's revenue is derived from business activities or occupations from trading listed financial-based derivatives (*i.e.,* security futures, stock index futures, stock and index options, foreign currency futures and options, and interest rate futures and options) on any exchange in the capacity of a member. As another alternative, the exchange member could be subject to rules that impose on it an affirmative obligation to quote on a regular or continuous basis in security futures.

*C. Interpretations of, and Exemptions From, the Final Rules*

The Commissions are adopting two provisions in the Final Rules to clarify the Commissions' authority to respond to issues that arise in connection with the implementation of the Final Rules. First, the Commissions are adding a provision regarding the interpretation of the security futures margin rules. The Final Rules provide that the Commissions shall jointly interpret the margin rules, consistent with the criteria set forth in clauses (i) through (iv) of section 7(c)(2)(B) of the Exchange Act and Regulation T.[92]

Second, the Final Rules add a provision providing that each Commission may issue an exemption from any provision of the Final Rules.[93] CFTC Rule 41.42(d) provides that the CFTC may grant an exemption with respect to any provision of CFTC Rules 41.42 through 41.49, provided that the CFTC finds that the exemption is consistent with the public interest and the protection of customers. Similarly, SEC Rule 400(d) provides that the SEC may grant an exemption with respect to any provision of SEC Rules 400 through 406, provided that the exemption is necessary or appropriate in the public interest and consistent with the protection of investors. Because financial relations involving security futures are subject to the Final Rules as adopted by both the CFTC and the SEC, any person seeking an exemption under these rules must request and obtain the same exemption from both the CFTC and SEC. The Commissions intend to work together on exemption requests to establish uniform policies for security futures trading.

*D. Definitions*

The definition section of the Proposed Rules has been expanded to include all applicable defined terms. Under the Proposed Rules, many of these definitions and provisions would have been incorporated through the application of Regulation T.

The terms ''contract multiplier,'' ''daily settlement price,'' and ''Regulation T'' are defined in the Final Rules as proposed.[94] The Proposed Rules defined the terms ''examining authority,'' ''initial margin,'' and ''maintenance margin.''[95] These terms are not, however, included in the Final Rules because modifications made to the Proposed Rules make them unnecessary. The Final Rules also define the term ''self-regulatory authority,''[96] instead of the term ''regulatory authority'' as proposed,[97] and its definition has been revised to include a reference to registration under the CEA. In addition, the Final Rules define the term ''current market value'' with respect to a security other than a security future consistently with the Regulation T definition.[98] Some of the defined terms incorporate by reference definitions from the CEA, the Exchange Act, or CFTC or SEC rules.[99]

[90] *See* CFTC Rule 41.42(c)(2)(v); SEC Rule 400(c)(2)(v).

[91] National securities exchanges registered under section 6(a) of the Exchange Act require their options market makers to conduct at least 50% of their total contract volume in option classes to which they have been appointed. *See* Amex Rule 958; Philadelphia Stock Exchange (''Phlx'') Rule 1014. In some cases, market makers are required to conduct at least 75 percent of their total contract volume in option classes to which they have been appointed. *See* CBOE Rule 8.7.03; International Securities Exchange Rule 805; Pacific Exchange (''PCX'') Rule 6.37.

[92] *See* CFTC Rule 41.42(b); SEC Rule 400(b).

[93] *See* CFTC Rule 41.42(d); SEC Rule 400(d). The SEC and CFTC exemption standards contained in the Final Rules are the same as those set forth in the recently adopted rules relating to cash settlement and regulatory halt requirements for security futures products. *See* Securities Exchange Act Release No. 45956 (May 17, 2002), 67 FR 36740 (May 24, 2002). As noted in connection with those rules, the SEC version of the exemption provision refers to the protection of ''investors,'' and the CFTC version of the provision refers to the protection of ''customers.'' *Id.* at 36745, n.64. The difference in terminology is not intended to have any substantive significance. Rather, the terms are used for purposes of conformity with terminology used in the Exchange Act and CEA.

[94] *See* CFTC Rules 41.43(a)(3), (a)(6), and (a)(24); SEC Rules 401(a)(3), (a)(6), and (a)(24).

[95] *See* Proposed CFTC Rules 41.44(a)(3), (a)(4), and (a)(5); Proposed SEC Rules 401(a)(3), (a)(4), and (a)(5).

[96] *See* CFTC Rule 41.43(a)(30); SEC Rule 401(a)(30). The terminology was modified to eliminate confusion as to a ''regulatory authority'' being a governmental regulator rather than an SRO.

[97] *See* Proposed CFTC Rule 41.44(a)(7); Proposed SEC Rule 401(a)(7).

[98] *See* CFTC Rule 41.43(a)(4); SEC Rule 401(a)(4); see also 12 CFR 220.2.

[99] *See, e.g.,* definitions of ''broker,'' CFTC Rule 41.43(a)(2) and SEC Rule 401(a)(2); ''dealer,'' CFTC Rule 41.43(a)(7) and SEC Rule 401(a)(7); ''exempted security,'' CFTC Rule 41.43(a)(10) and SEC Rule 401(a)(10); ''futures account,'' CFTC Rule 41.43(a)(13) and SEC Rule 401(a)(13); ''futures

Continued

Terms that are not otherwise defined in the definition section of the Final Rules will have the meaning set forth in the margin rules applicable to the account.[100] Terms that are neither defined in the definition section nor in the margin rules applicable to the account will have the meaning set forth in the Exchange Act and the CEA.[101] If the definitions of a term in the Exchange Act and the CEA are inconsistent as applied in particular circumstances, such term shall have the meaning set forth in rules, regulations, or interpretations jointly promulgated by the SEC and the CFTC.

*E. Application of Regulation T to Security Futures*

Section 7(c)(2)(B)(iv) of the Exchange Act requires that the margin requirements for security futures (other than levels of margin), including the type, form, and use of collateral, must be consistent with the requirements of Regulation T.[102] To carry out that statutory mandate, the Commissions proposed that Regulation T would apply to all transactions in security futures, to the extent consistent with the Proposed Rules. Thus, under the Proposed Rules, Regulation T would have applied both to securities accounts (which are already subject to Regulation T) and to futures accounts (which are not otherwise subject to Regulation T) that carry security futures.[103] This approach also would have applied existing and future Federal Reserve Board interpretations of Regulation T to the margin requirements for security futures and kept the margin requirements consistent with Regulation T without the need for amendments to the Final Rules.

The Commissions, however, also recognized that there could be more than one approach to prescribing rules that are ''consistent'' with Regulation T. Accordingly, the Commissions specifically requested commenters' views on alternative approaches to establishing consistency with Regulation T. In particular, the Commissions solicited comment on the approach of issuing comprehensive ''stand-alone'' margin rules that would parallel Regulation T requirements for securities to the extent that such requirements are relevant to security futures. Under that approach, the stand-alone rules would apply to security futures and any related securities or futures contracts that are used to offset positions in such security futures. However, the stand-alone rules would not apply to any other securities or futures transactions.

The Commissions received a total of 12 comment letters on the application of Regulation T to security futures transactions.[104] One commenter supported the Commissions' proposed approach regarding Regulation T.[105] Nine commenters opposed general application of Regulation T to security futures carried in futures accounts,[106] and two other commenters specifically opposed applying the Regulation T account structure to FCMs.[107]

The commenter that supported application of Regulation T to all security futures transactions believed that the alternative approach of stand-alone rules would not satisfy the statutory requirement that the margin requirements for security futures (other than levels of margin) be ''consistent'' with those imposed on securities.[108] The commenter expressed the view that the term ''consistent'' should mean that there is no appreciable difference between rules applicable to exchange-traded options and rules applicable to security futures. In addition, the commenter noted that if the Commissions adopt stand-alone margin rules there is a risk that over time such rules will vary materially from Regulation T because of the difficulty of promptly incorporating the Federal Reserve Board's future interpretations of Regulation T into stand-alone rules.

Commenters opposing the general application of Regulation T to security futures did not believe that the CFMA required such application. One commenter contended that application of Regulation T to futures accounts ''is impractical and unnecessary'' and ''not required,'' and that the CFMA's ''consistent'' standard did not necessarily require rules ''identical'' or ''equivalent'' to the rules applicable to exchange-traded options.[109] Rather, this commenter argued, Regulation T permits commodity futures to be recorded in an account other than a margin account (a ''good faith'' account) and, as a result, permitting security futures to be carried in a futures account (not a margin account) is ''consistent'' with Regulation T.[110] Another commenter observed that while ''consistency requires reasonable comparability * * * [, i]f Congress had meant 'consistent' to mean 'identical,' however, it would have used that word'' or would have clearly directed that Regulation T be applied to security futures.[111] Similarly, another commenter pointed out that ''the CFMA did not mandate the application of Reg[ulation] T to security futures maintained in a futures account'' and that the ''imposition of Reg[ulation] T with respect to security futures is inconsistent with Congress's goal of facilitating trading in security futures.'' [112]

Commenters that disagreed with the Commissions' proposed approach generally urged the Commissions to adopt ''stand-alone'' margin rules for security futures.[113] All of these commenters maintained that the programming changes necessary to enable FCMs to comply with Regulation T would be overly costly.[114] Generally, those commenters believed that it would be operationally difficult or impossible to carry security futures in a standard futures account without costly and time-consuming reprogramming.[115] Commenters were concerned that this would place FCMs at a considerable disadvantage in comparison to broker-dealers and would discourage them from trading security futures. One commenter pointed out that a broker-dealer ''would need to do little, relative to an FCM, to bring itself into compliance with the Proposed Rules.'' [116] Another commenter expressed concern that FCMs would have to undertake a substantial development project requiring 'the

commission merchant,'' CFTC Rule 41.43(a)(14) and SEC Rule 401(a)(14); and ''securities account,'' CFTC Rule 41.43(a)(28) and SEC Rule 401(a)(28).

[100] *See* CFTC Rule 41.43(b); SEC Rule 401(b). *See also infra* notes 125–126 and accompanying text.

[101] *See* CFTC Rule 41.43(c); SEC Rule 401(c).

[102] 15 U.S.C. 78g(c)(2)(B)(iv).

[103] *See* Proposed CFTC Rule 41.43(b)(1); Proposed SEC Rule 400(b)(1).

[104] *See* NFA Letter; SIA/FIA Letter; Nasdaq Liffe Letter; ABN AMRO Letter; CME/CBOT Letter; OneChicago Letter; Morgan Stanley Letter; Peregrine Letter; SunGard Letter; Options Exchanges Letter; Managed Funds Letter; and Rolfe and Nolan Letter.

[105] Options Exchanges Letter at 3.

[106] NFA Letter at 2–3; SIA/FIA Letter at 2, 4–7; ABN AMRO Letter at 1; CME/CBOT Letter at 2–3; OneChicago Letter at 3–7; Morgan Stanley Letter at 2, 5–6; Peregrine Letter at 2; Managed Funds Letter at 1; and Rolfe and Nolan Letter at 1–2.

[107] Nasdaq Liffe Letter at 6–7; and SunGard Letter at 2–3.

[108] Options Exchanges Letter at 3.

[109] OneChicago Letter at 3.

[110] *Id.* at 3–4.

[111] NFA Letter at 2.

[112] SIA/FIA Letter at 5.

[113] *See* NFA Letter at 2; SIA/FIA Letter at 5; Nasdaq Liffe Letter at 7; ABN AMRO Letter at 1; CME/CBOT Letter at 10; OneChicago Letter at 7; SunGard Letter at 3; and Peregrine Letter at 2.

[114] *See* NFA Letter at 3; SIA/FIA Letter at 4; Nasdaq Liffe Letter at 6; ABN AMRO Letter at 1; CME/CBOT Letter at 3; OneChicago Letter at 5; SunGard Letter at 1; and Peregrine Letter at 2.

[115] *See* NFA Letter at 2; SIA/FIA Letter at 4–5; Nasdaq Liffe Letter at 6; ABN AMRO Letter at 1; CME/CBOT Letter at 3; OneChicago Letter at 4; SunGard Letter at 1; Peregrine Letter at 2.

[116] OneChicago Letter at 5.

restructuring of FCMs' accounts and related systems changes.'' [117] The commenter estimated that this would result in the expenditure of ''several thousands of personnel hours,'' [118] while another commenter believed that costs would ''run well into six figures.'' [119]

Eight commenters recommended the adoption of an account-specific margin regime for purposes of account administration.[120] The adoption of an account-specific margin regime was effectively endorsed by two other commenters that advocated retention of specific existing practices [121] and one other that believed the imposition of Regulation T on FCMs would be highly burdensome.[122] One commenter argued against the adoption of an account-specific margin regime, stating that FCMs will have to revise a number of their operating procedures and there is no compelling reason to make an exception for margin procedures.[123]

After considering the commenters' suggestions, the Commissions have determined that it is not necessary to apply Regulation T in its entirety to security futures transactions to satisfy the requirements under section 7(c)(2) of the Exchange Act.[124] Given the relative infrequency of the Federal Reserve Board adopting amendments to Regulation T and issuing formal regulatory guidance, the Commissions do not believe that it will be unduly burdensome or impractical to amend these rules to maintain consistency with Regulation T. Accordingly, the Commissions have adopted stand-alone margin rules that include certain requirements of Regulation T. The Commissions believe that the inclusion of these requirements in the Final Rules satisfies the statutory requirement that margin requirements for security futures be and remain consistent with Regulation T.

The Commissions believe that many of the rules governing margin for positions carried in securities accounts are similar enough to the rules governing margin for positions carried in futures accounts that the differences do not, by themselves, create an incentive for customers either to trade security futures instead of options, or to hold security futures in a futures account rather than a securities account. Accordingly, the Commissions are adopting an ''account-specific'' approach for those aspects of account administration that need not be conformed to satisfy the requirement that the margin rules for security futures be consistent with Regulation T. Thus, the Final Rules provide that security futures held in a securities account are subject to the Final Rules, Regulation T, and to the margin requirements of the self-regulatory authorities of which the security futures intermediary is a member.[125] Security futures held in a futures account, on the other hand, will be subject to the Final Rules and the margin requirements of the self-regulatory authorities of which the security futures intermediary is a member.[126]

Notwithstanding the Commissions' determination not to apply Regulation T in its entirety to security futures, the Final Rules include certain uniform provisions that govern account administration, type, form, and use of collateral, calculation of equity, withdrawals from accounts, and treatment of undermargined accounts. The Commissions believe that the inclusion of these provisions in the Final Rules satisfies the statutory requirement that the margin rules for security futures be consistent with Regulation T.

*F. Account Administration Rules*

1. Separation and Consolidation of Accounts

Regulation T establishes specific types of accounts for recording different types of customer transactions (*e.g.,* a margin account, a cash account, a good faith account).[127] Regulation T generally provides that a customer can have only one margin account.[128] While a margin account may be divided into separate parts for bookkeeping purposes, as authorized by the customer, all parts must be considered as one unit in determining whether or not any transaction is permissible under Regulation T.[129] The determination as to whether an account satisfies the requirements of Regulation T, moreover, may not take into consideration items in any other account; bookkeeping entries must be made whenever cash or securities in one account are used for purposes of meeting requirements in another account.[130] Consistent with Regulation T, the Final Rules provide that the margin requirements for one account may not be met by considering items in another account, except where excess margin is transferred using appropriate bookkeeping entries.[131] To facilitate the enforcement of this general prohibition, this provision also requires that if withdrawals of cash, securities, or other assets deposited as margin are permitted under the Final Rules, a security futures intermediary must make and keep accurate bookkeeping entries when those assets are used to meet requirements in another account.[132] This provision parallels Section 220.3(b)(1) of Regulation T, and is intended to be consistent with existing futures account practices under Section 4d of the CEA,[133] CFTC Rules 1.20 and 1.22, and applicable futures exchange rules.

Currently, futures exchange rules or practices similarly recognize accounts of different types for different customer transactions (*e.g.,* customer segregated, customer secured, nonsegregated). Customers may maintain multiple accounts of the same regulatory classification or account type, although futures exchange rules provide that identically owned accounts within the same regulatory classification or account type should be combined for margin purposes.[134] Moreover, an FCM may not apply free funds in an account under identical ownership but of a different regulatory classification or account type to an account's margin deficiency.[135] As is the case under Regulation T, however, the Final Rules require the FCM to actually document through bookkeeping entries the transfer of funds from one account to satisfy the margin deficiency in another account. The Commissions do not believe that this provision will create any substantial operational burdens for FCMs carrying security futures in futures accounts.

The Final Rules provide that all futures accounts of the same regulatory

[117] SIA/FIA Letter at 4.

[118] *Id.*

[119] Rolfe and Nolan Letter at 1.

[120] *See* NFA Letter at 1–2; SIA/FIA Letter at 3–4; Nasdaq Liffe Letter at 6–7; ABN AMRO Letter at 1; OneChicago Letter at 6–7; Peregrine Letter at 2; Morgan Stanley Letter at 1; and Managed Funds Letter at 2.

[121] *See* Rolfe and Nolan Letter at 2; and CME/CBOT Letter at 10.

[122] SunGard Letter at 2.

[123] Options Exchanges Letter at 3–4.

[124] 15. U.S.C. 78g(c)(2).

[125] *See* CFTC Rule 41.44(a)(1); SEC Rule 402(a)(1).

[126] *See* CFTC Rule 41.44(a)(2); SEC Rule 402(a)(2).

[127] *See* 12 CFR 220.4(a)(1).

[128] *See* 12 CFR 220.4(a)(2).

[129] Fed. Res. Reg. Serv. § 5–634.11 (Staff Op. May 15, 1978).

[130] *See* 12 CFR 220.3(b)(1).

[131] *See* CFTC Rule 41.44(b)(1); SEC Rule 402(b)(1).

[132] *See* CFTC Rule 41.44(b)(1); SEC Rule 402(b)(1); *see also* section 17(a) of the Exchange Act (15 U.S.C. 78q–1(a)), and the rules thereunder; Section 4g of the CEA (7 U.S.C. 6g), and the rules thereunder; National Association of Securities Dealers (''NASD'') Rule 3110; and NFA Rule 2–10.

[133] 7 U.S.C. 6d.

[134] *See* Joint Audit Committee Handbook, Chapter 9 (June 1999), available at <*http://www.nfa.futures.org/compliance/publications/Margins/MarginsHandbook.pdf*>.

[135] *See* id.

type or classification that carry security futures shall be considered a single account for purposes of the Regulation.[136] The Final Rules also permit a securities futures intermediary to further consolidate all futures accounts of the same regulatory classification or account type, regardless of whether they carry security futures, for purposes of determining whether the required margin for all of a customer's futures positions (including security futures) is satisfied.[137]

2. Accounts of Partners

The Final Rules provide that if a partner of a security futures intermediary (organized as a partnership) has an account with the security futures intermediary in which security futures or related positions are held, the security futures intermediary must disregard the partner's financial relations with the firm (as shown in the partner's capital and ordinary drawing accounts) in calculating the margin or equity of any such account.[138] This provision parallels Section 220.4(b)(5) of Regulation T,[139] and is consistent with current futures exchange practices. The provision is intended to reinforce the principle of ''separation of accounts'' with respect to partners in a security futures intermediary organized as a partnership, when a partner maintains a trading account with the firm.

3. Contribution to a Joint Venture

Under the Final Rules, if an account in which security futures or related positions are held is the account of a joint venture in which the security futures intermediary participates, any interest of the security futures intermediary in the joint account in excess of the interest which the security futures intermediary would have on the basis of its right to share in the profits must be margined in accordance with the Final Rules.[140] This provision parallels Section 220.4(b)(6) of Regulation T,[141] which is intended to prevent firms from indirectly extending credit to customers in circumstances where the customer does not deposit equity in the account corresponding to its share of the profits in the account (*e.g.,* if the customer is entitled to 90% of the profits in an account, but only deposits 40% of the equity at the outset, the broker-dealer is effectively extending credit to the customer in the amount of 50% of the equity in the account).

4. Extensions of Credit

The Final Rules prohibit any extension of credit with respect to security futures, if the extension of credit is designed to evade or circumvent the security futures margin requirements.[142] Among other things, this provision is intended to prevent security futures intermediaries from extending unsecured credit to customers, or extending credit secured by securities or other assets in excess of the value such assets would have under the Final Rules,[143] to satisfy or maintain the required margin for security futures carried in the customer's account.[144] For example, a security futures intermediary may not lend a customer $100 in cash secured by less than $200 in margin equity securities to meet a margin call for a security future. This provision does not, however, preclude a security futures intermediary from advancing funds to a customer to meet variation settlement calls on behalf of an undermargined customer account, in the ordinary course of business, provided that the security futures intermediary issues a margin call for the funds advanced.

The Final Rules permit a security futures intermediary to arrange for an extension of credit to or for a customer by a person, provided that the extension of credit would not constitute a violation of Regulations T, U, or X by such person.[145] In this connection, the Commissions believe that credit extended for the purpose of satisfying or maintaining the required margin for a security future is ''purpose credit'' for purposes of the Federal Reserve Board's credit regulations. For example, a security futures intermediary may not arrange for a Regulation T creditor to extend credit to a customer against securities or other assets in a nonpurpose or nonsecurities credit account to enable the customer to meet a margin requirement with respect to a security future. Likewise, a security futures intermediary may not arrange for a bank or other Regulation U lender to extend credit secured directly or indirectly by margin stock in excess of the maximum loan value of the collateral (*i.e.,* 50% of current market value) securing the credit for the purpose of purchasing or carrying a security future. Similarly, a security futures intermediary may not arrange for a Regulation X borrower to obtain an extension of credit within or from outside the United States for the purpose of effecting or carrying a security futures transaction unless the credit conforms to the Federal Reserve Board's margin regulations, as provided in Regulation X.

*G. Customer Margin Levels for Security Futures*

The Commissions proposed to require both the seller and the buyer of a security future to provide and maintain, on a daily basis, cash or other acceptable assets equal to a percentage of the ''current market value'' of the security future. The Commissions are adopting those requirements substantially as proposed.

1. Definition of Current Market Value

The Commissions proposed to define the term ''current market value'' of a security future as the product of the daily settlement price of the security future (as shown by any regularly published reporting or quotation service) and either the applicable number of shares per contract (when the underlying instrument is a single stock), or the applicable contract multiplier (when the underlying instrument is a narrow-based security index).[146] The Commissions also proposed to define the term ''current market value'' with respect to a narrow-based security index future to mean the product of the daily settlement price of such security future, as shown by any regularly published reporting or quotation service, and the applicable contract multiplier.[147]

The Commissions received one comment on these definitions, which suggested that the pricing convention for determining current market value need not be the same for security futures held in a security account and for

[136] *See* CFTC Rule 41.44(b)(2); SEC Rule 402(b)(2).

[137] *Id.*

[138] *See* CFTC Rule 41.44(c); SEC Rule 402(c).

[139] 12 CFR 220.4(b)(5).

[140] *See* CFTC Rule 41.44(d); SEC Rule 402(d).

[141] 12 CFR 220.4(b)(6).

[142] *See* CFTC Rule 41.44(e); SEC Rule 402(e). CFTC Rule 1.30 permits FCMs to lend their own funds to customers on pledged securities; the proceeds of such loans are treated as customer funds for purposes of the CEA. 17 CFR 1.30. Extensions of credit by brokers and dealers with respect to securities are governed by Regulation T and the margin rules of the national securities exchanges and securities associations.

[143] *See* CFTC Rule 41.46(c); SEC Rule 404(c).

[144] Futures exchange rules also impose certain restrictions on the financing of futures positions. *See, e.g.,* CME Rule 930.G (''Clearing members may not extend loans to account holders for performance bond purposes unless such loans are secured as defined in [17 CFR] 1.17(c)(3)''); New York Mercantile Exchange (''NYMEX'') Rule 4.03 (''Clearing Members shall not be permitted to make loans to any customers for the purpose of financing margins on NYMEX Division contracts unless such loans are secured, as such term is defined in [17 CFR] 1.17'').

[145] *See* CFTC Rule 41.44(e)(2); SEC Rule 402(e)(2).

[146] *See* Proposed CFTC Rule 41.44(a)(2)(i); Proposed SEC Rule 401(a)(2)(i).

[147] *See* Proposed CFTC Rule 41.44(a)(2)(ii); Proposed SEC Rule 401(a)(2)(ii).

security futures held in a futures account.[148] The Commissions, however, believe that a uniform definition of current market value is necessary to ensure that identical contracts are not subject to different margin requirements based on the type of account in which they are carried.

As noted above, section 7(c)(2)(B)(3)(I) of the Exchange Act [149] requires that the margin requirements for security futures be consistent with the margin requirements for comparable exchange-traded options. The Commissions believe that using the daily settlement price [150] at the end of each trading day to calculate margin requirements for security futures on that day is consistent with the use of the closing price of the option and the underlying security for determining maintenance margin for equity options.[151] In addition, the Commissions continue to believe that using the daily settlement price of a security future on the day of a transaction to calculate the initial margin (rather than the daily settlement price on the day preceding the transaction) is consistent with using the underlying stock's closing price on the preceding business day. The daily settlement price of a security future on the preceding business day, for example, may not exist if such security future were not available for trading on the preceding business day. Accordingly, the Commissions are adopting the definition of ''current market value'' as proposed.

2. Margin Levels for Unhedged Positions

The Commissions proposed that the minimum initial and maintenance margin levels required of customers for each security future carried in a long or short position be 20% of the current market value of such security future.[152] This proposed level was based on the requirement under section 7(c)(2) of the Exchange Act that the initial and maintenance margin levels for a security future not be lower than the lowest level of margin, exclusive of premium, required for any comparable option contracts traded on any exchange registered pursuant to section 6(a) of the Exchange Act.[153]

Twelve commenters commented on this aspect of the Proposed Rules.[154] Six commenters found 20% to be an acceptable level.[155] Two commenters advocated a 25% margin level,[156] and one commenter, joined by a second, stated that its members could not reach a consensus as between 20% and 25%.[157] One commenter expressed the view 20% could be either too high or low, and suggested that for certain positions, 50% initial margin would be appropriate.[158]

One commenter considered the 20% level to be consistent with the margin requirements for exchange-traded options, but ''more than adequate'' in terms of preserving the financial integrity of the market and preventing systemic risk.[159] Another commenter stated that it ''does not oppose'' the 20% level, but favors portfolio margining.[160]

One commenter said that its members were split between recommending 20% and 25%.[161] Those supporting the 20% level believed that it was consistent with the levels applicable to exchange-traded options and consistent with the intent of the CFMA. This margin level in combination with a T+1 settlement period and the fact that the Proposed Rules permit higher margin levels, made some members conclude that 20% is a prudent minimum level.[162] Other members thought that 20% is too low, failing to take into account the varying volatility/share price profiles of equity securities and the credit risk implications of those differences. Those members favored a 25% minimum, finding this to be ''consistent'' with margin levels for options.[163] They further noted that a comparable option position consists of a long (short) call/short (long) put option pair struck at the forward price of the underlying security.[164]

Finally, one commenter urged the Commissions to adopt a 25% margin level, citing historical data and stating that this level is consistent with the minimum margin level applied under SRO rules to long equity positions.[165] It argued that the 20% level would create an advantage for security futures as compared to listed option put/call pairs, noting margin levels in excess of 30% for combinations based on relatively high volatility stocks, and margin levels in excess of 20% for combinations based on relatively low volatility stocks.[166]

After considering the commenters' views, the Commissions have adopted the margin levels as proposed. The Commissions believe that a security future is comparable to a short, at-the-money option, as discussed in the release accompanying the Proposed Rules (''Proposing Release'').[167] Currently, the margin requirement for a short, at-the-money option, where the underlying instrument is either an equity security (such as a stock or an instrument immediately convertible into a stock) or an index, is 100% of the option proceeds plus 20% of the value of the underlying security or index.[168]

Unlike an options contract, however, a futures contract involves obligations of both parties to perform in the future: The buyer (long) to purchase the asset underlying the future, and the seller (short) to deliver the asset. As a result, both the buyer and the seller of a futures contract must post and maintain margin on a daily basis to assure contract performance and the integrity of the marketplace. In addition, all market participants pay or receive daily variation settlement as a result of all open futures positions being marked to current market value. Accordingly, the margin levels apply equally for both buyers and sellers of security futures.

The Commissions have considered the comments, and have determined that a minimum margin level of 20% satisfies the comparability standard of section 7(c)(2) of the Exchange Act.[169] In addition, the Commissions note that the Final Rules permit self-regulatory

[148] SIA/FIA Letter at Appendix I, Q 18.

[149] 15 U.S.C. 78g(c)(2)(B)(3)(I).

[150] Under the Final Rules, the term ''daily settlement price'' means, with respect to a security future, the settlement price of such security future determined at the close of trading each day, as determined by the rules of the applicable exchange, clearing agency or derivatives clearing organization. *See* CFTC Rule 41.43(a)(6); SEC Rule 401(a)(6).

[151] Currently, the computation of the margin required on the sale of an uncovered option is based on the value of the security underlying the option. The initial margin on the sale of an uncovered option is based on the price at which the underlying security closed at the end of the business day before the day on which the option is sold. The maintenance margin on an uncovered short option is based on the closing price of the underlying security at the end of each business day.

[152] *See* Proposed CFTC Rule 41.45(b); Proposed SEC Rule 402(b).

[153] 15 U.S.C. 78g(c)(2)(B)(iii)(II).

[154] *See* SIA Credit Division Letter; Morgan Stanley Letter; Drinkard Letter; Partnoy Letter; Klein Letter; SIA/FIA Letter; One Chicago Letter; NFA Letter; Peregrine Letter; Options Exchanges Letter; Nasdaq Liffe Letter; and Managed Funds Letter.

[155] *See* NFA Letter at 4; Nasdaq Liffe Letter at 5; Options Exchanges Letter at 5; OneChicago Letter at 2; Peregrine Letter at 2; Managed Funds Letter at 3.

[156] *See* Morgan Stanley Letter at 6; SIA Credit Division Letter at 1.

[157] *See* SIA/FIA Letter at 2–3, 10–11; ABN AMRO Letter at 1.

[158] Partnoy Letter at 10–14.

[159] NFA Letter at 4.

[160] Nasdaq Liffe Letter at 5.

[161] SIA/FIA Letter at 2.

[162] *Id.* at 10.

[163] *Id.*

[164] *Id.*

[165] Morgan Stanley Letter at 6–8.

[166] *Id.* at 7.

[167] *See* Securities Exchange Act Release No. 44853 (September 26, 2001), 66 FR at 50776 (October 4, 2001).

[168] *See, e.g.,* Amex Rule 462; CBOE Rule 12.3; NASD Rule 2520; New York Stock Exchange (''NYSE'') Rule 431; PCX Rule 2.16; and Phlx Rule 722.

[169] *See* 15 U.S.C. 78g(c)(2).

authorities and security futures intermediaries to establish higher margin levels or to take appropriate action to preserve their own financial integrity.[170] As a result, the Commissions are adopting the minimum initial and maintenance margin levels for unhedged positions, as proposed.

3. Margin Offsets

The Proposed Rules included a provision to allow national securities exchanges and national securities associations to adopt rules that reduce the margin levels below 20% of current market value for customers with certain positions in securities or futures that offset the risk of their positions in security futures.[171] The Proposed Rules provided further that the resulting margin levels could not be lower than the lowest customer margin levels required for comparable offset positions involving exchange-traded options.[172] In addition, the Commissions published a table that included offsets for security futures that the Commissions had preliminarily identified as consistent with those permitted for comparable offset positions involving options and that would qualify for reduced margin levels.[173]

The Commissions received three comments with respect to the proposed offsets.[174] One of the commenters stated that offsets involving security futures and options should be recognized only if the risk from the security future is completely offset by the option.[175] Another commenter expressed concern that the offsets would produce margin levels that did not accurately reflect the risk of the positions and suggested that the Commissions adopt general provisions regarding margin levels for offsetting positions instead of providing specific examples. [176] Finally, one commenter suggested modifying the existing strategy-based rules to put security futures on a par with cash equities in connection with offsetting strategies involving listed options and to reduce the margin requirements for certain calendar and basket spreads involving security futures.[177] This commenter also suggested that the Commissions address the treatment of spreads involving non-fungible security futures.[178]

After considering the commenters' views, the Commissions have adopted, substantially as proposed, rules that permit self-regulatory authorities to establish margin levels for offset positions involving security futures that are lower than the required margin levels for unhedged positions.[179] Under the Final Rules, a self-regulatory authority may set the required initial or maintenance margin level for an offsetting position involving security futures and related positions at a level lower than the level that would be required if the positions were margined separately. Such rules must meet the criteria set forth in section 7(c)(2)(B) of the Exchange Act [180] and must be effective in accordance with section 19(b)(2) of the Exchange Act [181] and, as applicable, Section 5c(c) of the CEA.[182]

The Commissions have retained, with certain revisions, the table of offsets that they deem to be consistent with offsets recognized for comparable exchange-traded options. In particular, the revised table of offsets reflects an adjustment in the level of margin required for certain calendar and basket spreads involving security futures to more accurately reflect the risk of such positions relative to comparable spreads involving exchange-traded options. An offset position for spreads involving non-fungible security futures also has been added to the table.

When it approved strategy-based offsets for options, the SEC found that it was appropriate for the SROs to recognize the hedged nature of certain combined options strategies and prescribe margin requirements that better reflect the risk of those strategies.[183] The SEC also found that the SROs' proposals relating to strategy-based offsets involving options contracts were carefully crafted as they were based on the SROs' experiences in monitoring the credit exposures of options strategies. In particular, the SEC noted that the SROs regularly examine the coverage of options margin as it relates to price movements in the underlying securities and index components. Moreover, the SROs' proposals were thoroughly reviewed by the NYSE Rule 431 Review Committee, which is comprised of securities industry participants who have extensive experience in margin and credit matters. As a result of these factors, the SEC was confident that the SROs' proposed margin requirements were consistent with investor protection and properly reflected the risks of the underlying options positions.

The table of offsets reflects a reduction in the minimum initial and maintenance margin requirement for calendar spreads [184] and basket spreads,[185] in response to the comment that the risk posed by certain spreads involving security futures is lower than the risk posed by comparable spreads involving exchange-traded options. [186] In light of the observation that security futures are not subject to early exercise and therefore do not exhibit the same price volatility as options, the minimum initial and maintenance margin requirement recognized for calendar spreads and basket spreads has been reduced to 5% of the current market value of the long or short position.[187] The Commissions deliberated as to whether risk-based margin computations using SPAN could be applied to these strategies, so long as the offsetting positions were the only positions included in the margin computation. The Commissions have decided not to permit risk-based margin computations for these offsets at this time.

The table of offsets, likewise, reflects a reduction in the required margin recognized for spreads involving a long or short security future and a short or long position in the same security underlying the security future, given that these spreads are economically

[170] *See* CFTC Rule 41.42(c)(1); SEC Rule 400(c)(1).

[171] *See* Proposed CFTC Rule 41.45(d); Proposed SEC Rule 402(d).

[172] *Id.*

[173] *See* Securities Exchange Act Release No. 44853 (September 26, 2001), 66 FR at 50727–29 (October 4, 2001).

[174] *See* Options Exchanges Letter; Partnoy Letter; SIA/FIA Letter.

[175] Options Exchanges Letter at 6.

[176] Partnoy Letter at 14.

[177] SIA/FIA Letter at Appendix I, Q 19.

[178] Meeting between SEC and CFTC staff and representatives of SIA/FIA (February 6, 2002).

[179] *See* CFTC Rule 41.45(b)(2); SEC Rule 403(b)(2).

[180] 15 U.S.C. 78g(c)(2)(B).

[181] 15 U.S.C. 78s(b)(2).

[182] 7 U.S.C. 7a–2(c).

[183] *See* Securities Exchange Act Release Nos. 41658 (July 27, 1999), 64 FR 42736 (August 5, 1999) (order approving SR–CBOE–97–67 amending CBOE Rule 12.3); 42011 (October 14, 1999), 64 FR 57172 (October 22, 1999) (order approving SR–NYSE–99–03 amending NYSE Rule 431); 43582 (November 17, 2000), 65 FR 70854 (November 28, 2000) (order approving SR–Amex–99–27 amending Amex Rule 462); and 43581 (November 17, 2000), 65 FR 71151 (November 29, 2000) (order approving SR–NASD–00–15 amending NASD Rule 2520).

[184] A calendar spread is an offset position consisting of a long security future and short security future on the same underlying security, each contract expiring in a different month. *See* table of offsets, item 10.

[185] A basket spread is an offset consisting of a security future based on an index and a basket of security futures that replicates the index, *i.e.*, a basket that contains the same securities, and in the same proportion, as the index. *See* table of offsets, items 17 and 18.

[186] Meeting between SEC and CFTC staff and representatives of SIA/FIA (February 6, 2002).

[187] By way of comparison, the minimum margin required for offsetting long and short positions in the same security under the rules of the national securities exchanges is 5% of the current market value of the long position. *See, e.g.,* NYSE Rule 431(e)(1).

analogous to calendar spreads.[188] The Commissions intend to review the margin levels for the offsets discussed above after six months of security futures trading to determine whether the margin levels have resulted in regulatory arbitrage with comparable positions involving exchange-traded options, and may jointly undertake appropriate action.

Based on the same commenter's suggestion, the Commissions believe that an additional offset should be recognized for spreads involving identical, non-fungible security futures.[189] Because there is a possibility that certain security futures may not be fungible across markets, a customer may simultaneously hold a long security future and a short security future on the same underlying security even when those security futures have identical contract terms. As a result, the customer will be economically neutral but will be required to hold both positions to expiration and meet daily variation settlement calls with respect to each contract. The commenter expressed the view that a minimum margin level of 1% would be appropriate.[190] The Commissions recognize that the rules of a clearing agency or derivatives clearing organization may effectively net the two contracts at final settlement. However, due to potential differences in daily settlement prices across markets or other market-specific events, the Commissions have determined that such offset positions will be subject to a minimum margin requirement of 3%.

The Commissions believe that the offsets identified in the following table are consistent with the strategy-based offsets permitted for comparable offset positions involving exchange-traded options. The Commissions expect that self-regulatory authorities seeking to permit trading in security futures will submit to the Commissions proposed rules that impose levels of required margin for offsetting positions involving security futures in accordance with the minimum margin requirements identified in the following table of offsets.

| Description of offset | Security underlying the security future | Initial margin requirement | Maintenance margin requirement |
|---|---|---|---|
| 1. Long security future or short security future. | Individual stock or narrow-based security index. | 20% of the current market value of the security future. | 20% of the current market value of the security future. |
| 2. Long security future (or basket of security futures representing each component of a narrow-based securities index[1]) and long put option[2] on the same underlying security (or index). | Individual stock or narrow-based security index. | 20% of the current market value of the long security future, plus pay for the long put in full. | The lower of: (1) 10% of the aggregate exercise price[3] of the put plus the aggregate put out-of-the-money[4] amount, if any; or (2) 20% of the current market value of the long security future. |
| 3. Short security future (or basket of security futures representing each component of a narrow-based securities index[1]) and short put option on the same underlying security (or index). | Individual stock or narrow-based security index. | 20% of the current market value of the short security future, plus the aggregate put in-the-money amount, if any. Proceeds from the put. Proceeds from the put sale may be applied. | 20% of the current market value of the short security future, plus the aggregate put in-the-money amount, if any.[5] |
| 4. Long security future and short position in the same security (or securities basket[1]) underlying the security future. | Individual stock or narrow-based security index. | The initial margin required under Regulation T for the short stock or stocks. | 5% of the current market value as defined in Regulation T of the stock or stocks underlying the security future. |
| 5. Long security future (or basket of security futures representing each component of a narrow-based securities index[1]) and Short call option on the same underlying security (or index). | Individual stock or narrow-based security index. | 20% of the current market value of the long security future, plus the aggregate call in-the-money amount, if any. Proceeds from the call sale may be applied. | 20% of the current market value of the long security future, plus the aggregate call in-the-money amount, if any. |
| 6. Long a basket of narrow-based security futures that together tracks a broad based index[1] and short a broad-based security index call option contract on the same index. | Narrow-based security index ..... | 20% of the current market value of the long basket of narrow-based security futures, plus the aggregate call in-the-money amount, if any. Proceeds from the call sale may be applied. | 20% of the current market value of the long basket of narrow-based security futures, plus the aggregate call in-the-money amount, if any. |
| 7. Short a basket of narrow-based security futures that together tracks a broad-based security index[1] and short a broad-based security index put option contract on the same index. | Narrow-based security index ..... | 20% of the current market value of the short basket of narrow-based security futures, plus the aggregate put in-the-money amount, if any. Proceeds from the put sale may be applied. | 20% of the current market value of the short basket of narrow-based security futures, plus the aggregate put in-the-money amount, if any. |
| 8. Long security a basket a narrow-based securities futures that together tracks a broad-based security index[1] and long a broad-based security index put option contract on the same index. | Narrow-based security index ..... | 20% of the current market value of the long basket of narrow-based security futures, plus pay for the long put in full. | The lower of: (1) 10% of the aggregate exercise price of the put, plus the aggregate put out-of-the-money amount, if any; or (2) 20% of the current market value of the long basket of security futures. |

[188] *See* table of offsets, items 4 and 13.

[189] *See* table of offsets, item 19.

[190] Meeting between SEC and CFTC staff and representatives of SIA/FIA (February 6, 2002).

| Description of offset | Security underlying the security future | Initial margin requirement | Maintenance margin requirement |
|---|---|---|---|
| 9. Short a basket of narrow-based security futures that together tracks a broad-based security index [1] and long a broad-based security index call option contract on the same index. | Narrow-based security index ..... | 20% of the current market value of the short basket of narrow-based security futures, plus pay for the long call in full. | The lower of: (1) 10% of the aggregate exercise price of the call, plus the aggregate call out-of-the-money amount, if any; or (2) 20% of the current market value of the short basket of security futures |
| 10. Long security future and short security future on the same underlying security (or index). | Individual stock or narrow-based security index. | The greater of: 5% of the current market value of the long security future; or 2) 5% of the current market value of the short security future. | The greater of: 5% of the current market value of the long security future; or (2) 5% of the current market value of the short security future. |
| 11. Long security future, long put option and short call option. The long security future, long put and short call must be on the same underlying security and the put and call must have the same exercise price. (Conversion). | Individual stock or narrow-based security index. | 20% of the current market value of the long security future, plus the aggregate call in-the-money amount, if any, plus pay for the put in full. Proceeds from the call sale may be applied. | 10% of the aggregate exercise price, plus the aggregate call in-the-money amount, if any. |
| 12. Long security future, long put option and short call option. The long security future, long put and short call must be on the same underlying security and the put exercise price must be below the call exercise price. (Collar). | Individual stock or narrow-based security index. | 20% of the current market value of the long security future, plus the aggregate call in-the-money amount, if any, plus pay for the put in full. Proceeds from call sale may be applied. | The lower of: (1) 10% of the aggregate exercise price of the put plus the aggregate put out-of-the-money amount, if any; or (2) 20% of the aggregate exercise price of the call, plus the aggregate call in-the-money amount, if any. |
| 13. Short security future and long position in the same security (or securities basket [1]) underlying the security future. | Individual stock or narrow-based security index. | The initial margin required under Regulation T for the long stock or stocks. | 5% of the current market value, as defined in Regulation T, of the long stock or stocks. |
| 14. Short security future and long position in a security immediately convertible into the same security underlying the security future, without restriction, including the payment of money. | Individual stock or narrow-based security index. | The initial margin required under Regulation T for the long security. | 10% of the current market value, as defined in Regulation T, of the long security |
| 15. Short security future (or basket of security futures representing each component of a narrow-based securities index [1]) and long call option or warrant on the same underlying security (or index). | Individual stock or narrow-based security index. | 20% of the current market value of the short security future, plus pay for the call in full. | The lower of: (1) 10% of the aggregate exercise price of the call, plus the aggregate call out-of-the-money amount, if any; or (2) 20% of the current market value of the short security future. |
| 16. Short security future, Short put option and long call option. The short security future, short put and long call must be on the same underlying security and the put and call must have the same exercise price. (Reverse Conversion). | Individual stock of narrow-based security index. | 20% of the current market value of the short security future, plus the aggregate put in-the-money amount, if any, plus pay for the call in full. Proceeds from put sale may be applied. | 10% of the aggregate exercise price, plus the aggregate put in-the-money amount, if any. |
| 17. Long (short) a basket of security futures, each based on a narrow-based security index that together tracks the broad-based index [1] and short (long) a broad based-index future. | Narrow-based security index ..... | 5% of the current market value of the long (short) basket of security futures. | 5% of the current market value of the long (short) basket of security futures. |
| 18. Long (short) a basket of security futures that together tracks a narrow-based index [1] and short (long) a narrow based index future. | Individual stock and narrow-based security index. | The greater of: (1) 5% of the current market value of the long security future(s); or (2) 5% of the current market value of the short security future(s). | The greater of: (1) 5% of the current market value of the long security future(s); or (2) 5% of the current market value of the short security future(s). |
| 19. Long (short) a security future and short (long) an identical security future traded on a different market.[6]. | Individual stock and narrow-based security index. | The greater of: (1) 3% of the current market value of the long security future(s); or (2) 3% of the current market value of the short security future(s). | The greater of: (1) 3% of the current market value of the long security future(s); or (2) 3% of the current market value of market value of the short security future(s). |

[1] Baskets of securities or security futures contracts must replicate the securities that comprise the index, and in the same proportion.
[2] Generally, for the purposes of these rules, unless otherwise specified, stock index warrants shall be treated as if they were index options.

[3] ''Aggregate exercise price,'' with respect to an option or warrant based on an underlying security, means the exercise price of an option or warrant contract multiplied by the numbers of units of the underlying security covered by the option contract or warrant. ''Aggregate exercise price'' with respect to an index option means the exercise price multiplied by the index multiplier. *See, e.g.*, Amex Rules 900 and 900C; CBOE Rule 12.3; and NASD Rule 2522.

[4] ''Out-of-the-money'' amounts must be determined as follows:

(1) For stock call options and warrants, any excess of the aggregate exercise price of the option or warrant over the current market value of the equivalent number of shares of the underlying security;

(2) for stock put options or warrants, any excess of the current market value of the equivalent number of shares of the underlying security over the aggregate exercise price of the option or warrant;

(3) for stock index call options and warrants, any excess of the aggregate exercise price of the option or warrant over the product of the current index value and the applicable index multiplier; and

(4) for stock index put options and warrants, any excess of the product of the current index value and the applicable index multiplier over the aggregate exercise price of the option or warrant. *See, e.g.*, NYSE Rule 431 (Exchange Act Release No. 42011 (October 14, 1999), 64 FR 57172 (October 22, 1999) (order approving SR–NYSE–99–03)); Amex Rule 462 (Exchange Act Release No. 43582 (November 17, 2000), 65 FR 71151 (November 29, 2000) (order approving SR–Amex–99–27)); CBOE Rule 12.3 (Exchange Act Release No. 41658 (July 27, 1999), 64 FR 42736 (August 5, 1999) (order approving SR–CBOE–97–67)); or NASD Rule 2520 (Exchange Act Release No. 43581 (November 17, 2000), 65 FR 70854 (November 28, 2000) (order approving SR–NASD–00–15)).

[5] ''In the-money'' amounts must be determined as follows:

(1) for stock call options and warrants, any excess of the current market value of the equivalent number of shares of the underlying security over the aggregate exercise price of the option or warrant;

(2) for stock put options or warrants, any excess of the aggregate exercise price of the option or warrant over the current market value of the equivalent number of shares of the underlying security;

(3) for stock index call options and warrants, any excess of the product of the current index value and the applicable index multiplier over the aggregate exercise price of the option or warrant; and

(4) for stock index put options and warrants, any excess of the aggregate exercise price of the option or warrant over the product of the current index value and the applicable index multiplier.

[6] Two security futures will be considered ''identical'' for this purpose if they are issued by the same clearing agency or cleared and guaranteed by the same derivatives clearing organization, have identical contract specifications, and would offset each other at the clearing level.

The Commissions note that positions in a securities account may not be cross-margined with positions in a futures account except in accordance with the rules of a self-regulatory authority that have become effective under section 19(b)(2) of the Exchange Act and, as applicable, section 5c(c) of the CEA. At present, the Commissions have not approved the use of a cross-margining methodology for customer securities and futures accounts. Accordingly, security futures or other positions carried in a futures account may not currently be offset against security futures or other positions carried in a securities account to reduce a customer's total margin requirement.

4. Higher Margin Levels

The Proposed Rules expressly provided that self-regulatory authorities could impose on their members initial and maintenance margin levels that are higher than the minimum levels otherwise specified in the rules.[191] The Proposed Rules also provided that self-regulatory authorities could permit their members to use a method for computing required margin that could result in margin levels that are higher than the minimum levels specified in the rules.[192]

The Commissions have decided that it is not necessary to adopt these provisions of the Proposed Rules because other provisions of the Final Rules make clear the ability of a self-regulatory authority to establish higher margin levels. The Final Rules establish minimum levels and do not set any limitations as to maximum levels. Moreover, the Final Rules expressly do not preclude a self-regulatory authority or a security futures intermediary from imposing additional margin requirements, including higher initial and maintenance margin levels, consistent with the Final Rules.[193]

As noted previously, a portfolio margining system such as SPAN may be used to compute required margin based on the parameters established in accordance with the Final Rules. Each security futures intermediary remains responsible for collecting margin in compliance with the Final Rules.

5. Procedures for Certain Margin Level Adjustments

The Commissions proposed to allow national securities exchanges registered under section 6(g) of the Exchange Act[194] and national securities associations registered under section 15A(k) of the Exchange Act[195] to raise or lower margin levels in accordance with section 19(b)(7) of the Exchange Act,[196] as long as the resulting levels satisfy the minimum level requirements.[197] The Commissions received no comments on this aspect of the proposal, and are adopting it as proposed.[198]

*H. Satisfaction of Required Margin*

Section 7(c)(2)(B)(iv) of the Exchange Act[199] requires that the type, form and use of collateral for security futures products be and remain consistent with the requirements of Regulation T. To fulfill this statutory requirement, the Commissions proposed to permit security futures intermediaries to accept as margin for security futures any of the types of collateral permitted under Regulation T to satisfy a margin deficiency in a margin account.[200] The Commissions also proposed to allow self-regulatory authorities to establish their own margin collateral requirements as long as those requirements were consistent with the requirements of Regulation T.[201]

The Final Rules continue to limit the type, form, and use of collateral deposits that security futures intermediaries may accept to satisfy the required margin for security futures to those permitted under Regulation T.[202] The Commissions are, however, permitting security futures intermediaries to include the net value of certain additional items—specifically, long options[203] and open trade equity[204]—in computing the equity in an account. Moreover, for purposes of determining whether the required margin in an account is satisfied, the final rules

[191] *See* Proposed CFTC Rule 41.45(b)(2)(i); Proposed SEC Rule 402(b)(2)(i).

[192] *See* Proposed CFTC Rule 41.45(b)(2)(ii); Proposed SEC Rule 402(b)(2)(ii).

[193] *See* CFTC Rule 41.42(c)(1); SEC Rule 400(c)(1).

[194] 15 U.S.C. 78f(g).

[195] 15 U.S.C. 78*o*–3(k).

[196] 15 U.S.C. 78s(b)(7).

[197] *See* Proposed CFTC Rule 41.45(c); Proposed SEC Rule 402(c).

[198] *See* CFTC Rule 41.45(c); SEC Rule 403(c).

[199] 15 U.S.C. 78g(c)(2)(B)(iv).

[200] *See* Proposed CFTC Rule 41.47(a)(4); Proposed SEC Rule 404(a)(4).

[201] *See* Proposed CFTC Rule 41.47(b); Proposed SEC Rule 404(b).

[202] *See* CFTC Rule 41.46(a); SEC Rule 404(a).

[203] *See* CFTC Rule 41.46(c)(1)(iv); SEC Rule 404(c)(1)(ii).

[204] *See* CFTC Rule 41.46(c)(1)(vi) and (c)(2)(iii); SEC Rule 404(c)(1)(vi) and (c)(2)(iii).

permit security futures intermediaries to compute equity in accordance with applicable self-regulatory authority rules, subject to certain adjustments to ensure consistency with Regulation T.[205]

1. Type, Form and Use of Collateral

a. *Acceptable Collateral Deposits.* The Commissions proposed to permit security futures intermediaries to accept as margin for security futures a deposit of any combination of cash, margin securities as defined in Regulation T,[206] exempted securities as defined in section 3(a)(12) of the Exchange Act,[207] and other collateral permitted under Regulation T to satisfy a margin deficiency in the margin account.[208]

The Commissions received four comments on this issue.[209] One commenter supported the Commissions' proposal with respect to permissible collateral.[210] The other three commenters suggested that the Commissions should permit security futures intermediaries to accept other forms of collateral in addition to those permitted by Regulation T.[211]

Two of these commenters suggested that the type of collateral permitted should be determined based on the type of account. Under an account-specific approach, for security futures held in futures accounts, the types of permissible collateral would be determined by SRO rules; and for security futures held in securities accounts, the types of permissible collateral would be governed by Regulation T.[212] The other commenter maintained that, unless the Commissions recognize other instruments that are commonly accepted as collateral within a futures account (*e.g.*, letters of credit), the margin requirements would disadvantage the futures community and would make it unlikely that customers would carry security futures products in a futures account.[213]

The Commissions have considered the commenters' views, and have adopted the provisions regarding acceptable collateral deposits substantially as proposed. In particular, the Commissions do not believe that it would be consistent with the requirements regarding type, form, and use of collateral under Regulation T to permit customers to satisfy the required margin for security futures in a futures account using letters of credit or other types of collateral not currently permitted under Regulation T. Any types of collateral the Federal Reserve Board may subsequently permit in a Regulation T margin account, however, may also be used to satisfy the required margin for security futures under the Final Rules.[214]

b. *Use of Money Market Mutual Funds.* The definition of ''margin security'' under Regulation T includes, among other securities, money market mutual funds. A number of futures exchanges currently accept money market mutual fund shares as performance bond deposits for futures and options on futures, subject to certain conditions imposed under CFTC Rule 1.25.[215] Regulation T also permits creditors to extend good faith loan value to shares in money market mutual funds and other mutual funds carried in a securities account, although the limitations on extensions of credit in connection with new issues of securities under section 11(d)(1) of the Exchange Act have limited the practicability of their use.[216]

The Final Rules permit the use of money market mutual fund shares [217] to satisfy the required margin for security futures and related positions carried in a securities account or futures account, subject to certain conditions.[218] These conditions are intended to facilitate a security futures intermediary's hypothecation or liquidation of money market mutual fund shares deposited as margin for security futures, as necessary to meet a customer's clearing obligations.

Specifically, a security futures intermediary may accept money market mutual fund shares as margin if the following conditions are met (*e.g.,* under the rules of a self-regulatory authority or pursuant to a three-way agreement among the security futures intermediary, the customer, and the money market mutual fund or its transfer agent):

(1) The customer waives any right to redeem the fund shares without the consent of the security futures intermediary and instructs the fund or its transfer agent accordingly;

(2) The security futures intermediary (or clearing agency or derivatives clearing organization with which the security is deposited as margin) obtains the right to redeem the shares in cash, promptly upon request; and

(3) The fund agrees to satisfy any conditions necessary or appropriate to ensure that the shares may be redeemed in cash, promptly upon request.

2. Computation of Equity

The Proposed Rules would have required security futures intermediaries to compute the equity in an account in accordance with Regulation T for purposes of determining whether the required margin for security futures is satisfied.[219] The Commissions received one comment on this issue.[220] The commenter expressed the opinion that the rules governing collateral haircuts in securities and futures accounts need not be identical, as long as the relevant standards do not create a material incentive for customers to carry security futures positions in a futures account rather than a securities account.[221]

The Commissions have considered this commenter's views and have determined not to require security futures intermediaries to compute equity in accordance with Regulation T. The Final Rules provide that, for purposes of determining whether the required margin for security futures carried in an account is satisfied, the equity in an account shall be computed in accordance with the margin rules

[205] *See* CFTC Rule 41.46; SEC Rule 404.

[206] Under Section 202.2 of Regulation T (12 CFR 220.2), margin securities include: (1) Any security registered or having unlisted trading privileges on a national securities exchange; (2) any security listed on the Nasdaq Stock Market; (3) any nonequity security; (4) any security issued by either an open-end investment company or unit investment trust which is registered under section 8 of the Investment Company Act of 1940 (15 U.S.C. 80a–8); (5) any foreign margin stock; and (6) any debt security convertible into a margin security.

[207] 15 U.S.C. 78c(a)(12).

[208] *See* Proposed CFTC Rule 41.47(a)(4); Proposed SEC Rule 404(a)(4).

[209] *See* Options Exchanges Letter; NFA Letter; CME/CBOT Letter; SIA/FIA Letter.

[210] Options Exchanges Letter at 6–7.

[211] *See* NFA Letter at 6–7; CME/CBOT Letter at 3–4; and SIA/FIA Letter 6–8.

[212] *See* NFA Letter at 7; SIA/FIA Letter at 6.

[213] CME/CBOT Letter at 4.

[214] CFTC Rule 41.46(b)(1); SEC Rule 404(b)(1).

[215] *See, e.g.,* CME Rule 930.C.

[216] In a recent interpretive release providing guidance on the application of certain provisions of the federal securities laws to trading in security futures products, the SEC expressed the view that a security future is not an extension of credit under section 11(d)(1) of the Exchange Act (15 U.S.C. 78k(d)(1)), and that margin collected in connection with a security futures transaction represents a good faith deposit against performance and not ''partial payment'' for the security. Securities Exchange Act Release No. 46101 (June 21, 2002), 67 FR 43234, 43245 (June 27, 2002). Accordingly, a deposit of money market mutual fund shares by a customer to satisfy the required margin for a security future does not, in the SEC's view, constitute a direct or indirect extension or maintenance of credit to or for the customer on such shares for purposes of Section 11(d)(1) (15 U.S.C. 78k(d)(1)).

[217] *See* CFTC Rule 41.43(a)(22); SEC Rule 401(a)(22).

[218] *See* CFTC Rule 41.46(b)(2); SEC Rule 404(b)(2).

[219] *See* Proposed CFTC Rule 41.43(b); Proposed SEC Rule 400(b).

[220] SIA/FIA Letter.

[221] *Id.,* at 6.

applicable to the account.[222] However, so that that collateral and other components of equity are valued consistently in securities and futures accounts, the Final Rules require security futures intermediaries to make certain adjustments to equity when determining whether the required margin for security futures carried in an account is satisfied.[223] Each of these components of equity is discussed in turn below.

a. *Security Futures.* The Proposed Rules provided that security futures would not be ''margin securities'' for purposes of the margin requirements and therefore would not have loan value for margin purposes.[224] One commenter addressed this provision and supported the view that security futures should not have loan value for margin purposes.[225]

The Commissions have considered the commenter's views and have adopted Final Rules that provide that security futures will have no value for purposes of determining whether the required margin in a securities or futures account is satisfied.[226] This is consistent with the treatment of other futures contracts carried in futures accounts.

To avoid confusion as to whether extensions of credit in connection with security futures are considered ''purpose credit'' for purposes of the Federal Reserve Board's credit regulations,[227] however, the Commissions have revised the Final Rules to eliminate the statement that security futures are not margin securities.

b. *Option Value.* The Proposed Rules did not address the question of whether the net value of options in a securities or futures account could be applied to satisfy the required margin for security futures.[228] The rules of the futures exchanges generally permit FCMs to include the value of listed options on contracts for future delivery in computing the equity in a futures account. The rules of the national securities exchanges and the NASD, however, generally deny value to options carried for a customer for the purpose of computing the equity in the customer's account.[229]

One commenter expressed concern that the exclusion of net option value from the calculation of equity in a futures account would create significant operational difficulties for security futures intermediaries that carry security futures in futures accounts.[230] Two other commenters noted, however, that recognition of option value for purposes of determining whether the required margin for security futures is satisfied in a futures account would create a significant regulatory disparity with exchange-traded options carried in securities accounts.[231]

The Commissions, having considered the commenters' concerns, are adopting Final Rules that provide that a net long or short position in a listed put or call option carried in a futures account shall be valued in accordance with the margin rules applicable to the account for purposes of determining whether the required margin for a security future in the account is satisfied.[232] For these purposes, the term ''listed option'' is defined to mean any put or call option that is (i) issued by a clearing agency that is registered under section 17A of the Exchange Act [233] or cleared and guaranteed by a derivatives clearing organization that is registered under Section 5b of the CEA; [234] and (ii) traded on or subject to the rules of a self-regulatory authority.[235]

The SEC is willing to entertain proposed rule changes by the national securities exchanges and the NASD to grant value to listed options in a securities account under appropriate circumstances. In addition, the Commissions intend to review their determination to grant value to long options carried in futures accounts after six months of security futures trading to determine whether it has created a material disparity between the margin requirements for security futures and the margin requirements for comparable exchange-traded options, and may jointly undertake appropriate action.

c. *Open Trade Equity.* The Proposed Rules did not address in detail how ''open trade equity'' (*i.e.,* the daily marked-to-market gain or loss in value of futures or other exchange-traded contracts) would be included in the equity in an account for purposes of determining whether the required margin for security futures is satisfied. However, eight commenters raised the issue and requested clarification from the Commissions.[236] Those commenters generally requested that the Commissions clarify that broker-dealers and FCMs could treat open trade equity on security futures positions as cash for purposes of margin and collateral.

One of those commenters maintained that disallowing the use of open trade equity to satisfy margin on trades and position in other markets could dampen customers' interest in security futures.[237] Another of the commenters suggested that FCMs would have to make costly systems changes if they were not allowed to recognize open trade equity for security futures as they are permitted to do for other futures positions.[238]

In light of commenters' views on this issue, the Final Rules clarify that ''open trade equity'' may be applied to satisfy the required margin for security futures and related positions. Specifically, the Final Rules define a new term, ''variation settlement,'' to mean any credit or debit to a customer account, made on a daily or intraday basis, for the purpose of marking to market a security future or any other contract that is: (i) issued by a clearing agency that is registered under section 17A of the

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[222] *See* CFTC Rule 41.46(c); SEC Rule 404(c). For purposes of determining whether the required margin for security futures and related positions is satisfied under the Final Rules, the equity in a futures account is defined to include the account's net liquidating equity plus the collateral value of margin securities, exempted securities, and other acceptable margin deposits. *See* Joint Audit Committee, Margins Handbook, Chapter 1 (June 1999) (definition of ''margin equity''). Securities may not be combined with security futures carried in a futures account to create an offset position except pursuant to a cross-margining arrangement, as described in Section II.G.3 of this release.

[223] *See* CFTC Rule 41.46(c), (d), and (e); SEC Rule 404(c), (d), and (e).

[224] *See* Proposed CFTC Rule 41.47(c); Proposed SEC Rule 404(c).

[225] Options Exchanges Letter at 6–7.

[226] *See* CFTC Rule 41.46(c)(1)(i) and (c)(2)(i); SEC Rule 404(c)(1)(i) and (c)(2)(i). As discussed below, open trade equity resulting from the daily settlement of security futures can be used to satisfy the required margin.

[227] *See* discussion of extensions of credit in Section II.F.4. of this release.

[228] Regulation T generally delegates the authority to specify the amount or other position to satisfy the required margin for put or call options on a security, certificate of deposit, securities index or foreign currency, or a warrant on a securities index or currency carried in a securities account to the registered securities exchange or association authorized to trade the option (in the case of exchange-listed options) and to the creditor's examining authority (in the case of all other options), subject in each case to approval by the SEC. *See* 12 CFR 220.12(f).

[229] The rules of the national securities exchanges and the NASD recognize an exception for long listed or OTC options and warrants with a remaining period to expiration exceeding 9 months. Such contracts are valued at their current market value (as defined in Section 220.2 of Regulation T (12 CFR 220.2)), subject to a 75% margin requirement. *See, e.g.,* NYSE Rule 431(f)(2)(C).

[230] Meeting between SEC and CFTC staff and representatives of SIA/FIA (February 6, 2002).

[231] Telephone conversations between SEC staff and The OCC staff (February 20, 2002) and between SEC staff and CBOE staff (February 5, 2002).

[232] *See* CFTC Rule 41.46(c)(1)(ii); SEC Rule 404(c)(1)(ii).

[233] 15 U.S.C. 78q–1.

[234] 7 U.S.C. 7a–1.

[235] *See* CFTC Rule 41.43(a)(16); SEC Rule 401(a)(16).

[236] *See* Peregrine Letter; OneChicago Letter; NFA Letter; CME Letter; SIA/FIA Letter; Nasdaq Liffe Letter; SunGard Letter; and Morgan Stanley Letter.

[237] OneChicago Letter at 6.

[238] SunGard Letter at 2.

Exchange Act [239] or cleared and guaranteed by a derivatives clearing organization that is registered under Section 5b of the CEA,[240] and (ii) traded on or subject to the rules of a self-regulatory authority.[241] The Final Rules provide that variation settlement receivable (or payable) by an account at the close of trading on any day shall be treated as a credit (or debit) to the account on that day.[242]

d. *Margin Equity Securities.* The Final Rules generally limit the value of a margin equity security deposited as margin for security futures in a futures account to the security's ''Regulation T collateral value,'' *i.e.,* the current market value of the security (based on its most recent closing price) less the percentage of required margin for a position in the security held in a margin account under Regulation T.[243] This amount, which is currently set at 50% of current market value, represents the amount of the value of a fully-paid margin equity security deposited into a securities margin account that would be available to satisfy the required margin for other positions in the account under Regulation T, *e.g.,* stock options. Margin equity securities deposited as collateral for security futures in a securities account remain subject to Regulation T margin requirements as well as the margin requirements of applicable self-regulatory authority rules.

By requiring FCMs to value margin equity securities as collateral for security futures at the levels established under Regulation T,[244] the Commissions intend to provide that margin equity securities used to satisfy margin requirements for security futures are valued in a consistent manner, regardless of the type of account in which a security future is carried. The Commissions recognize, however, that the Regulation T margin requirement applies only to new transactions that create or increase a margin deficiency in an account.[245] As a result, a uniform 50% haircut on margin equity securities in a futures account may result in the collection of more margin for security futures carried in a futures account than would be required for comparable positions carried in a securities account.

Accordingly, the Final Rules provide an alternative method for valuing margin equity securities used as collateral for security futures in a futures account based on the same initial and maintenance computations required under Regulation T and securities SRO rules with respect to transactions in the account.[246] Under this alternative method, the haircut for margin equity securities is equal to the lowest percentage of margin required for a margin equity security under the rules of a national securities exchange (currently, 25%). On any day when security futures transactions or related transactions [247] are effected in the account, however, a customer must satisfy a special margin requirement equal to the amount of any margin deficiency created or increased in the account if the margin equity securities were valued at their Regulation T collateral value (*i.e.,* 50% of current market value).

The Final Rules provide further that, if this alternative method for valuing margin equity securities is used in an account in which security futures or related positions are carried and such account is transferred from one security futures intermediary to another, the account may be treated as if it had been maintained by the transferee security futures intermediary from the date of its origin if the transferee accepts, in good faith, a signed statement of the transferor security futures intermediary (or, if that is not practicable, of the customer), that any margin call issued under the Final Rules has been satisfied.[248] This provision parallels Section 220.4(b)(7) of Regulation T, and is consistent with futures industry practices under Section 4d of the CEA.[249] It is intended to prevent one security futures intermediary from transferring an undermargined account to another security futures intermediary.

e. *Other Securities.* The Final Rules impose a haircut on exempt securities and nonequity securities deposited as margin for security futures carried in a futures account equal to the haircut established under the SEC's net capital rule.[250] This provision is intended to codify the haircut currently imposed on Treasury securities and other debt securities deposited as collateral for futures and options on futures under the rules of the designated contract markets. Exempt securities and nonequity securities deposited as collateral for security futures in a securities account will remain subject to the higher margin requirements applicable to such securities under Regulation T and self-regulatory authority rules.

f. *Foreign Currency.* The Final Rules provide that freely convertible foreign currency may be valued at an amount no greater than its daily marked-to-market U.S. dollar equivalent for purposes of determining whether the required margin for security futures carried in a securities or futures account is satisfied.[251] This provision reflects the maximum value assigned to foreign currencies under Regulation T.[252]

g. *Other Components of Equity.* The Final Rules provide that each other acceptable margin deposit or component of equity in a securities or futures account shall be valued at an amount no greater than its value in a Regulation T securities margin account.[253] This

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[239] 15 U.S.C. 78q–1.

[240] 7 U.S.C. 7a–1.

[241] *See* CFTC Rule 41.43(a)(32); SEC Rule 401(a)(32).

[242] *See* CFTC Rule 41.46(c)(1)(vi) and (c)(2)(iii); SEC Rule 404(c)(1)(vi) and (c)(2)(iii).

[243] *See* CFTC Rule 41.43(a)(25); SEC Rule 401(a)(25). The Final Rules define the ''current market value'' of a security other than a security future to mean the most recent closing sale price of the security, as shown by any regularly published reporting or quotation service. CFTC Rule 41.43(a)(4); SEC Rule 401(a)(4). If there is no recent closing sale price, the security futures intermediary may use any reasonable estimate of the market value of the security as of the most recent close of business. *Id.*

[244] *See* CFTC Rule 41.46(c)(1)(iii); SEC Rule 404(c)(1)(iii).

[245] The initial margin required for the purchase of a margin equity security in a securities account under Regulation T is 50% of its current market value. However, the maintenance margin required for a position in a margin equity security under the rules of the securities self-regulatory organizations is 25% of current market value. *See, e.g.,* NYSE Rule 431(c)(1). Accordingly, a customer that seeks to use a fully paid equity security to satisfy the required margin for a new short option transaction may apply no more than 50% of the current market value of the security for that purpose. On subsequent days, the customer will not be required to deposit additional margin, regardless of changes in the price of the short option or equity security, unless the required margin for the short option exceeds 75% of the current market value of the equity security.

[246] *See* CFTC Rule 41.46(e); SEC Rule 404(e).

[247] A ''related transaction'' is defined to include any transaction in a related position that creates, eliminates, increases or reduces an offsetting position involving a security future, or any deposit or withdrawal of collateral (other than the deduction of variation settlement and other periodic deductions by a security futures intermediary from a customer account). CFTC Rule 41.43(a)(27); SEC Rule 401(a)(27). For example, if a customer unwinds an offsetting position in a futures account, such as by liquidating a long broad-based index future offsetting a basket of security futures, any margin equity securities used to satisfy the additional margin in the account required as a result of the transaction would have to be valued at their Regulation T value.

[248] *See* CFTC Rule 41.46(e)(3); SEC Rule 404(e)(3).

[249] 12 CFR 220.4(b)(7) and 7 U.S.C. 6d. *See* also NASD Rule 11870(d) and NFA Rule 2–27.

[250] *See* CFTC Rule 41.46(c)(1)(iv); SEC Rule 404(c)(1)(iv).

[251] *See* CFTC Rule 41.46(c)(1)(v) and (c)(2)(ii); SEC Rule 404(c)(1)(v) and (c)(2)(ii).

[252] Many foreign currencies already are subject to significant additional haircuts or margin requirements in securities and futures accounts under self-regulatory authority rules. As discussed above, security futures intermediaries and their customers would also have to observe limitations under applicable margin rules.

[253] *See* CFTC Rule 41.46(c)(1)(vii); SEC Rule 404(c)(1)(vii).

provision is intended to provide that any additional forms of collateral permitted under Regulation T in the future or other items in an account are valued under the Final Rules in accordance with Regulation T.

h. *Guarantees.* The Final Rules provide that no guarantee of a customer's account shall be given any effect for purposes of determining whether the required margin in an account is satisfied, except as permitted under the margin rules applicable to the account.[254] This provision is consistent with both the requirements currently applicable to securities accounts under Regulation T [255] and the requirements currently applicable to futures accounts under CFTC Rule 1.10.[256] Thus, the account-specific practices related to guarantees that are currently followed in securities accounts and futures accounts, respectively, would remain effective under this provision.

3. Satisfaction of the Required Margin for Positions Other than Security Futures

Because the scope of the Final Rules is limited to security futures and related positions, the rules require additional margin to be deposited in an account only when the required margin for security futures is not satisfied by the equity in the account. The required margin for all other positions carried in an account, and acceptable collateral for such positions, shall be determined in accordance with the margin rules applicable to the account.

The Final Rules do not prohibit security futures intermediaries from accepting different collateral or assigning greater collateral value to assets deposited as collateral with respect to other positions carried in an account, if permitted under applicable self-regulatory authority rules. For example, security futures intermediaries may use letters of credit to satisfy the required margin for commodity futures and commodity options (other than security futures) in a futures account, even if a security future is carried in the account, as long as the collateral or other equity allocated to the security future is sufficient to satisfy the requirement established under the Final Rules. Likewise, security futures intermediaries may value margin equity securities deposited to satisfy the required margin for commodity futures or commodity options (other than security futures) according to the rules of the applicable board of trade.

Moreover, security futures intermediaries may allocate collateral or other components of equity among security futures and such other positions as they consider appropriate. For example, a security futures intermediary may elect to allocate cash, open trade equity, option value, and nonequity securities to satisfy the required margin for security futures and related positions in a futures account, and allocate margin equity securities to satisfy the required margin for commodity futures and commodity options (other than security futures). This allocation would allow the security futures intermediary to value the margin equity securities as permitted by the applicable margin rules, rather than at the security's Regulation T collateral value, provided that the security futures in the account are adequately margined by the other collateral in the account.

To prevent assets used to satisfy the required margin for security futures from being counted twice for margin purposes, the Final Rules provide that transactions, positions or deposits used to satisfy the required margin for security futures or related positions shall be unavailable to satisfy the required margin for any other position or transaction or any other requirement.[257] In particular, a related position used to reduce the required margin for a security future may not be used in a strategy-based offset with another item in the account. This provision is consistent with the satisfaction restriction in Section 220.4(c)(4) of Regulation T.[258] For example:

- A deposit of $1000 in margin equity securities used to satisfy the required margin for a $500 margin call on a security future cannot also be used to satisfy a $350 margin call on a broad-based index future in a futures account, even if, under the margin rules applicable to the account, equity securities used as collateral for the broad-based index future may be valued at 85% of current market value (*i.e.* $850).
- A 100-share XYZ put option contract in a securities account may not be used to cover both a 100-share long XYZ security future contract as well as 100 shares of XYZ common stock.

The collateral used to satisfy the margin requirement with respect to a security future may of course be used to satisfy the margin requirement with respect to the same position under self-regulatory authority rules.

*I. When Margin May Be Withdrawn*

The Final Rules include provisions that specify when margin may be withdrawn from an account that contains security futures. Under the Proposed Rules, these provisions would have been incorporated into the Commissions' margin requirements through the application of Regulation T. Because the Final Rules do not expressly apply Regulation T, the Commissions have identified the circumstances in which a customer or a security futures intermediary may withdraw cash, securities or other collateral deposited as margin for security futures and related positions.[259]

1. Withdrawal of Margin by the Customer

The Final Rules provide that a customer may withdraw cash, securities, or other assets deposited as margin for security futures or related positions, provided that the equity in the account after such withdrawal is sufficient to satisfy the required margin for the security futures and related positions in the account under the Final Rules.[260]

Customers that use the alternative collateral valuation method for equity securities, pursuant to CFTC Rule 41.46(e) and SEC Rule 404(e), are subject to an additional restriction on withdrawals that parallels the withdrawal restrictions of Regulation T.[261] Specifically, cash, securities or other assets may not be withdrawn with respect to an account that uses the alternative method if:

(i) Additional cash, securities, or other assets are required to be deposited as margin for a transaction in the account on the same or a previous day pursuant to a special margin requirement; or

(ii) The withdrawal, together with other transactions, deposits, and withdrawals on the same day, would create or increase a margin deficiency if the margin equity securities were valued at their Regulation T collateral value.[262]

This restriction is intended to prevent a customer from withdrawing margin

[254] *See* CFTC Rule 41.46(f); SEC Rule 404(f).

[255] *See* 12 CFR 220.3(d). The Regulation T prohibition governs initial margin. The use of guarantees for purposes of maintenance margin is otherwise treated under applicable margin rules.

[256] 17 CFR 1.10. CFTC Rule 1.10(d) requires that an FCM's financial report be completed in accordance with the CFTC's Form 1–FR–FCM Instructions for reporting an FCM's net capital position. These instructions provide further that ''an FCM may not consider a guarantee agreement as a substitute for margin'' in customers' accounts. Thus, margin deficits are only satisfied with the actual transfer of free funds from the guaranteeing account.

[257] *See* CFTC Rule 41.46(d); SEC Rule 404(d).

[258] 12 CFR 220.4(c)(4).

[259] *See* CFTC Rule 41.47; SEC Rule 405.

[260] *See* CFTC Rule 41.47(a); SEC Rule 405(a).

[261] *See* 12 CFR 220.4(e).

[262] *See* CFTC Rule 41.46(e); SEC Rule 404(e).

deposited to satisfy a special margin requirement unless the customer's equity exceeds the required margin in the account or the customer substitutes securities of equivalent value.

2. Withdrawal of Margin by the Security Futures Intermediary

The Final Rules provide that a security futures intermediary may deduct certain payments and charges from a customer account to meet the customer's obligations to the security futures intermediary and third parties.[263] Specifically, without regard to the other provisions of the rule, the security futures intermediary may deduct the following items from an account:

(i) Variation settlement payable, directly or indirectly,[264] to a clearing agency or derivatives clearing organization to settle the customer's obligations under a security futures contract or other contracts cleared through the clearing agency or derivatives clearing organization;

(ii) Interest charged on credit maintained in the account;

(iii) Communication or shipping charges with respect to transactions in the account;

(iv) Payment of commissions, brokerage, taxes, storage and other charges lawfully accruing in connection with the positions and transactions in the account; and

(v) Any service charges that the security futures intermediary may impose. These items reflect the permissible withdrawals from a securities account and a futures account under Regulation T [265] and Section 4d of the CEA,[266] respectively. The Final Rules also permit a security futures intermediary to deduct any other items that may be deducted under Regulation T (*e.g.,* premiums on securities borrowed, dividends, interest, or other distributions due on borrowed securities), to the extent permitted under applicable margin rules.

*J. Consequences of Failure To Collect Required Margin*

The Commissions proposed that the amount of initial or maintenance margin required would be obtained as promptly as possible and in any event within three business days or within such shorter time period as may be imposed by applicable regulatory authority rules.[267] The Commissions also proposed that the time limits for collection of initial margin could be extended upon application by the creditor to its examining authority, as defined in Proposed CFTC Rule 41.44(a)(3) and Proposed SEC Rule 401(a)(3), to the extent permitted by applicable regulatory authority rules.[268] Failure to collect additional margin within the established period would have required the creditor to liquidate the account, as required by Regulation T.[269]

The Commissions received six comments on the issue of timing for collection of margin.[270] One commenter supported the proposed time limit for collection of margin, stating that a time limit of three business days or shorter, with the opportunity for extensions upon application, would be a reasonable time frame for initial and maintenance margin calls.[271]

One commenter disagreed with the proposed time limits and recommended that the Commissions adopt the time limits provided in Regulation T, which requires the collection of margin within five business days after the position is established (T+5), and the collection of maintenance margin as promptly as possible and in any event within fifteen business days.[272] Another commenter supported a T+1 margin settlement cycle and a T+5 collection period.[273] The same commenter observed that ''[g]iven that the initial margin collection period for securities and listed securities options is T+5, and that, as a result of required capital charges, futures have an effective collection period of T+5, the Associations' members feel strongly that a T+5 collection period should also apply to security futures.'' [274]

Two other commenters urged the Commissions to recognize the existing time limits in both the securities and futures industries.[275] Specifically, these commenters believed that although the provisions governing the time of collection in Regulation T are different from those set forth by the CFTC and the futures exchange rules, the outcome is substantially similar.

Finally, another commenter recommended that the period for collecting initial and maintenance margin be extended to four days (T+4) in order to be consistent with existing requirements in the futures and securities industries.[276] That commenter also expressed concern regarding the procedures that must be followed if margin is not received in the time prescribed, noting that the Proposed Rules would require liquidation of positions in accordance with Regulation T. The commenter believed that requiring a firm to liquidate positions if a margin call is not met, or providing that the time period for collection could be extended by the firm's examining authority, could create significant burdens for both an FCM and its examining authority because these are not the current practices in the futures industry.

The Commissions have considered the commenters views and have decided not to adopt uniform time periods for collection of margin. The Commissions have determined that deference to account-specific rules in this instance will avoid operational costs that would be incurred in modifying existing practices, and will not provide an incentive for customers to select one type of account (securities or futures) over another.

In addition, the Commissions have decided not to require immediate liquidation of the positions in a customer account if the customer fails to deposit additional required margin within a prescribed number of days. The Commissions believe that, in general, a security futures intermediary should be adequately protected against potential adverse movements in customers' positions if it takes a capital charge for the amount by which the customer's account is undermargined. Accordingly, the Final Rules provide that if any margin call required by this Regulation (§§ 242.400 through 242.406) is not met in full, the security futures intermediary shall take the deduction required under CFTC or SEC rules,[277] as applicable, in computing its net capital.[278]

The Commissions have decided, however, to require that a security futures intermediary liquidate positions in an account if the account would liquidate to a deficit.[279] To provide

[263] *See* CFTC Rule 41.47(b); SEC Rule 405(b).

[264] The phrase ''directly or indirectly'' is intended to encompass payments either directly to a clearing agency or derivatives clearing organization, or payments made through a clearing broker.

[265] 12 CFR 220.4(f).

[266] 7 U.S.C. 6d.

[267] *See* Proposed CFTC Rule 41.46(a) and (b); Proposed SEC Rule 403(a) and (b).

[268] *See* Proposed CFTC Rule 41.46(c); Proposed SEC Rule 403(c).

[269] 12 CFR 220.4(d).

[270] *See* Peregrine Letter; SIA Credit Division Letter; SIA/FIA Letter; Morgan Stanley Letter; CME/CBOT Letter; and NFA Letter.

[271] Peregrine Letter at 2.

[272] SIA Credit Division Letter at 2.

[273] SIA/FIA Letter at 11.

[274] *Id.*

[275] *See* Morgan Stanley Letter at 10; CME/CBOT Letter at 5.

[276] NFA Letter at 5.

[277] 17 CFR 1.17(c)(5)(viii) or (ix); 17 CFR 240.15c3–1(c)(2)(xii).

[278] CFTC Rule 41.48(a); SEC Rule 406(a).

[279] CFTC Rule 41.48(b); SEC Rule 406(b). This is the same standard that applies to options specialists

firms with the flexibility to control liquidation of positions during adverse market conditions, the Final Rules provide that firms shall liquidate such positions promptly and in an orderly manner. This is consistent with futures industry practices in which FCMs, pursuant to customer agreements, exercise discretion in making liquidation decisions. In this regard, the Commissions believe that it is prudent business practice for security futures intermediaries to take steps to liquidate customer accounts well before they are in a deficit condition. The uniform liquidation requirement adopted under the Final Rules differs from the liquidation requirements imposed under Regulation T and securities SRO rules with respect to undermargined accounts.[280] The Final Rules clarify that this Regulation T liquidation requirement does not apply to security futures held in a securities account.[281]

*K. CFTC Procedures for Notification of Proposed Rule Changes Related to Margin*

In general, a designated contract market, including a ''notice-designated'' contract market,[282] or registered derivatives transaction execution facility (''DTF'') that proposes to make a rule change regarding its security futures margin requirements (other than proposed rule changes that result in higher margin levels) must submit the proposed rule change to the SEC for approval in accordance with section 19(b) of the Exchange Act.[283] In addition, contract markets designated pursuant to Section 5 of the CEA and registered DTFs are also required under Section 5c(c) of the CEA to make certain filings with the CFTC regarding rule changes, including those for security futures products.[284] Because ATSs are not SROs under the Exchange Act, notice-designated contract markets that are ATSs are not required to submit proposed rule changes to the SEC for approval in accordance with section 19(b) of the Exchange Act.

Section 5c(c) of the CEA provides for two alternative procedures by which such a designated contract market or registered DTF may implement a proposed rule change.[285] First, in accordance with Section 5c(c)(1) of the CEA, a proposed rule change may be implemented by providing the CFTC with a written certification that the proposed rule change complies with the CEA.[286] Second, Section 5c(c)(2) of the CEA provides that, before the implementation of a proposed rule change, an entity may request that the CFTC grant prior approval of the rule change.[287]

Proposed CFTC Rule 41.48(a) required any notice-designated contract market that files a proposed rule change regarding customer margin for security futures with the SEC for approval in accordance with section 19(b)(2) of the Exchange Act [288] to concurrently provide to the CFTC a copy of such a proposed rule change and any accompanying documentation filed with the SEC.[289] Such notice-designated contract market was not required to provide any supplemental information, even if such information were subsequently provided to the SEC in the course of the SEC's review of the proposed rule change. The purpose of this Proposed Rule was to provide the CFTC, as a joint regulator of markets offering security futures products, with timely notification of a proposed rule change.

Proposed CFTC Rule 41.48(b) established the notification process for contract markets designated pursuant to Section 5 of the CEA [290] and registered DTFs. The process by which such an entity would notify the CFTC of having filed a proposed rule change with the SEC would depend on which procedure under Section 5c(c) of the CEA [291] the entity elected to follow.

Proposed CFTC Rule 41.48(b)(1) applied to any designated contract market registered under section 5 of the CEA or registered DTF that elects to seek the prior approval of the CFTC for a proposed rule change, in accordance with Section 5c(c)(2) of the CEA.[292] In such case, the contract market or DTF would file its requests with the SEC and CFTC concurrently.

Under Proposed CFTC Rule 41.48(b)(2), an entity that elects to implement a proposed rule change by filing a written certification with the CFTC in accordance with Section 5c(c)(1) of the CEA [293] would be required to provide a copy of the proposed rule change and any accompanying documentation that was filed with the SEC, concurrent with the SEC filing. Promptly after the SEC approves the proposed rule change, the designated contract market or registered DTF would file the written certification with the CFTC.

The CFTC requested comments on an alternative procedure under which an entity would file its written certification with the CFTC at the same time as it files the proposed rule change with the SEC, rather than after the SEC approves the proposed rule change.

The CFTC did not receive any comments relating to this issue, and it is therefore adopting the notification provisions as proposed, in all material respects.

**III. Paperwork Reduction Act**

*A. CFTC*

The Paperwork Reduction Act of 1995 (''PRA'') [294] imposes certain requirements on federal agencies (including the CFTC and the SEC) in connection with their conducting or sponsoring any collection of information as defined by the PRA. The Final Rules that have been adopted do not require a new collection of information on the part of any entities subject to these rules. Accordingly, the requirements imposed by the PRA are not applicable to these rules.

*B. SEC*

The Paperwork Reduction Act does not apply because the rules do not impose recordkeeping or information collection requirements, or other collections of information that require

under the SEC's net capital rule. Exchange Act Rule 15c3–1(c)(2)(x)(D) (17 CFR 240.15c3–1(c)(2)(x)(D)).

[280] Under Regulation T, if any initial margin call is not met in full within one payment period after a margin deficiency is created or increased, a creditor must liquidate securities sufficient to meet the margin call or to eliminate any margin deficiency existing on the day such liquidation is required, whichever is less (unless the margin deficiency created or increased is $1000 or less). 12 CFR 220.4(d). The Regulation T payment period is currently five business days, although it may be extended for one or more limited periods upon application by the creditor to its examining authority. *Id.* at 12 CFR 220.2, 220.4(c)(3). NYSE Rule 431 requires the amount of maintenance margin or mark to market required by any provision of the NYSE Rule 431 to be obtained within fifteen business days from the date such deficiency occurred, unless the Exchange has specifically granted the member organization additional time. NYSE Rule 431(f)(6).

[281] CFTC Rule 41.48(c); SEC Rule 406(c).

[282] A notice-designated contract market is a national securities exchange registered pursuant to section 6(a) of the Exchange Act (15 U.S.C. 78f(a)), a national securities association registered pursuant to section 15A(a) of the Exchange Act (15 U.S.C. 78*o*–3(a)), or an alternative trading system (''ATS'') as defined in Section 1a(1) of the CEA (7 U.S.C. 1a(1)) that is designated as a contract market pursuant to Section 5f of the CEA (7 U.S.C. 7b–1).

[283] 15 U.S.C. 78s(b).

[284] 7 U.S.C. 7a–2(c). Notice-designated contract markets are exempt from the requirements of Section 5c of the CEA pursuant to Section 5f(b)(1)(D) of the CEA (7 U.S.C. 7a–2(b)(1)(D)).

[285] *See also* 66 FR 42256 (August 10, 2001) (CFTC rules implementing these procedures, codified in a new Part 40 of Title 17, CFTC Rules 40.5 and 40.6).

[286] 7 U.S.C. 7a–2(c)(1).

[287] 7 U.S.C. 7a–2(c)(2).

[288] 15 U.S.C. 78s(b)(2).

[289] The copy may be submitted to the CFTC electronically, by facsimile, or by delivery of a hard copy.

[290] 7 U.S.C. 7a–2.

[291] 7 U.S.C. 7a–2(c).

[292] 7 U.S.C. 7a–2(c)(2).

[293] 7 U.S.C. 7a–2(c)(1).

[294] 44 U.S.C. 3501 *et seq.*

the approval of the Office of Management and Budget under 44 U.S.C. 3501, *et. seq.*

**IV. Costs and Benefits of the Final Rules**

*A. CFTC*

Section 15(a) of the CEA [295] requires that the CFTC, before promulgating a regulation under the CEA or issuing an order, consider the costs and benefits of its action. By its terms, Section 15(a) does not require the CFTC to quantify the costs and benefits of a new rule or determine whether the benefits of the rule outweigh its costs. Rather, Section 15(a) simply requires the CFTC to ''consider the costs and benefits'' of its action.

Section 15(a) further specifies that costs and benefits shall be evaluated in light of the following considerations: (1) Protection of market participants and the public; (2) efficiency, competitiveness, and financial integrity of futures markets; (3) price discovery; (4) sound risk management practices; and (5) other public interest considerations. Accordingly, the CFTC could, in its discretion, give greater weight to any one of the five considerations and could, in its discretion, determine that, notwithstanding its costs, a particular rule was necessary or appropriate to protect the public interest or to effectuate any of the provisions or to accomplish any of the purposes of the CEA.

This rulemaking constitutes a package of related rule provisions. The Final Rules establish the amount of initial and maintenance customer margin for transactions in security futures. The CFTC believes that the customer margin requirements for security futures are, in accordance with the CFMA, consistent with the margin requirements for comparable option contracts traded on any exchange registered pursuant to section 6(a) of the Exchange Act.[296] The CFTC has evaluated the costs and benefits of these rules in light of the specific considerations identified in Section 15(a) of the CEA:

1. Protection of market participants and the public. In general, the Final Rules should further the protection of market participants and the public.

2. Efficiency and competition. As noted above, the margin requirements are consistent with the margin requirements for comparable option contracts traded on any exchange registered pursuant to section 6(a) of the Exchange Act, as required under the CFMA. To the extent that the Final Rules permit FCMs and futures exchanges to maintain existing operational and business practices, the Final Rules enable market participants to minimize operational costs associated with the introduction of security futures, and preserve meaningful customer choice as to the type of account (securities or futures) in which the customer may elect to carry security futures. In certain respects, the Final Rules promote a level playing field between options exchanges and security futures exchanges, and between broker-dealers/securities accounts and FCMs/futures accounts. Accordingly, the Final Rules are not expected to have a negative impact on competition.

3. Financial integrity of futures markets and price discovery. The Final Rules should have a positive effect on the financial integrity of security futures markets by protecting against systemic risk.

4. Sound risk management practices. The Final Rules are consistent with sound risk management practices.

5. Other public considerations. The Final Rules are expected to preserve the financial integrity of markets trading security futures and prevent systemic risk, thereby benefiting the public. The CFTC believes that the Final Rules give rise to an acceptable level of cost in light of the expected benefits of the rules.

After evaluating these considerations, the CFTC has determined to adopt the Final Rules discussed above. The CFTC invited public comment on its cost-benefit analysis, but did not receive any comments in response to this invitation. Moreover, insofar as the comments received raise any matters that might be deemed to relate to the cost-benefit analysis, the CFTC has addressed such comments in the foregoing discussion and through modifications to the Proposed Rules.

*B. SEC*

Section 7 of the Exchange Act, which governs the amount of credit that may be initially extended and subsequently maintained on any security (other than an exempted security), was amended by the CFMA to add provisions related to margin for security futures. On March 6, 2001, the Federal Reserve Board delegated its authority under section 7(c)(2) of the Exchange Act to establish margin requirements for security futures to the SEC and CFTC. The Final Rules establish such margin requirements.

Specifically, the CFMA amended section 7(c) of the Exchange Act to require that the rules preserve the financial integrity of markets trading security futures products, prevent systemic risk, and to require that: (1) The margin requirements for a security future be consistent with the margin requirements for comparable option contracts traded on any exchange registered pursuant to section 6(a) of the Exchange Act; [297] and (2) the initial and maintenance margin levels for a security future not be lower than the lowest level of margin, exclusive of premium, required for any comparable option contract traded on any exchange registered pursuant to section 6(a) of the Exchange Act, other than an option on a security future, and to ensure that the margin requirements (other than levels of margin), including the type, form, and use of collateral for security futures, are and remain consistent with the requirements established by the Federal Reserve Board under Regulation T.

The SEC provided an estimate of the costs and benefits of the Proposed Rules, and requested comments on all aspects of its estimate, including identification of any additional costs or benefits of the proposed rules. The SEC encouraged commenters to identify and supply any relevant data, analysis and estimates concerning the costs and benefits of the proposed rules. Several commenters expressed the view that certain aspects of the Proposed Rules would impose costs. However, none of the commenters provided specific data regarding the overall costs and benefits of the Proposed Rules.

The SEC has considered the costs and benefits of the Final Rules. We are sensitive to the costs and benefits that might arise from compliance with our rules and amendments. In response to commenters' concerns about the potential costs related to the application of Regulation T to all transactions in security futures, the Commissions are adopting stand alone margin rules for security futures that apply only certain requirements of Regulation T that are necessary to satisfy the statutory requirement that the margin requirements for security futures be and remain consistent with Regulation T. The SEC understands that some aspects of the Final Rules may impose costs on some persons or entities. However, the Final Rules are being adopted pursuant to statutory directive and are necessary to permit trading in security futures. In addition, the SEC notes that the Final Rules will apply only to those broker-dealers and FCMs that choose to do a business in security futures.

[295] 7 U.S.C. 19(a).

[296] 15 U.S.C. 78f(a).

[297] 15 U.S.C. 78f(a).

1. Costs

The Final Rules will impose administrative costs on security futures intermediaries. Further, security futures intermediaries are responsible for complying with the Final Rules and thus will incur various costs. The SEC has identified below areas where the Final Rules may impose costs.

a. *Compliance with Regulation T.* The Proposed Rules would have applied Regulation T to financial relations between brokers, dealers, and members of national securities exchanges and their customers with respect to transactions in security futures and any related securities or futures contracts that are used to offset positions in such security futures. Accordingly, under the Proposed Rules, Regulation T would have applied to all transactions in security futures, whether they were effected in a securities account or a futures account. Several commenters expressed concern that applying Regulation T to security futures in futures accounts would result in substantial costs to FCMs resulting from the need to reprogram their margin systems to comply with Regulation T.

As noted above, the Final Rules do not apply Regulation T to all security futures transactions. Instead, as noted above, the Final Rules incorporate certain requirements of Regulation T as necessary to satisfy the requirement under section 7(c)(2) of the Exchange Act that the Final Rules be and remain consistent with Regulation T. The SEC believes that this aspect of the Final Rules should only impose minimal administrative costs on security futures intermediaries. For broker-dealers and members of national securities exchanges that trade security futures, there should be little or no cost imposed by this aspect of the Final Rules because they already are subject to Regulation T for other securities transactions. For FCMs, there will be some administrative costs associated with this aspect of the final rules to program their systems to comply with the specific provisions of Regulation T that are included in the Final Rules.

b. *Levels of Margin.* SEC Rule 403(b)(1) sets the level of margin at 20 percent of current market value, which is the same level that would have been set under the Proposed Rules. The 20 percent level is necessary to fulfill the requirement under Section 7(c)(2)(B)(iii) that the margin requirements for security futures be consistent with the margin requirements for comparable exchange-traded options.[298]

When the Proposed Rules were issued for comment, the SEC noted that the 20 percent margin level could appear to be high when compared to margining methodologies currently used for futures other than security futures. As a result, a potential cost of the margin levels is that they may lead to reduced interest in trading security futures and, therefore, foregone hedging opportunities.

However, while margin requirements on futures other than security futures generally range from 2–10 percent,[299] SEC staff estimated that applying traditional futures risk-based margining methods to security futures would require margin of greater than 10 percent.[300] In addition, however, SEC staff estimated that the proposed margin levels would reduce the chances that a margin account would not contain sufficient funds to cover a given day's price movement from approximately 5 percent using traditional risk-based futures margining to 0.3 percent. Further, economic research has thus far not been able to establish a strong relationship between futures margin levels and interest in the product.[301] Therefore, while the margin levels under the Final Rules may impose a cost, the SEC believes that the margin levels should lower chances of customer default and therefore lower systemic risk to the markets. For these reasons, and the statutory mandate that requires comparability between security futures margin and options margin, the SEC believes that the margin levels adopted in the Final Rules are appropriate.

c. *Computation of Margin.* The Final Rules require security futures intermediaries to compute and collect, on a daily basis, required margin for each customer's security future carried or held by such entity. This requirement is designed to assure contract performance and the integrity of the marketplace. In addition, all security futures intermediaries will pay or receive daily variation settlement (*i.e.,* the daily net gain or loss on a security future) as a result of all open futures positions being marked to current market value by the clearing organization.

The SEC believes that the daily required computation of the initial and maintenance margin requirements and the collection and disbursement of daily settlement variation for security futures by security futures intermediaries will require these entities to program or reprogram their computer systems to implement the margin computations and the settlement variation procedures for security futures. These entities may also incur additional data storage costs and resource costs associated with these calculations.

d. *Undermargined Accounts.* SEC Rule 406(a) requires a security futures intermediary to take a deduction in computing its net capital to the extent that any margin call required by the Final Rules is not met in full. In addition, SEC Rule 406(b) requires that a security futures intermediary liquidate positions in a prompt and orderly manner in any account in which security futures are held at any time there is a liquidating deficit in the account. The SEC believes that these aspects of the Final Rules may impose costs on security futures intermediaries by requiring them to evaluate information to determine for each customer's account involving security futures when margin calls required under the Final Rules have not been met. Security futures intermediaries may also incur costs in the form of capital charges with respect to customers that do not meet margin calls. In addition, security futures intermediaries that have customer accounts that fall into a liquidating deficit may incur costs in complying with the mandatory liquidation provisions of the Final Rules.

2. Benefits

The benefits of the Final Rules are related to the benefits that will accrue as a result of the enactment of the CFMA. By repealing the ban on futures

[298] 15 U.S.C. 78g(c)(2)(B)(iii).

[299] Catrath, A., Adrangi, B and Alleder, M. (2001), *The Impact of Margins in Futures Markets: Evidence from the Gold and Silver Markets,* The Quarterly Review of Economics and Finance, 279.

[300] The SEC staff examined all securities with average daily trading volume greater than 50,000, using data from 2000 from the Center for Research in Security Prices (''CRSP''). Based on these data, the SEC staff calculated the daily price returns and the 30-day historical price volatility for each of the securities examined.

Based on the assumption that cash and futures prices typically move together, the SEC staff conducted a simulation, using actual security price movements as estimates for would be futures price movements. Based upon these security futures' price estimates, the staff determined the margin requirements for each of these security futures under both the 20 percent strategy-based approach and the traditional risk-based futures approach. The staff examined how often the funds attributable to margin requirements are insufficient to cover the daily price movements of these security futures. This is relevant to the examination of systemic risk because a necessary condition for customer default to occur is the depletion of the funds attributable to margin requirements (assuming no market risk to close out such position).

[301] For further details on these issues, *see* Fishe, R. P. H., Goldberg, L.G., (1986), *The Effects of Margins on Trading in Futures Markets,* Journal of Futures Markets, 261; Fishe, P.H., Goldberg, L.A., Gosnell, T.F. and Sinha, S. (1990), *Margin Requirement in Futures Markets: Their Relationship to Price Volatility,* The Journal of Futures Markets, 541.

on single securities and futures on narrow-based security indexes, the CFMA will enable a greater variety of financial products to be traded that potentially could facilitate price discovery and the ability to hedge. Investors will benefit by having a wider choice of financial products to buy and sell, and markets and market participants will benefit by having the ability to trade these products. These rules are a prerequisite to the commencement of trading in the new products, and therefore they are also a prerequisite to any benefits that may derive from the availability of these products.

a. *Benefits to Security Futures Intermediaries.* SEC Rule 403(b)(1) provides that the minimum initial and maintenance margin levels for each security future would be 20 percent of the current market value of such contract. Moreover, SEC Rule 404(b) provides that a security futures intermediary may accept as collateral cash, margin securities, exempted securities, or other collateral permitted under Regulation T, as well as shares in money market mutual funds, to satisfy a margin deficiency. The SEC believes that these aspects of the Final Rules will provide sound protection from customer default by reducing chances of depletion of margin accounts. Accordingly, the Final Rules should reduce systemic risk associated with the trading of these new products.

b. *Benefits to Customers.* SEC Rule 403(b)(2) provides that customers be permitted to offset positions involving security futures with certain related securities or futures. Such offsets would be proposed by regulatory authority rules that would be approved by the SEC pursuant to section 19(b)(2) of the Exchange Act and, as applicable, by the CFTC pursuant to Section 5c(c) of the CEA if such offsets were consistent with the requirements of section 7(c)(2)(B) of the Exchange Act, including the requirement that margin requirements for security futures be no less restrictive than those imposed on options. These offsets will provide benefits to customers because they will recognize the hedged nature of certain specified combined strategies and will permit lower margin requirements that better reflect the true risk of those strategies.

## V. Consideration of Burden on Competition, Promotion of Efficiency and Capital Formation

Section 3(f) of the Exchange requires the SEC, when it is engaged in rulemaking and is required to consider or determine whether an action is necessary or appropriate in the public interest, to consider whether the action would promote efficiency, competition, and capital formation.[302] Section 23(a)(2) requires the SEC, in adopting rules under the Exchange Act, to consider the impact any rule would have on competition.[303] Section 23(a)(2) further provides that the SEC may not adopt a rule not necessary or appropriate in furtherance of the purposes of the Exchange Act. In the proposing release, the SEC requested comments on these statutory considerations. The SEC received no comments on the issue of competition, efficiency, or capital formation.

The SEC believes that the rules should promote efficiency by setting forth clear guidelines for security futures intermediaries when collecting customer margin related to security futures. Further, the SEC believes that the rules will provide sound protection from customer default by reducing the chances of depletion of margin accounts, thereby reducing systemic risk associated with the trading of these new products.

The SEC also believes that the rules would not impose any significant burden on competition. The Final Rules provide that security futures generally will be governed by the existing margin rules applicable to securities accounts and to futures accounts, which are not identical in all cases. However, the Final Rules also include uniform provisions, applicable to security futures regardless of the type of account in which they are held, which are designed to prevent competitive advantages from arising simply because security futures are held in one type of account rather than the other. The rules serve only to set forth margin requirements for security futures. In addition, the Final Rules satisfy section 7(c)(2)(B)(iii) of the Exchange Act, which, among other things, requires that the margin rules for security futures be consistent with those for comparable exchange-traded options. Accordingly, the Final Rules are designed to prevent competitive advantages from arising solely out of differences between the margin requirements for security futures and those for exchange-traded options. Lastly, the SEC believes that the rules will not have any impact on capital formation because the rules, as adopted, merely establish requirements governing the collection of customer margin. The SEC reiterates that the margin requirements would protect security futures intermediaries from customers' default, thus encouraging participation by these market participants in the trading of futures on both single securities and narrow-based security indexes. Therefore, the SEC believes that there could be an increased demand for the underlying securities, resulting in increased capital formation.

## VI. Regulatory Flexibility Act

### *A. CFTC*

The Regulatory Flexibility Act (''RFA'')[304] requires that federal agencies, in promulgating rules, consider the impact of those rules on small entities. The Final Rules will affect designated contract markets, registered DTFs, and FCMs. The CFTC has previously established certain definitions of ''small entities'' to be used by the CFTC in evaluating the impact of its rules on small entities in accordance with the RFA.[305]

In its previous determinations, the CFTC has concluded that contract markets are not small entities for purposes of the RFA, based on the vital role contract markets play in the national economy and the significant amount of resources required to operate as SROs.[306] Recently, the CFTC determined that notice-designated contract markets are not small entities for purposes of the RFA.[307] In addition, the CFTC has determined that other trading facilities subject to its jurisdiction, including registered DTFs, are not small entities for purposes of the RFA.[308]

In the Proposing Release, it was observed that the CFTC has previously determined that FCMs are not small entities for purposes of the RFA, based on the fiduciary nature of FCM-customer relationships as well as the requirements that FCMs meet certain minimum financial requirements.[309] The CFTC proposed to determine that notice-registered FCMs,[310] for the reasons applicable to FCMs registered in accordance with Section 4f(a)(1) of the CEA,[311] are not small entities for purposes of the RFA. Brokers or dealers that carry customer accounts and receive or hold funds for those customers, and are notice-registered as FCMs for the purpose of trading security futures, similarly have a fiduciary

[302] 15 U.S.C. 78c(f).

[303] 15 U.S.C. 78w(a)(2).

[304] 5 U.S.C. 601 *et seq.*

[305] 47 FR 18618–21 (April 30, 1982).

[306] *Id.* at 18619.

[307] 66 FR 44960, 44964 (August 27, 2001).

[308] 66 FR 42256, 42268 (August 10, 2001).

[309] 47 FR at 18619.

[310] A broker or dealer that is registered with the SEC and that limits its futures activities to those involving security futures products, may notice register with the CFTC as an FCM in accordance with Section 4f(a)(2) of the CEA (7 U.S.C. 6f(a)(2)).

[311] 7 U.S.C. 6f(a)(1).

relationship with their customers and must meet analogous minimum financial requirements.[312]

The CFTC invited the public to comment on its proposed determination that notice-registered FCMs would not be small entities for purposes of the RFA. The CFTC also invited comments on its finding that there would not be a significant economic impact on a substantial number of small entities. The CFTC notes that no comments were received regarding either of these issues. Additionally, the CFTC notes that Congress mandated that customer margin for security futures be consistent with the margin requirements for comparable option contracts traded on any exchange registered pursuant to section 6(a) of the Exchange Act.[313] In adopting the Final Rules, the Commissions have striven to fulfill this requirement in the least burdensome way possible. The CFTC hereby determines that notice-registered FCMs are not small entities for purposes of the RFA. Further, the CFTC believes that the Final Rules will not have a significant economic impact on a substantial number of small entities.

*B. SEC*

Pursuant to section 605(b) of the Regulatory Flexibility Act (''RFA''),[314] the SEC certified that the adopted rule would not have a significant economic impact on a substantial number of small entities. This certification was attached to the Proposing Release No. 34–50720 (October 4, 2001) as Appendix A.[315] The SEC solicited comments concerning the impact on small entities and the RFA certification, but received no comments.

**VII. Statutory Basis**

The SEC is adopting Rules 400 through 406 pursuant to the Exchange Act, particularly Sections, 3(b), 6, 7(c), 15A, and 23(a). Further, these rules are adopted pursuant to the authority delegated jointly to the SEC, together with the CFTC, by the Federal Reserve Board in accordance with Exchange Act Section 7(c)(2)(A).

**Text of Rules**

**List of Subjects**

*17 CFR Part 41*

Brokers, Margin, Reporting and recordkeeping requirements, Security futures products.

*17 CFR Part 242*

Brokers, Securities.

**Commodity Futures Trading Commission**

**17 CFR Chapter I**

In accordance with the foregoing, Title 17, chapter I of the Code of Federal Regulations is amended as follows:

## PART 41—SECURITY FUTURES PRODUCTS

1. The authority citation for Part 41 is revised to read as follows:

**Authority:** Sections 206, 251 and 252, Pub. L. 106–554, 114 Stat. 2763; 7 U.S.C. 1a, 2, 6f, 6j, 7a–2, 12a; 15 U.S.C. 78g(c)(2).

2. The part heading for Part 41 is revised to read as set forth above.

**§ 41.41 [Redesignated]**

3. In Part 41, § 41.41 is redesignated as § 41.3.

4. Part 41 is amended by adding Subpart E (§§ 41.42 through 41.49) to read as follows:

**Subpart E—Customer Accounts and Margin Requirements**

Sec.



## Subpart E—Customer Accounts and Margin Requirements

**§ 41.42 Customer margin requirements for security futures—authority, purpose, interpretation, and scope.**

(a) *Authority and purpose.* Subpart E, §§ 41.42 through 41.49, and 17 CFR 242.400 through 242.406 (''this Regulation'') are issued by the Commodity Futures Trading Commission (''Commission'') jointly with the Securities and Exchange Commission (''SEC''), pursuant to authority delegated by the Board of Governors of the Federal Reserve System under section 7(c)(2)(A) of the Securities Exchange Act of 1934 (''Exchange Act''). The principal purpose of this Regulation (Subpart E, §§ 41.42 through 41.49) is to regulate customer margin collected by brokers, dealers, and members of national securities exchanges, including futures commission merchants required to register as brokers or dealers under section 15(b)(11) of the Exchange Act, relating to security futures.

(b) *Interpretation.* This Regulation (Subpart E, §§ 41.42 through 41.49) shall be jointly interpreted by the SEC and the Commission, consistent with the criteria set forth in clauses (i) through (iv) of section 7(c)(2)(B) of the Exchange Act and the provisions of Regulation T (12 CFR part 220).

(c) *Scope.*

(1) This Regulation (Subpart E, §§ 41.42 through 41.49) does not preclude a self-regulatory authority, under rules that are effective in accordance with section 19(b)(2) of the Exchange Act or section 19(b)(7) of the Exchange Act and, as applicable, section 5c(c) of the Commodity Exchange Act (''Act''), or a security futures intermediary from imposing additional margin requirements on security futures, including higher initial or maintenance margin levels, consistent with this Regulation (Subpart E, §§ 41.42 through 41.49), or from taking appropriate action to preserve its financial integrity.

(2) This Regulation (Subpart E, §§ 41.42 through 41.49) does not apply to:

(i) Financial relations between a customer and a security futures intermediary to the extent that they comply with a portfolio margining system under rules that meet the criteria set forth in section 7(c)(2)(B) of the Exchange Act and that are effective in accordance with section 19(b)(2) of the Exchange Act and, as applicable, section 5c(c) of the Act;

(ii) Financial relations between a security futures intermediary and a foreign person involving security futures traded on or subject to the rules of a foreign board of trade;

(iii) Margin requirements that clearing agencies registered under section 17A of the Exchange Act or derivatives clearing organizations registered under section 5b of the Act impose on their members;

(iv) Financial relations between a security futures intermediary and a person based on a good faith determination by the security futures intermediary that such person is an exempted person; and

(v) Financial relations between a security futures intermediary and, or arranged by a security futures intermediary for, a person relating to trading in security futures by such person for its own account, if such person:

(A) Is a member of a national securities exchange or national securities association registered pursuant to section 15A(a) of the Exchange Act; and

[312] *See* Exchange Act Rule 15c3–1(a)(2), 17 CFR 240.15c3–1(a)(2).

[313] 15 U.S.C. 78f(a).

[314] 5 U.S.C. 601 *et seq.*

[315] *See* Proposing Release, *supra* note 6.

(B) Is registered with such exchange or such association as a security futures dealer pursuant to rules that are effective in accordance with section 19(b)(2) of the Exchange Act and, as applicable, section 5c(c) of the Act, that:

(*1*) Require such member to be registered as a floor trader or a floor broker with the Commission under section 4f(a)(1) of the Act, or as a dealer with the SEC under section 15(b) of the Exchange Act;

(*2*) Require such member to maintain records sufficient to prove compliance with this paragraph (c)(2)(v) and the rules of the exchange or association of which it is a member;

(*3*) Require such member to hold itself out as being willing to buy and sell security futures for its own account on a regular or continuous basis; and

(*4*) Provide for disciplinary action, including revocation of such member's registration as a security futures dealer, for such member's failure to comply with this Regulation (Subpart E, §§ 41.42 through 41.49) or the rules of the exchange or association.

(d) *Exemption.* The Commission may exempt, either unconditionally or on specified terms and conditions, financial relations involving any security futures intermediary, customer, position, or transaction, or any class of security futures intermediaries, customers, positions, or transactions, from one or more requirements of this Regulation (Subpart E, §§ 41.42 through 41.49), if the Commission determines that such exemption is necessary or appropriate in the public interest and consistent with the protection of customers. An exemption granted pursuant to this paragraph shall not operate as an exemption from any SEC rules. Any exemption that may be required from such rules must be obtained separately from the SEC.

**§ 41.43 Definitions.**

(a) For purposes of this Regulation (Subpart E, §§ 41.42 through 41.49) only, the following terms shall have the meanings set forth in this section.

(1) *Applicable margin rules* and *margin rules applicable to an account* mean the rules and regulations applicable to financial relations between a security futures intermediary and a customer with respect to security futures and related positions carried in a securities account or futures account as provided in § 41.44(a) of this subpart.

(2) *Broker* shall have the meaning provided in section 3(a)(4) of the Exchange Act.

(3) *Contract multiplier* means the number of units of a narrow-based security index expressed as a dollar amount, in accordance with the terms of the security future contract.

(4) *Current market value* means, on any day:

(i) With respect to a security future:

(A) If the instrument underlying such security future is a stock, the product of the daily settlement price of such security future as shown by any regularly published reporting or quotation service, and the applicable number of shares per contract; or

(B) If the instrument underlying such security future is a narrow-based security index, as defined in section 1a(25)(A) of the Act, the product of the daily settlement price of such security future as shown by any regularly published reporting or quotation service, and the applicable contract multiplier.

(ii) With respect to a security other than a security future, the most recent closing sale price of the security, as shown by any regularly published reporting or quotation service. If there is no recent closing sale price, the security futures intermediary may use any reasonable estimate of the market value of the security as of the most recent close of business.

(5) *Customer* excludes an exempted person and includes:

(i) Any person or persons acting jointly:

(A) On whose behalf a security futures intermediary effects a security futures transaction or carries a security futures position; or

(B) Who would be considered a customer of the security futures intermediary according to the ordinary usage of the trade;

(ii) Any partner in a security futures intermediary that is organized as a partnership who would be considered a customer of the security futures intermediary absent the partnership relationship; and

(iii) Any joint venture in which a security futures intermediary participates and which would be considered a customer of the security futures intermediary if the security futures intermediary were not a participant.

(6) *Daily settlement price* means, with respect to a security future, the settlement price of such security future determined at the close of trading each day, under the rules of the applicable exchange, clearing agency, or derivatives clearing organization.

(7) *Dealer* shall have the meaning provided in section 3(a)(5) of the Exchange Act.

(8) *Equity* means the equity or margin equity in a securities or futures account, as computed in accordance with the margin rules applicable to the account and subject to adjustment under § 41.46(c), (d) and (e) of this subpart.

(9) *Exempted person* means:

(i) A member of a national securities exchange, a registered broker or dealer, or a registered futures commission merchant, a substantial portion of whose business consists of transactions in securities, commodity futures, or commodity options with persons other than brokers, dealers, futures commission merchants, floor brokers, or floor traders, and includes a person who:

(A) Maintains at least 1000 active accounts on an annual basis for persons other than brokers, dealers, persons associated with a broker or dealer, futures commission merchants, floor brokers, floor traders, and persons affiliated with a futures commission merchant, floor broker, or floor trader that are effecting transactions in securities, commodity futures, or commodity options;

(B) Earns at least $10 million in gross revenues on an annual basis from transactions in securities, commodity futures, or commodity options with persons other than brokers, dealers, persons associated with a broker or dealer, futures commission merchants, floor brokers, floor traders, and persons affiliated with a futures commission merchant, floor broker, or floor trader; or

(C) Earns at least 10 percent of its gross revenues on an annual basis from transactions in securities, commodity futures, or commodity options with persons other than brokers, dealers, persons associated with a broker or dealer, futures commission merchants, floor brokers, floor traders, and persons affiliated with a futures commission merchant, floor broker, or floor trader.

(ii) For purposes of paragraph (a)(9)(i) of this section only, *persons affiliated with* a futures commission merchant, floor broker, or floor trader means any partner, officer, director, or branch manager of such futures commission merchant, floor broker, or floor trader (or any person occupying a similar status or performing similar functions), any person directly or indirectly controlling, controlled by, or under common control with such futures commission merchant, floor broker, or floor trader, or any employee of such a futures commission merchant, floor broker, or floor trader.

(iii) A member of a national securities exchange, a registered broker or dealer, or a registered futures commission merchant that has been in existence for less than one year may meet the

definition of exempted person based on a six-month period.

(10) *Exempted security* shall have the meaning provided in section 3(a)(12) of the Exchange Act.

(11) *Floor broker* shall have the meaning provided in section 1a(16) of the Act.

(12) *Floor trader* shall have the meaning provided in section 1a(17) of the Act.

(13) *Futures account* shall have the meaning provided in § 1.3(vv) of this chapter.

(14) *Futures commission merchant* shall have the meaning provided in section 1a(20) of the Act.

(15) *Good faith,* with respect to making a determination or accepting a statement concerning financial relations with a person, means that the security futures intermediary is alert to the circumstances surrounding such financial relations, and if in possession of information that would cause a prudent person not to make the determination or accept the notice or certification without inquiry, investigates and is satisfied that it is correct.

(16) *Listed option* means a put or call option that is:

(i) Issued by a clearing agency that is registered under section 17A of the Exchange Act or cleared and guaranteed by a derivatives clearing organization that is registered under section 5b of the Act; and

(ii) Traded on or subject to the rules of a self-regulatory authority.

(17) *Margin call* means a demand by a security futures intermediary to a customer for a deposit of cash, securities or other assets to satisfy the required margin for security futures or related positions or a special margin requirement.

(18) *Margin deficiency* means the amount by which the required margin in an account is not satisfied by the equity in the account, as computed in accordance with § 41.46 of this subpart.

(19) *Margin equity security* shall have the meaning provided in Regulation T.

(20) *Margin security* shall have the meaning provided in Regulation T.

(21) *Member* shall have the meaning provided in section 3(a)(3) of the Exchange Act, and shall include persons registered under section 15(b)(11) of the Exchange Act that are permitted to effect transactions on a national securities exchange without the services of another person acting as executing broker.

(22) *Money market mutual fund* means any security issued by an investment company registered under section 8 of the Investment Company Act of 1940 that is considered a money market fund under § 270.2a-7 of this title.

(23) *Persons associated with a broker or dealer* shall have the meaning provided in section 3(a)(18) of the Exchange Act.

(24) *Regulation T* means Regulation T promulgated by the Board of Governors of the Federal Reserve System, 12 CFR part 220, as amended from time to time.

(25) *Regulation T collateral value,* with respect to a security, means the current market value of the security reduced by the percentage of required margin for a position in the security held in a margin account under Regulation T.

(26) *Related position,* with respect to a security future, means any position in an account that is combined with the security future to create an offsetting position as provided in § 41.45(b)(2) of this subpart.

(27) *Related transaction,* with respect to a position or transaction in a security future, means:

(i) Any transaction that creates, eliminates, increases or reduces an offsetting position involving a security future and a related position, as provided in § 41.45(b)(2) of this subpart; or

(ii) Any deposit or withdrawal of margin for the security future or a related position, except as provided in § 41.47(b) of this subpart.

(28) *Securities account* shall have the meaning provided in § 1.3(ww) of this chapter.

(29) *Security futures intermediary* means any creditor as defined in Regulation T with respect to its financial relations with any person involving security futures, including:

(i) Any futures commission merchant;

(ii) Any partner, officer, director, or branch manager (or person occupying a similar status or performing similar functions) of a futures commission merchant;

(iii) Any person directly or indirectly controlling, controlled by, or under common control with (except for business entities controlling or under common control with) a futures commission merchant; and

(iv) Any employee of a futures commission merchant (except an employee whose functions are solely clerical or ministerial).

(30) *Self-regulatory authority* means a national securities exchange registered under section 6 of the Exchange Act, a national securities association registered under section 15A of the Exchange Act, a contract market registered under section 5 of the Act or section 5f of the Act, or a derivatives transaction execution facility registered under section 5a of the Act.

(31) *Special margin requirement* shall have the meaning provided in § 41.46(e)(1)(ii) of this subpart.

(32) *Variation settlement* means any credit or debit to a customer account, made on a daily or intraday basis, for the purpose of marking to market a security future or any other contract that is:

(i) Issued by a clearing agency that is registered under section 17A of the Exchange Act or cleared and guaranteed by a derivatives clearing organization that is registered under section 5b of the Act; and

(ii) Traded on or subject to the rules of a self-regulatory authority.

(b) Terms used in this Regulation (Subpart E, §§ 41.42 through 41.49) and not otherwise defined in this section shall have the meaning set forth in the margin rules applicable to the account.

(c) Terms used in this Regulation (Subpart E, §§ 41.42 through 41.49) and not otherwise defined in this section or in the margin rules applicable to the account shall have the meaning set forth in the Exchange Act and the Act; if the definitions of a term in the Exchange Act and the Act are inconsistent as applied in particular circumstances, such term shall have the meaning set forth in rules, regulations, or interpretations jointly promulgated by the SEC and the Commission.

**§ 41.44 General provisions.**

(a) *Applicable margin rules.* Except to the extent inconsistent with this Regulation (Subpart E, §§ 41.42 through 41.49):

(1) A security futures intermediary that carries a security future on behalf of a customer in a securities account shall record and conduct all financial relations with respect to such security future and related positions in accordance with Regulation T and the margin rules of the self-regulatory authorities of which the security futures intermediary is a member.

(2) A security futures intermediary that carries a security future on behalf of a customer in a futures account shall record and conduct all financial relations with respect to such security future and related positions in accordance with the margin rules of the self-regulatory authorities of which the security futures intermediary is a member.

(b) *Separation and consolidation of accounts.*

(1) The requirements for security futures and related positions in one account may not be met by considering items in any other account, except as

permitted or required under paragraph (b)(2) of this section or applicable margin rules. If withdrawals of cash, securities or other assets deposited as margin are permitted under this Regulation (Subpart E, §§ 41.42 through 41.49), bookkeeping entries shall be made when such cash, securities, or assets are used for purposes of meeting requirements in another account.

(2) Notwithstanding paragraph (b)(1) of this section, the security futures intermediary shall consider all futures accounts in which security futures and related positions are held that are within the same regulatory classification or account type and are owned by the same customer to be a single account for purposes of this Regulation (Subpart E, §§ 41.42 through 41.49). The security futures intermediary may combine such accounts with other futures accounts that are within the same regulatory classification or account type and are owned by the same customer for purposes of computing a customer's overall margin requirement, as permitted or required by applicable margin rules.

(c) *Accounts of partners.* If a partner of the security futures intermediary has an account with the security futures intermediary in which security futures or related positions are held, the security futures intermediary shall disregard the partner's financial relations with the firm (as shown in the partner's capital and ordinary drawing accounts) in calculating the margin or equity of any such account.

(d) *Contribution to joint venture.* If an account in which security futures or related positions are held is the account of a joint venture in which the security futures intermediary participates, any interest of the security futures intermediary in the joint account in excess of the interest which the security futures intermediary would have on the basis of its right to share in the profits shall be margined in accordance with this Regulation (Subpart E, §§ 41.42 through 41.49).

(e) *Extensions of credit.* (1) No security futures intermediary may extend or maintain credit to or for any customer for the purpose of evading or circumventing any requirement under this Regulation (Subpart E, §§ 41.42 through 41.49).

(2) A security futures intermediary may arrange for the extension or maintenance of credit to or for any customer by any person, provided that the security futures intermediary does not willfully arrange credit that would constitute a violation of Regulation T, U or X of the Board of Governors of the Federal Reserve System (12 CFR parts 220, 221, and 224) by such person.

(f) *Change in exempted person status.* Once a person ceases to qualify as an exempted person, it shall notify the security futures intermediary of this fact before entering into any new security futures transaction or related transaction that would require additional margin to be deposited under this Regulation (Subpart E, §§ 41.42 through 41.49). Financial relations with respect to any such transactions shall be subject to the provisions of this Regulation (Subpart E, §§ 41.42 through 41.49).

### § 41.45 Required margin.

(a) *Applicability.* Each security futures intermediary shall determine the required margin for the security futures and related positions held on behalf of a customer in a securities account or futures account as set forth in this section.

(b) *Required margin.*—(1) *General rule.* The required margin for each long or short position in a security future shall be twenty (20) percent of the current market value of such security future.

(2) *Offsetting positions.* Notwithstanding the margin levels specified in paragraph (b)(1) of this section, a self-regulatory authority may set the required initial or maintenance margin level for an offsetting position involving security futures and related positions at a level lower than the level that would be required under paragraph (b)(1) of this section if such positions were margined separately, pursuant to rules that meet the criteria set forth in section 7(c)(2)(B) of the Exchange Act and are effective in accordance with section 19(b)(2) of the Exchange Act and, as applicable, section 5c(c) of the Act.

(c) *Procedures for certain margin level adjustments.* An exchange registered under section 6(g) of the Exchange Act, or a national securities association registered under section 15A(k) of the Exchange Act, may raise or lower the required margin level for a security future to a level not lower than that specified in this section, in accordance with section 19(b)(7) of the Exchange Act.

### § 41.46 Type, form and use of margin.

(a) *When margin is required.* Margin is required to be deposited whenever the required margin for security futures and related positions in an account is not satisfied by the equity in the account, subject to adjustment under paragraph (c) of this section.

(b) *Acceptable margin deposits.* (1) The required margin may be satisfied by a deposit of cash, margin securities (subject to paragraph (b)(2) of this section), exempted securities, any other asset permitted under Regulation T to satisfy a margin deficiency in a securities margin account, or any combination thereof, each as valued in accordance with paragraph (c) of this section.

(2) Shares of a money market mutual fund may be accepted as a margin deposit for purposes of this Regulation (Subpart E, §§ 41.42 through 41.49), *Provided that:*

(i) The customer waives any right to redeem the shares without the consent of the security futures intermediary and instructs the fund or its transfer agent accordingly;

(ii) The security futures intermediary (or clearing agency or derivatives clearing organization with which the shares are deposited as margin) obtains the right to redeem the shares in cash, promptly upon request; and

(iii) The fund agrees to satisfy any conditions necessary or appropriate to ensure that the shares may be redeemed in cash, promptly upon request.

(c) *Adjustments.*— (1) *Futures accounts.* For purposes of this section, the equity in a futures account shall be computed in accordance with the margin rules applicable to the account, subject to the following:

(i) A security future shall have no value;

(ii) Each net long or short position in a listed option on a contract for future delivery shall be valued in accordance with the margin rules applicable to the account;

(iii) Except as permitted in paragraph (e) of this section, each margin equity security shall be valued at an amount no greater than its Regulation T collateral value;

(iv) Each other security shall be valued at an amount no greater than its current market value reduced by the percentage specified for such security in § 240.15c3–1(c)(2)(vi) of this title;

(v) Freely convertible foreign currency may be valued at an amount no greater than its daily marked-to-market U.S. dollar equivalent;

(vi) Variation settlement receivable (or payable) by an account at the close of trading on any day shall be treated as a credit (or debit) to the account on that day; and

(vii) Each other acceptable margin deposit or component of equity shall be valued at an amount no greater than its value under Regulation T.

(2) *Securities accounts.* For purposes of this section, the equity in a securities account shall be computed in accordance with the margin rules

applicable to the account, subject to the following:

(i) A security future shall have no value;

(ii) Freely convertible foreign currency may be valued at an amount no greater than its daily mark-to-market U.S. dollar equivalent; and

(iii) Variation settlement receivable (or payable) by an account at the close of trading on any day shall be treated as a credit (or debit) to the account on that day.

(d) *Satisfaction restriction.* Any transaction, position or deposit that is used to satisfy the required margin for security futures or related positions under this Regulation (Subpart E, §§ 41.42 through 41.49), including a related position, shall be unavailable to satisfy the required margin for any other position or transaction or any other requirement.

(e) *Alternative collateral valuation for margin equity securities in a futures account.*

(1) Notwithstanding paragraph (c)(1)(iii) of this section, a security futures intermediary need not value a margin equity security at its Regulation T collateral value when determining whether the required margin for the security futures and related positions in a futures account is satisfied, *provided that:*

(i) The margin equity security is valued at an amount no greater than the current market value of the security reduced by the lowest percentage level of margin required for a long position in the security held in a margin account under the rules of a national securities exchange registered pursuant to section 6(a) of the Exchange Act;

(ii) Additional margin is required to be deposited on any day when the day's security futures transactions and related transactions would create or increase a margin deficiency in the account if the margin equity securities were valued at their Regulation T collateral value, and shall be for the amount of the margin deficiency so created or increased (a ''special margin requirement''); and

(iii) Cash, securities, or other assets deposited as margin for the positions in an account are not permitted to be withdrawn from the account at any time that:

(A) Additional cash, securities, or other assets are required to be deposited as margin under this section for a transaction in the account on the same or a previous day; or

(B) The withdrawal, together with other transactions, deposits, and withdrawals on the same day, would create or increase a margin deficiency if the margin equity securities were valued at their Regulation T collateral value.

(2) All security futures transactions and related transactions on any day shall be combined to determine the amount of a special margin requirement. Additional margin deposited to satisfy a special margin requirement shall be valued at an amount no greater than its Regulation T collateral value.

(3) If the alternative collateral valuation method set forth in paragraph (e) of this section is used with respect to an account in which security futures or related positions are carried:

(i) An account that is transferred from one security futures intermediary to another may be treated as if it had been maintained by the transferee from the date of its origin, if the transferee accepts, in good faith, a signed statement of the transferor (or, if that is not practicable, of the customer), that any margin call issued under this Regulation (Subpart E, §§ 41.42 through 41.49) has been satisfied; and

(ii) An account that is transferred from one customer to another as part of a transaction, not undertaken to avoid the requirements of this Regulation (Subpart E, §§ 41.42 through 41.49), may be treated as if it had been maintained for the transferee from the date of its origin, if the security futures intermediary accepts in good faith and keeps with the transferee account a signed statement of the transferor describing the circumstances for the transfer.

(f) *Guarantee of accounts.* No guarantee of a customer's account shall be given any effect for purposes of determining whether the required margin in an account is satisfied, except as permitted under applicable margin rules.

### § 41.47 Withdrawal of margin.

(a) *By the customer.* Except as otherwise provided in § 41.46(e)(1)(ii) of this subpart, cash, securities, or other assets deposited as margin for positions in an account may be withdrawn, provided that the equity in the account after such withdrawal is sufficient to satisfy the required margin for the security futures and related positions in the account under this Regulation (Subpart E, §§ 41.42 through 41.49).

(b) *By the security futures intermediary.* Notwithstanding paragraph (a) of this section, the security futures intermediary, in its usual practice, may deduct the following items from an account in which security futures or related positions are held if they are considered in computing the balance of such account:

(1) Variation settlement payable, directly or indirectly, to a clearing agency that is registered under section 17A of the Exchange Act or a derivatives clearing organization that is registered under section 5b of the Act;

(2) Interest charged on credit maintained in the account;

(3) Communication or shipping charges with respect to transactions in the account;

(4) Payment of commissions, brokerage, taxes, storage and other charges lawfully accruing in connection with the positions and transactions in the account;

(5) Any service charges that the security futures intermediary may impose; or

(6) Any other withdrawals that are permitted from a securities margin account under Regulation T, to the extent permitted under applicable margin rules.

### § 41.48 Undermargined accounts.

(a) *Failure to satisfy margin call.* If any margin call required by this Regulation (Subpart E, §§ 41.42 through 41.49) is not met in full, the security futures intermediary shall take the deduction required with respect to an undermargined account in computing its net capital under SEC or Commission rules.

(b) *Accounts that liquidate to a deficit.* If at any time there is a liquidating deficit in an account in which security futures are held, the security futures intermediary shall take steps to liquidate positions in the account promptly and in an orderly manner.

(c) *Liquidation of undermargined accounts not required.* Notwithstanding § 41.44(a)(1) of this subpart, § 220.4(d) of Regulation T (12 CFR 220.4(d)) respecting liquidation of positions in lieu of deposit shall not apply with respect to security futures carried in a securities account.

### § 41.49 Filing proposed margin rule changes with the Commission.

(a) *Notification requirement for notice-designated contract markets.* Any self-regulatory authority that is registered with the Commission as a designated contract market under section 5f of the Act shall, when filing a proposed rule change regarding customer margin for security futures with the SEC for approval in accordance with section 19(b)(2) of the Exchange Act, concurrently provide to the Commission a copy of such proposed rule change and any accompanying documentation filed with the SEC.

(b) *Filing requirements under the Act.* Any self-regulatory authority that is

registered with the Commission as a designated contract market under section 5 of the Act or a derivatives transaction execution facility under section 5a of the Act shall, when filing a proposed rule change regarding customer margin for security futures with the SEC for approval in accordance with section 19(b)(2) of the Exchange Act, submit such proposed rule change to the Commission as follows:

(1) If the self-regulatory authority elects to request the Commission's prior approval for the proposed rule change pursuant to section 5c(c)(2) of the Act, it shall concurrently file the proposed rule change with the Commission in accordance with § 40.5 of this chapter.

(2) If the self-regulatory authority elects to implement a proposed rule change by written certification pursuant to section 5c(c)(1) of the Act, it shall concurrently provide to the Commission a copy of the proposed rule change and any accompanying documentation filed with the SEC. Promptly after obtaining SEC approval for the proposed rule change, such self-regulatory authority shall file its written certification with the Commission in accordance with § 40.6 of this chapter.

Dated: July 31, 2002.

By the Commodity Futures Trading Commission.

**Catherine D. Dixon,**

*Assistant Secretary.*

**Securities and Exchange Commission**

**17 CFR Chapter II**

In accordance with the foregoing Title 17, chapter II, part 242 of the Code of Federal Regulations is amended as follows:

## PART 242—REGULATIONS M AND ATS

1. The authority citation for part 242 is revised to read as follows:

**Authority:** 15 U.S.C. 77g, 77q(a), 77s(a), 78b, 78c, 78g(c)(2), 78i(a), 78j, 78k–1(c), 78*l*, 78m, 78mm, 78n, 78o(b), 78o(c), 78o(g), 78q(a), 78q(b), 78q(h), 78w(a), 78dd–1, 80a–23, 80a–29, and 80a–37.

2. Part 242 is amended by adding the undesignated center heading ''Regulation M'' before § 242.100.

3. An undesignated center heading and §§ 242.400 through 242.406 are added to read as follows:

**Customer Margin Requirements for Security Futures**

Sec.



**Customer Margin Requirements for Security Futures**

**§ 242.400 Customer margin requirements for security futures—authority, purpose, interpretation, and scope.**

(a) *Authority and purpose.* Sections 242.400 through 242.406 and 17 CFR 41.42 through 41.49 (''this Regulation, §§ 242.400 through 242.406'') are issued by the Securities and Exchange Commission (''Commission'') jointly with the Commodity Futures Trading Commission (''CFTC''), pursuant to authority delegated by the Board of Governors of the Federal Reserve System under section 7(c)(2)(A) of the Securities Exchange Act of 1934 (''Act'') (15 U.S.C. 78g(c)(2)(A)). The principal purpose of this Regulation (§§ 242.400 through 242.406) is to regulate customer margin collected by brokers, dealers, and members of national securities exchanges, including futures commission merchants required to register as brokers or dealers under section 15(b)(11) of the Act (15 U.S.C. 78*o*(b)(11)), relating to security futures.

(b) *Interpretation.* This Regulation (§§ 242.400 through 242.406) shall be jointly interpreted by the Commission and the CFTC, consistent with the criteria set forth in clauses (i) through (iv) of section 7(c)(2)(B) of the Act (15 U.S.C. 78g(c)(2)(B)) and the provisions of Regulation T (12 CFR part 220).

(c) *Scope.* (1) This Regulation (§§ 242.400 through 242.406) does not preclude a self-regulatory authority, under rules that are effective in accordance with section 19(b)(2) of the Act (15 U.S.C. 78s(b)(2)) or section 19(b)(7) of the Act (15 U.S.C. 78s(b)(7)) and, as applicable, section 5c(c) of the Commodity Exchange Act (''CEA'') (7 U.S.C. 7a–2(c)), or a security futures intermediary from imposing additional margin requirements on security futures, including higher initial or maintenance margin levels, consistent with this Regulation (§§ 242.400 through 242.406), or from taking appropriate action to preserve its financial integrity.

(2) This Regulation (§§ 242.400 through 242.406) does not apply to:

(i) Financial relations between a customer and a security futures intermediary to the extent that they comply with a portfolio margining system under rules that meet the criteria set forth in section 7(c)(2)(B) of the Act (15 U.S.C. 78g(c)(2)(B)) and that are effective in accordance with section 19(b)(2) of the Act (15 U.S.C. 78s(b)(2)) and, as applicable, section 5c(c) of the CEA (7 U.S.C. 7a–2(c));

(ii) Financial relations between a security futures intermediary and a foreign person involving security futures traded on or subject to the rules of a foreign board of trade;

(iii) Margin requirements that clearing agencies registered under section 17A of the Exchange Act (15 U.S.C. 78q–1) or derivatives clearing organizations registered under section 5b of the CEA (7 U.S.C. 7a–1) impose on their members;

(iv) Financial relations between a security futures intermediary and a person based on a good faith determination by the security futures intermediary that such person is an exempted person; and

(v) Financial relations between a security futures intermediary and, or arranged by a security futures intermediary for, a person relating to trading in security futures by such person for its own account, if such person:

(A) Is a member of a national securities exchange or national securities association registered pursuant to section 15A(a) of the Act (15 U.S.C. 78o–3(a)); and

(B) Is registered with such exchange or such association as a security futures dealer pursuant to rules that are effective in accordance with section 19(b)(2) of the Act (15 U.S.C. 78s(b)(2)) and, as applicable, section 5c(c) of the CEA (7 U.S.C. 7a–2(c)), that:

(*1*) Require such member to be registered as a floor trader or a floor broker with the CFTC under Section 4f(a)(1) of the CEA (7 U.S.C. 6f(a)(1)), or as a dealer with the Commission under section 15(b) of the Act (15 U.S.C. 78o(b));

(*2*) Require such member to maintain records sufficient to prove compliance with this paragraph (c)(2)(v) and the rules of the exchange or association of which it is a member;

(*3*) Require such member to hold itself out as being willing to buy and sell security futures for its own account on a regular or continuous basis; and

(*4*) Provide for disciplinary action, including revocation of such member's registration as a security futures dealer, for such member's failure to comply with this Regulation (§§ 242.400 through 242.406) or the rules of the exchange or association.

(d) *Exemption.* The Commission may exempt, either unconditionally or on specified terms and conditions, financial relations involving any security futures intermediary, customer, position, or transaction, or any class of

security futures intermediaries, customers, positions, or transactions, from one or more requirements of this Regulation (§§ 242.400 through 242.406), if the Commission determines that such exemption is necessary or appropriate in the public interest and consistent with the protection of investors. An exemption granted pursuant to this paragraph shall not operate as an exemption from any CFTC rules. Any exemption that may be required from such rules must be obtained separately from the CFTC.

**§ 242.401 Definitions.**

(a) For purposes of this Regulation (§§ 242.400 through 242.406) only, the following terms shall have the meanings set forth in this section.

(1) *Applicable margin rules* and *margin rules applicable to an account* mean the rules and regulations applicable to financial relations between a security futures intermediary and a customer with respect to security futures and related positions carried in a securities account or futures account as provided in § 242.402(a) of this Regulation (§§ 242.400 through 242.406).

(2) *Broker* shall have the meaning provided in section 3(a)(4) of the Act (15 U.S.C. 78c(a)(4)).

(3) *Contract multiplier* means the number of units of a narrow-based security index expressed as a dollar amount, in accordance with the terms of the security future contract.

(4) *Current market value* means, on any day:

(i) With respect to a security future:

(A) If the instrument underlying such security future is a stock, theproduct of the daily settlement price of such security future as shown by any regularly published reporting or quotation service, and the applicable number of shares per contract; or

(B) If the instrument underlying such security future is a narrow-based security index, as defined in section 3(a)(55)(B) of the Act (15 U.S.C. 78c(a)(55)(B)), the product of the daily settlement price of such security future as shown by any regularly published reporting or quotation service, and the applicable contract multiplier.

(ii) With respect to a security other than a security future, the most recent closing sale price of the security, as shown by any regularly published reporting or quotation service. If there is no recent closing sale price, the security futures intermediary may use any reasonable estimate of the market value of the security as of the most recent close of business.

(5) *Customer* excludes an exempted person and includes:

(i) Any person or persons acting jointly:

(A) On whose behalf a security futures intermediary effects a security futures transaction or carries a security futures position; or

(B) Who would be considered a customer of the security futures intermediary according to the ordinary usage of the trade;

(ii) Any partner in a security futures intermediary that is organized as a partnership who would be considered a customer of the security futures intermediary absent the partnership relationship; and

(iii) Any joint venture in which a security futures intermediary participates and which would be considered a customer of the security futures intermediary if the security futures intermediary were not a participant.

(6) *Daily settlement price* means, with respect to a security future, the settlement price of such security future determined at the close of trading each day, under the rules of the applicable exchange, clearing agency, or derivatives clearing organization.

(7) *Dealer* shall have the meaning provided in section 3(a)(5) of the Act (15 U.S.C. 78c(a)(5)).

(8) *Equity* means the equity or margin equity in a securities or futures account, as computed in accordance with the margin rules applicable to the account and subject to adjustment under § 242.404(c), (d) and (e) of this Regulation (§§ 242.400 through 242.406).

(9) *Exempted person* means:

(i) A member of a national securities exchange, a registered broker or dealer, or a registered futures commission merchant, a substantial portion of whose business consists of transactions in securities, commodity futures, or commodity options with persons other than brokers, dealers, futures commission merchants, floor brokers, or floor traders, and includes a person who:

(A) Maintains at least 1000 active accounts on an annual basis for persons other than brokers, dealers, persons associated with a broker or dealer, futures commission merchants, floor brokers, floor traders, and persons affiliated with a futures commission merchant, floor broker, or floor trader that are effecting transactions in securities, commodity futures, or commodity options;

(B) Earns at least $10 million in gross revenues on an annual basis from transactions in securities, commodity futures, or commodity options with persons other than brokers, dealers, persons associated with a broker or dealer, futures commission merchants, floor brokers, floor traders, and persons affiliated with a futures commission merchant, floor broker, or floor trader; or

(C) Earns at least 10 percent of its gross revenues on an annual basis from transactions in securities, commodity futures, or commodity options with persons other than brokers, dealers, persons associated with a broker or dealer, futures commission merchants, floor brokers, floor traders, and persons affiliated with a futures commission merchant, floor broker, or floor trader.

(ii) For purposes of paragraph (a)(9)(i) of this section only, persons affiliated with a futures commission merchant, floor broker, or floor trader means any partner, officer, director, or branch manager of such futures commission merchant, floor broker, or floor trader (or any person occupying a similar status or performing similar functions), any person directly or indirectly controlling, controlled by, or under common control with such futures commission merchant, floor broker, or floor trader, or any employee of such a futures commission merchant, floor broker, or floor trader.

(iii) A member of a national securities exchange, a registered broker or dealer, or a registered futures commission merchant that has been in existence for less than one year may meet the definition of exempted person based on a six-month period.

(10) *Exempted security* shall have the meaning provided in section 3(a)(12) of the Act (15 U.S.C. 78c(a)(12)).

(11) *Floor broker* shall have the meaning provided in Section 1a(16) of the CEA (7 U.S.C. 1a(16)).

(12) *Floor trader* shall have the meaning provided in Section 1a(17) of the CEA (7 U.S.C. 1a(17)).

(13) *Futures account* shall have the meaning provided in § 240.15c3–3(a) of this chapter.

(14) *Futures commission merchant* shall have the meaning provided in Section 1a of the CEA (7 U.S.C. 1a).

(15) *Good faith*, with respect to making a determination or accepting a statement concerning financial relations with a person, means that the security futures intermediary is alert to the circumstances surrounding such financial relations, and if in possession of information that would cause a prudent person not to make the determination or accept the notice or certification without inquiry, investigates and is satisfied that it is correct.

(16) *Listed option* means a put or call option that is:

(i) Issued by a clearing agency that is registered under section 17A of the Act (15 U.S.C. 17q–1) or cleared and guaranteed by a derivatives clearing organization that is registered under Section 5b of the CEA (7 U.S.C. 7a–1); and

(ii) Traded on or subject to the rules of a self-regulatory authority.

(17) *Margin call* means a demand by a security futures intermediary to a customer for a deposit of cash, securities or other assets to satisfy the required margin for security futures or related positions or a special margin requirement.

(18) *Margin deficiency* means the amount by which the required margin in an account is not satisfied by the equity in the account, as computed in accordance with § 242.404 of this Regulation (§§ 242.400 through 242.406).

(19) *Margin equity security* shall have the meaning provided in Regulation T.

(20) *Margin security* shall have the meaning provided in Regulation T.

(21) *Member* shall have the meaning provided in section 3(a)(3) of the Act (15 U.S.C. 78c(a)(3)), and shall include persons registered under section 15(b)(11) of the Act (15 U.S.C. 78*o*(b)(11)) that are permitted to effect transactions on a national securities exchange without the services of another person acting as executing broker.

(22) *Money market mutual fund* means any security issued by an investment company registered under section 8 of the Investment Company Act of 1940 (15 U.S.C. 80a–8) that is considered a money market fund under § 270.2a–7 of this chapter.

(23) *Persons associated with a broker or dealer* shall have the meaning provided in section 3(a)(18) of the Act (15 U.S.C. 78c(a)(18)).

(24) *Regulation T* means Regulation T promulgated by the Board of Governors of the Federal Reserve System, 12 CFR part 220, as amended from time to time.

(25) *Regulation T collateral value*, with respect to a security, means the current market value of the security reduced by the percentage of required margin for a position in the security held in a margin account under Regulation T.

(26) *Related position*, with respect to a security future, means any position in an account that is combined with the security future to create an offsetting position as provided in § 242.403(b)(2) of this Regulation (§§ 242.400 through 242.406).

(27) *Related transaction*, with respect to a position or transaction in a security future, means:

(i) Any transaction that creates, eliminates, increases or reduces an offsetting position involving a security future and a related position, as provided in § 242.403(b)(2) of this Regulation (§§ 242.400 through 242.406); or

(ii) Any deposit or withdrawal of margin for the security future or a related position, except as provided in § 242.405(b) of this Regulation (§§ 242.400 through 242.406).

(28) *Securities account* shall have the meaning provided in § 240.15c3–3(a) of this chapter.

(29) *Security futures intermediary* means any creditor as defined in Regulation T with respect to its financial relations with any person involving security futures.

(30) *Self-regulatory authority* means a national securities exchange registered under section 6 of the Act (15 U.S.C. 78f), a national securities association registered under section 15A of the Act (15 U.S.C. 78o–3), a contract market registered under Section 5 of the CEA (7 U.S.C. 7) or Section 5f of the CEA (7 U.S.C. 7b–1), or a derivatives transaction execution facility registered under Section 5a of the CEA (7 U.S.C. 7a).

(31) *Special margin requirement* shall have the meaning provided in § 242.404(e)(1)(ii) of this Regulation (§§ 242.400 through 242.406).

(32) *Variation settlement* means any credit or debit to a customer account, made on a daily or intraday basis, for the purpose of marking to market a security future or any other contract that is:

(i) Issued by a clearing agency that is registered under section 17A of the Act (15 U.S.C. 78q–1) or cleared and guaranteed by a derivatives clearing organization that is registered under Section 5b of the CEA (7 U.S.C. 7a–1); and

(ii) Traded on or subject to the rules of a self-regulatory authority.

(b) Terms used in this Regulation (§§ 242.400 through 242.406) and not otherwise defined in this section shall have the meaning set forth in the margin rules applicable to the account.

(c) Terms used in this Regulation (§§ 242.400 through 242.406) and not otherwise defined in this section or in the margin rules applicable to the account shall have the meaning set forth in the Act and the CEA; if the definitions of a term in the Act and the CEA are inconsistent as applied in particular circumstances, such term shall have the meaning set forth in rules, regulations, or interpretations jointly promulgated by the Commission and the CFTC.

**§ 242.402 General provisions.**

(a) *Applicable margin rules.* Except to the extent inconsistent with this Regulation (§§ 242.400 through 242.406):

(1) A security futures intermediary that carries a security future on behalf of a customer in a securities account shall record and conduct all financial relations with respect to such security future and related positions in accordance with Regulation T and the margin rules of the self-regulatory authorities of which the security futures intermediary is a member.

(2) A security futures intermediary that carries a security future on behalf of a customer in a futures account shall record and conduct all financial relations with respect to such security future and related positions in accordance with the margin rules of the self-regulatory authorities of which the security futures intermediary is a member.

(b) *Separation and consolidation of accounts.*

(1) The requirements for security futures and related positions in one account may not be met by considering items in any other account, except as permitted or required under paragraph (b)(2) of this section or applicable margin rules. If withdrawals of cash, securities or other assets deposited as margin are permitted under this Regulation (§§ 242.400 through 242.406), bookkeeping entries shall be made when such cash, securities, or assets are used for purposes of meeting requirements in another account.

(2) Notwithstanding paragraph (b)(1) of this section, the security futures intermediary shall consider all futures accounts in which security futures and related positions are held that are within the same regulatory classification or account type and are owned by the same customer to be a single account for purposes of this Regulation (§§ 242.400 through 242.406). The security futures intermediary may combine such accounts with other futures accounts that are within the same regulatory classification or account type and are owned by the same customer for purposes of computing a customer's overall margin requirement, as permitted or required by applicable margin rules.

(c) *Accounts of partners.* If a partner of the security futures intermediary has an account with the security futures intermediary in which security futures or related positions are held, the

security futures intermediary shall disregard the partner's financial relations with the firm (as shown in the partner's capital and ordinary drawing accounts) in calculating the margin or equity of any such account.

(d) *Contribution to joint venture.* If an account in which security futures or related positions are held is the account of a joint venture in which the security futures intermediary participates, any interest of the security futures intermediary in the joint account in excess of the interest which the security futures intermediary would have on the basis of its right to share in the profits shall be margined in accordance with this Regulation (§§ 242.400 through 242.406).

(e) *Extensions of credit.* (1) No security futures intermediary may extend or maintain credit to or for any customer for the purpose of evading or circumventing any requirement under this Regulation (§§ 242.400 through 242.406).

(2) A security futures intermediary may arrange for the extension or maintenance of credit to or for any customer by any person, provided that the security futures intermediary does not willfully arrange credit that would constitute a violation of Regulation T, U or X of the Board of Governors of the Federal Reserve System (12 CFR parts 220, 221, and 224) by such person.

(f) *Change in exempted person status.* Once a person ceases to qualify as an exempted person, it shall notify the security futures intermediary of this fact before entering into any new security futures transaction or related transaction that would require additional margin to be deposited under this Regulation (§§ 242.400 through 242.406). Financial relations with respect to any such transactions shall be subject to the provisions of this Regulation (§§ 242.400 through 242.406).

**§ 242.403 Required margin.**

(a) *Applicability.* Each security futures intermediary shall determine the required margin for the security futures and related positions held on behalf of a customer in a securities account or futures account as set forth in this section.

(b) *Required margin.*—(1) *General rule.* The required margin for each long or short position n a security future shall be twenty (20) percent of the current market value of such security future.

(2) *Offsetting positions.* Notwithstanding the margin levels specified in paragraph (b)(1) of this section, a self-regulatory authority may set the required initial or maintenance margin level for an offsetting position involving security futures and related positions at a level lower than the level that would be required under paragraph (b)(1) of this section if such positions were margined separately, pursuant to rules that meet the criteria set forth in section 7(c)(2)(B) of the Act (15 U.S.C. 78g(c)(2)(B)) and are effective in accordance with section 19(b)(2) of the Act (15 U.S.C. 78s(b)(2)) and, as applicable, Section 5c(c) of the CEA (7 U.S.C. 7a–2(c)).

(c) *Procedures for certain margin level adjustments.* An exchange registered under section 6(g) of the Act (15 U.S.C. 78f(g)), or a national securities association registered under section 15A(k) of the Act (15 U.S.C. 78*o*–3(k)), may raise or lower the required margin level for a security future to a level not lower than that specified in this section, in accordance with section 19(b)(7) of the Act (15 U.S.C. 78s(b)(7)).

**§ 242.404 Type, form and use of margin.**

(a) *When margin is required.* Margin is required to be deposited whenever the required margin for security futures and related positions in an account is not satisfied by the equity in the account, subject to adjustment under paragraph (c) of this section.

(b) *Acceptable margin deposits.* (1) The required margin may be satisfied by a deposit of cash, margin securities (subject to paragraph (b)(2) of this section), exempted securities, any other asset permitted under Regulation T to satisfy a margin deficiency in a securities margin account, or any combination thereof, each as valued in accordance with paragraph (c) of this section.

(2) Shares of a money market mutual fund may be accepted as a margin deposit for purposes of this Regulation (§§ 242.400 through 242.406), *provided that:*

(i) The customer waives any right to redeem the shares without the consent of the security futures intermediary and instructs the fund or its transfer agent accordingly;

(ii) The security futures intermediary (or clearing agency or derivatives clearing organization with which the shares are deposited as margin) obtains the right to redeem the shares in cash, promptly upon request; and

(iii) The fund agrees to satisfy any conditions necessary or appropriate to ensure that the shares may be redeemed in cash, promptly upon request.

(c) *Adjustments.*

(1) *Futures accounts.* For purposes of this section, the equity in a futures account shall be computed in accordance with the margin rules applicable to the account, subject to the following:

(i) A security future shall have no value;

(ii) Each net long or short position in a listed option on a contract for future delivery shall be valued in accordance with the margin rules applicable to the account;

(iii) Except as permitted in paragraph (e) of this section, each margin equity security shall be valued at an amount no greater than its Regulation T collateral value;

(iv) Each other security shall be valued at an amount no greater than its current market value reduced by the percentage specified for such security in § 240.15c3–1(c)(2)(vi) of this chapter;

(v) Freely convertible foreign currency may be valued at an amount no greater than its daily marked-to-market U.S. dollar equivalent;

(vi) Variation settlement receivable (or payable) by an account at the close of trading on any day shall be treated as a credit (or debit) to the account on that day; and

(vii) Each other acceptable margin deposit or component of equity shall be valued at an amount no greater than its value under Regulation T.

(2) *Securities accounts.* For purposes of this section, the equity in a securities account shall be computed in accordance with the margin rules applicable to the account, subject to the following:

(i) A security future shall have no value;

(ii) Freely convertible foreign currency may be valued at an amount no greater than its daily mark-to-market U.S. dollar equivalent; and

(iii) Variation settlement receivable (or payable) to an account at the close of trading on any day shall be treated as a credit (or debit) by the account on that day.

(d) *Satisfaction restriction.* Any transaction, position or deposit that is used to satisfy the required margin for security futures or related positions under this Regulation (§§ 242.400 through 242.406), including a related position, shall be unavailable to satisfy the required margin for any other position or transaction or any other requirement.

(e) *Alternative collateral valuation for margin equity securities in a futures account.*

(1) Notwithstanding paragraph (c)(1)(iii) of this section, a security futures intermediary need not value a margin equity security at its Regulation T collateral value when determining whether the required margin for the security futures and related positions in

a futures account is satisfied, *provided that:*

(i) The margin equity security is valued at an amount no greater than the current market value of the security reduced by the lowest percentage level of margin required for a long position in the security held in a margin account under the rules of a national securities exchange registered pursuant to section 6(a) of the Act (15 U.S.C. 78f(a));

(ii) Additional margin is required to be deposited on any day when the day's security futures transactions and related transactions would create or increase a margin deficiency in the account if the margin equity securities were valued at their Regulation T collateral value, and shall be for the amount of the margin deficiency so created or increased (a ''special margin requirement''); and

(iii) Cash, securities, or other assets deposited as margin for the positions in an account are not permitted to be withdrawn from the account at any time that:

(A) Additional cash, securities, or other assets are required to be deposited as margin under this section for a transaction in the account on the same or a previous day; or

(B) The withdrawal, together with other transactions, deposits, and withdrawals on the same day, would create or increase a margin deficiency if the margin equity securities were valued at their Regulation T collateral value.

(2) All security futures transactions and related transactions on any day shall be combined to determine the amount of a special margin requirement. Additional margin deposited to satisfy a special margin requirement shall be valued at an amount no greater than its Regulation T collateral value.

(3) If the alternative collateral valuation method set forth in paragraph (e) of this section is used with respect to an account in which security futures or related positions are carried:

(i) An account that is transferred from one security futures intermediary to another may be treated as if it had been maintained by the transferee from the date of its origin, if the transferee accepts, in good faith, a signed statement of the transferor (or, if that is not practicable, of the customer), that any margin call issued under this Regulation (§§ 242.400 through 242.406) has been satisfied; and

(ii) An account that is transferred from one customer to another as part of a transaction, not undertaken to avoid the requirements of this Regulation (§§ 242.400 through 242.406), may be treated as if it had been maintained for the transferee from the date of its origin, if the security futures intermediary accepts in good faith and keeps with the transferee account a signed statement of the transferor describing the circumstances for the transfer.

(f) *Guarantee of accounts.* No guarantee of a customer's account shall be given any effect for purposes of determining whether the required margin in an account is satisfied, except as permitted under applicable margin rules.

### § 242.405 Withdrawal of margin.

(a) *By the customer.* Except as otherwise provided in § 242.404(e)(1)(ii) of this Regulation (§§ 242.400 through 242.406), cash, securities, or other assets deposited as margin for positions in an account may be withdrawn, provided that the equity in the account after such withdrawal is sufficient to satisfy the required margin for the security futures and related positions in the account under this Regulation (§§ 242.400 through 242.406).

(b) *By the security futures intermediary.* Notwithstanding paragraph (a) of this section, the security futures intermediary, in its usual practice, may deduct the following items from an account in which security futures or related positions are held if they are considered in computing the balance of such account:

(1) Variation settlement payable, directly or indirectly, to a clearing agency that is registered under section 17A of the Act (15 U.S.C. 78q–1) or a derivatives clearing organization that is registered under section 5b of the CEA (7 U.S.C. 7a–1);

(2) Interest charged on credit maintained in the account;

(3) Communication or shipping charges with respect to transactions in the account;

(4) Payment of commissions, brokerage, taxes, storage and other charges lawfully accruing in connection with the positions and transactions in the account;

(5) Any service charges that the security futures intermediary may impose; or

(6) Any other withdrawals that are permitted from a securities margin account under Regulation T, to the extent permitted under applicable margin rules.

### § 242.406 Undermargined accounts.

(a) *Failure to satisfy margin call.* If any margin call required by this Regulation (§§ 242.400 through 242.406) is not met in full, the security futures intermediary shall take the deduction required with respect to an undermargined account in computing its net capital under Commission or CFTC rules.

(b) *Accounts that liquidate to a deficit.* If at any time there is a liquidating deficit in an account in which security futures are held, the security futures intermediary shall take steps to liquidate positions in the account promptly and in an orderly manner.

(c) *Liquidation of undermargined accounts not required.* Notwithstanding Section 402(a) of this Regulation (§§ 242.400 through 242.406), section 220.4(d) of Regulation T (12 CFR 220.4(d)) respecting liquidation of positions in lieu of deposit shall not apply with respect to security futures carried in a securities account.

Dated: August 1, 2002.

By the Securities and Exchange Commission.

**Margaret H. McFarland,**

*Deputy Secretary.*

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## Part V

# Department of Health and Human Services

**Office of the Secretary**

**45 CFR Parts 160 and 164**

**Standards for Privacy of Individually Identifiable Health Information; Final Rule**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Office of the Secretary**

**45 CFR Parts 160 and 164**

**RIN 0991–AB14**

# Standards for Privacy of Individually Identifiable Health Information

**AGENCY:** Office for Civil Rights, HHS.

**ACTION:** Final rule.

**SUMMARY:** The Department of Health and Human Services (''HHS'' or ''Department'') modifies certain standards in the Rule entitled ''Standards for Privacy of Individually Identifiable Health Information'' (''Privacy Rule''). The Privacy Rule implements the privacy requirements of the Administrative Simplification subtitle of the Health Insurance Portability and Accountability Act of 1996.

The purpose of these modifications is to maintain strong protections for the privacy of individually identifiable health information while clarifying certain of the Privacy Rule's provisions, addressing the unintended negative effects of the Privacy Rule on health care quality or access to health care, and relieving unintended administrative burdens created by the Privacy Rule.

**DATES:** This final rule is effective on October 15, 2002.

**FOR FURTHER INFORMATION CONTACT:** Felicia Farmer, 1–866–OCR–PRIV (1–866–627–7748) or TTY 1–866–788–4989.

**SUPPLEMENTARY INFORMATION:**

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## I. Background

### *A. Statutory Background*

Congress recognized the importance of protecting the privacy of health information given the rapid evolution of health information systems in the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Public Law 104–191, which became law on August 21, 1996. HIPAA's Administrative Simplification provisions, sections 261 through 264 of the statute, were designed to improve the efficiency and effectiveness of the health care system by facilitating the electronic exchange of information with respect to certain financial and administrative transactions carried out by health plans, health care clearinghouses, and health care providers who transmit information electronically in connection with such transactions. To implement these provisions, the statute directed HHS to adopt a suite of uniform, national standards for transactions, unique health identifiers, code sets for the data elements of the transactions, security of health information, and electronic signature.

At the same time, Congress recognized the challenges to the confidentiality of health information presented by the increasing complexity of the health care industry, and by advances in the health information systems technology and communications. Thus, the Administrative Simplification provisions of HIPAA authorized the Secretary to promulgate standards for the privacy of individually identifiable health information if Congress did not enact health care privacy legislation by August 21, 1999. HIPAA also required the Secretary of HHS to provide Congress with recommendations for legislating to protect the confidentiality of health care information. The Secretary submitted such recommendations to Congress on September 11, 1997, but Congress did not pass such legislation within its self-imposed deadline.

With respect to these regulations, HIPAA provided that the standards, implementation specifications, and requirements established by the Secretary not supersede any contrary State law that imposes more stringent privacy protections. Additionally, Congress required that HHS consult with the National Committee on Vital and Health Statistics, a Federal advisory committee established pursuant to section 306(k) of the Public Health Service Act (42 U.S.C. 242k(k)), and the Attorney General in the development of HIPAA privacy standards.

After a set of HIPAA Administrative Simplification standards is adopted by the Department, HIPAA provides HHS with authority to modify the standards as deemed appropriate, but not more frequently than once every 12 months. However, modifications are permitted during the first year after adoption of the standards if the changes are necessary to permit compliance with the standards. HIPAA also provides that compliance with modifications to standards or implementation specifications must be accomplished by a date designated by the Secretary, which may not be earlier than 180 days after the adoption of the modification.

### *B. Regulatory and Other Actions to Date*

HHS published a proposed Rule setting forth privacy standards for individually identifiable health information on November 3, 1999 (64 FR 59918). The Department received more than 52,000 public comments in response to the proposal. After reviewing and considering the public comments, HHS issued a final Rule (65 FR 82462) on December 28, 2000, establishing ''Standards for Privacy of Individually Identifiable Health Information'' (''Privacy Rule'').

In an era where consumers are increasingly concerned about the privacy of their personal information, the Privacy Rule creates, for the first time, a floor of national protections for the privacy of their most sensitive information—health information. Congress has passed other laws to protect consumers' personal information contained in bank, credit card, other financial records, and even video rentals. These health privacy protections are intended to provide consumers with similar assurances that their health information, including genetic information, will be properly protected. Under the Privacy Rule, health plans, health care clearinghouses, and certain health care providers must guard against misuse of individuals' identifiable health information and limit the sharing of such information, and consumers are afforded significant new rights to enable them to understand and control how their health information is used and disclosed.

After publication of the Privacy Rule, HHS received many inquiries and unsolicited comments through

telephone calls, e-mails, letters, and other contacts about the impact and operation of the Privacy Rule on numerous sectors of the health care industry. Many of these commenters exhibited substantial confusion and misunderstanding about how the Privacy Rule will operate; others expressed great concern over the complexity of the Privacy Rule. In response to these communications and to ensure that the provisions of the Privacy Rule would protect patients' privacy without creating unanticipated consequences that might harm patients' access to health care or quality of health care, the Secretary of HHS opened the Privacy Rule for additional public comment in March 2001 (66 FR 12738).

After an expedited review of the comments by the Department, the Secretary decided that it was appropriate for the Privacy Rule to become effective on April 14, 2001, as scheduled (65 FR 12433). At the same time, the Secretary directed the Department immediately to begin the process of developing guidelines on how the Privacy Rule should be implemented and to clarify the impact of the Privacy Rule on health care activities. In addition, the Secretary charged the Department with proposing appropriate changes to the Privacy Rule during the next year to clarify the requirements and correct potential problems that could threaten access to, or quality of, health care. The comments received during the comment period, as well as other communications from the public and all sectors of the health care industry, including letters, testimony at public hearings, and meetings requested by these parties, have helped to inform the Department's efforts to develop proposed modifications and guidance on the Privacy Rule.

On July 6, 2001, the Department issued its first guidance to answer common questions and clarify certain of the Privacy Rule's provisions. In the guidance, the Department also committed to proposing modifications to the Privacy Rule to address problems arising from unintended effects of the Privacy Rule on health care delivery and access. The guidance will soon be updated to reflect the modifications adopted in this final Rule. The revised guidance will be available on the HHS Office for Civil Rights (OCR) Privacy Web site at *http://www.hhs.gov/ocr/hipaa/*.

In addition, the National Committee for Vital and Health Statistics (NCVHS), Subcommittee on Privacy and Confidentiality, held public hearings on the implementation of the Privacy Rule on August 21–23, 2001, and January 24–25, 2002, and provided recommendations to the Department based on these hearings. The NCVHS serves as the statutory advisory body to the Secretary of HHS with respect to the development and implementation of the Rules required by the Administrative Simplification provisions of HIPAA, including the privacy standards. Through the hearings, the NCVHS specifically solicited public input on issues related to certain key standards in the Privacy Rule: consent, minimum necessary, marketing, fundraising, and research. The resultant public testimony and subsequent recommendations submitted to the Department by the NCVHS also served to inform the development of these proposed modifications.

## II. Overview of the March 2002 Notice of Proposed Rulemaking (NPRM)

As described above, through public comments, testimony at public hearings, meetings at the request of industry and other stakeholders, as well as other communications, the Department learned of a number of concerns about the potential unintended effects certain provisions would have on health care quality and access. On March 27, 2002, in response to these concerns, and pursuant to HIPAA's provisions for modifications to the standards, the Department proposed modifications to the Privacy Rule (67 FR 14776).

The Department proposed to modify the following areas or provisions of the Privacy Rule: consent; uses and disclosures for treatment, payment, and health care operations; notice of privacy practices; minimum necessary uses and disclosures, and oral communications; business associates; uses and disclosures for marketing; parents as the personal representatives of unemancipated minors; uses and disclosures for research purposes; uses and disclosures for which authorizations are required; and de-identification. In addition to these key areas, the proposal included changes to other provisions where necessary to clarify the Privacy Rule. The Department also included in the proposed Rule a list of technical corrections intended as editorial or typographical corrections to the Privacy Rule.

The proposed modifications collectively were designed to ensure that protections for patient privacy are implemented in a manner that maximizes the effectiveness of such protections while not compromising either the availability or the quality of medical care. They reflected a continuing commitment on the part of the Department to strong privacy protections for medical records and the belief that privacy is most effectively protected by requirements that are not exceptionally difficult to implement. The Department welcomed comments and suggestions for alternative ways effectively to protect patient privacy without adversely affecting access to, or the quality of, health care.

Given that the compliance date of the Privacy Rule for most covered entities is April 14, 2003, and the Department's interest in having the compliance date for these revisions also be no later than April 14, 2003, the Department solicited public comment on the proposed modifications for only 30 days. As stated above, the proposed modifications addressed public concerns already communicated to the Department through a wide variety of sources since publication of the Privacy Rule in December 2000. For these reasons, the Department believed that 30 days should be sufficient for the public to state its views fully to the Department on the proposed modifications to the Privacy Rule. During the 30-day comment period, the Department received in excess of 11,400 comments.

## III. Section-by-Section Description of Final Modifications and Response to Comments

### *A. Section 164.501—Definitions*

#### 1. Marketing

*December 2000 Privacy Rule*

The Privacy Rule defined ''marketing'' at § 164.501 as a communication about a product or service, a purpose of which is to encourage recipients of the communication to purchase or use the product or service, subject to certain limited exceptions. To avoid interfering with, or unnecessarily burdening communications about, treatment or about the benefits and services of health plans and health care providers, the Privacy Rule explicitly excluded two types of communications from the definition of ''marketing:'' (1) communications made by a covered entity for the purpose of describing the participating providers and health plans in a network, or describing the services offered by a provider or the benefits covered by a health plan; and (2) communications made by a health care provider as part of the treatment of a patient and for the purpose of furthering that treatment, or made by a provider or health plan in the course of managing an individual's treatment or recommending an alternative treatment. Thus, a health plan could send its

enrollees a listing of network providers, and a health care provider could refer a patient to a specialist without either an authorization under § 164.508 or having to meet the other special requirements in § 164.514(e) that attach to marketing communications. However, these communications qualified for the exception to the definition of ''marketing'' only if they were made orally or, if in writing, were made without remuneration from a third party. For example, it would not have been marketing for a pharmacy to call a patient about the need to refill a prescription, even if that refill reminder was subsidized by a third party; but it would have been marketing for that same, subsidized refill reminder to be sent to the patient in the mail.

Generally, if a communication was marketing, the Privacy Rule required the covered entity to obtain the individual's authorization to use or disclose protected health information to make the communication. However, the Privacy Rule, at § 164.514(e), permitted the covered entity to make health-related marketing communications without such authorization, provided it complied with certain conditions on the manner in which the communications were made. Specifically, the Privacy Rule permitted a covered entity to use or disclose protected health information to communicate to individuals about the health-related products or services of the covered entity or of a third party, without first obtaining an authorization for that use or disclosure of protected health information, if the communication: (1) Identified the covered entity as the party making the communication; (2) identified, if applicable, that the covered entity received direct or indirect remuneration from a third party for making the communication; (3) with the exception of general circulation materials, contained instructions describing how the individual could opt-out of receiving future marketing communications; and (4) where protected health information was used to target the communication about a product or service to individuals based on their health status or health condition, explained why the individual had been targeted and how the product or service related to the health of the individual.

For certain permissible marketing communications, however, the Department did not believe these conditions to be practicable. Therefore, § 164.514(e) also permitted a covered entity to make a marketing communication that occurred in a face-to-face encounter with the individual, or that involved products or services of only nominal value, without meeting the above conditions or requiring an authorization. These provisions, for example, permitted a covered entity to provide sample products during a face-to-face communication, or to distribute calendars, pens, and the like, that displayed the name of a product or provider.

*March 2002 NPRM*

The Department received many complaints concerning the complexity and unworkability of the Privacy Rule's marketing requirements. Many entities expressed confusion over the Privacy Rule's distinction between health care communications that are excepted from the definition of ''marketing'' versus those that are marketing but permitted subject to the special conditions in § 164.514(e). For example, questions were raised as to whether disease management communications or refill reminders were ''marketing'' communications subject to the special disclosure and opt-out conditions in § 164.514(e). Others stated that it was unclear whether various health care operations activities, such as general health-related educational and wellness promotional activities, were to be treated as marketing under the Privacy Rule.

The Department also learned that consumers were generally dissatisfied with the conditions required by § 164.514(e). Many questioned the general effectiveness of the conditions and whether the conditions would properly protect consumers from unwanted disclosure of protected health information to commercial entities, and from the intrusion of unwanted solicitations. They expressed specific dissatisfaction with the provision at § 164.514(e)(3)(iii) for individuals to opt-out of future marketing communications. Many argued for the opportunity to opt-out of marketing communications before any marketing occurred. Others requested that the Department limit marketing communications to only those consumers who affirmatively chose to receive such communications.

In response to these concerns, the Department proposed to modify the Privacy Rule to make the marketing provisions clearer and simpler. First, the Department proposed to simplify the Privacy Rule by eliminating the special provisions for marketing health-related products and services at § 164.514(e). Instead, any use or disclosure of protected health information for a communication defined as ''marketing'' in § 164.501 would require an authorization by the individual. Thus, covered entities would no longer be able to make any type of marketing communications that involved the use or disclosure of protected health information without authorization simply by meeting the disclosure and opt-out conditions in the Privacy Rule. The Department intended to effectuate greater consumer privacy protection by requiring authorization for all uses or disclosures of protected health information for marketing communications, as compared to the disclosure and opt-out conditions of § 164.514(e).

Second, the Department proposed minor clarifications to the Privacy Rule's definition of ''marketing'' at § 164.501. Specifically, the Department proposed to define ''marketing'' as ''to make a communication about a product or service to encourage recipients of the communication to purchase or use the product or service.'' The proposed modification retained the substance of the ''marketing'' definition, but changed the language slightly to avoid the implication that in order for a communication to be marketing, the purpose or intent of the covered entity in making such a communication would have to be determined. The simplified language permits the Department to make the determination based on the communication itself.

Third, with respect to the exclusions from the definition of ''marketing'' in § 164.501, the Department proposed to simplify the language to avoid confusion and better conform to other sections of the regulation, particularly in the area of treatment communications. The proposal retained the exclusions for communications about a covered entity's own products and services and about the treatment of the individual. With respect to the exclusion for a communication made ''in the course of managing the treatment of that individual,'' the Department proposed to modify the language to use the terms ''case management'' and ''care coordination'' for that individual. These terms are more consistent with the terms used in the definition of ''health care operations,'' and were intended to clarify the Department's intent.

One substantive change to the definition proposed by the Department was to eliminate the condition on the above exclusions from the definition of ''marketing'' that the covered entity could not receive remuneration from a third party for any written communication. This limitation was not well understood and treated similar communications differently. For

example, a prescription refill reminder was marketing if it was in writing and paid for by a third party, while a refill reminder that was not subsidized, or was made orally, was not marketing. With the proposed elimination of the health-related marketing requirements in § 164.514(e) and the proposed requirement that any marketing communication require an individual's prior written authorization, retention of this condition would have adversely affected a health care provider's ability to make many common health-related communications. Therefore, the Department proposed to eliminate the remuneration prohibition to the exceptions to the definition so as not to interfere with necessary and important treatment and health-related communications between a health care provider and patient.

To reinforce the policy requiring an authorization for most marketing communications, the Department proposed to add a new marketing provision at § 164.508(a)(3) explicitly requiring an authorization for a use or disclosure of protected health information for marketing purposes. Additionally, if the marketing was expected to result in direct or indirect remuneration to the covered entity from a third party, the Department proposed that the authorization state this fact. As noted above, because a use or disclosure of protected health information for marketing communications required an authorization, the disclosure and opt-out provisions in § 164.514(e) no longer would be necessary and the Department proposed to eliminate them. As in the December 2000 Privacy Rule at § 164.514(e)(2), the proposed modifications at § 164.508(a)(3) excluded from the marketing authorization requirements face-to-face communications made by a covered entity to an individual. The Department proposed to retain this exception so that the marketing provisions would not interfere with the relationship and dialogue between health care providers and individuals. Similarly, the Department proposed to retain the exception to the authorization requirement for a marketing communication that involved products or services of nominal value, but proposed to replace the language with the common business term ''promotional gift of nominal value.''

As noted above, because some of the proposed simplifications were a substitute for § 164.514(e), the Department proposed to eliminate that section, and to make conforming changes to remove references to § 164.514(e) at § 164.502(a)(1)(vi) and in paragraph (6)(v) of the definition of ''health care operations'' in § 164.501.

*Overview of Public Comments*

The following discussion provides an overview of the public comment received on this proposal. Additional comments received on this issue are discussed below in the section entitled, ''Response to Other Public Comments.''

The Department received generally favorable comment on its proposal to simplify the marketing provisions by requiring authorizations for uses or disclosures of protected health information for marketing communications, instead of the special provisions for health-related products and services at § 164.514(e). Many also supported the requirement that authorizations notify the individual of marketing that results in direct or indirect remuneration to the covered entity from a third party. They argued that for patients to make informed decisions, they must be notified of potential financial conflicts of interest. However, some commenters opposed the authorization requirement for marketing, arguing instead for the disclosure and opt-out requirements at § 164.514(e) or for a one-time, blanket authorization from an individual for their marketing activities.

Commenters were sharply divided on whether the Department had properly defined what is and what is not marketing. Most of those opposed to the Department's proposed definitions objected to the elimination of health-related communications for which the covered entity received remuneration from the definition of ''marketing.'' They argued that these communications would have been subject to the consumer protections in § 164.514(e) but, under the proposal, could be made without any protections at all. The mere presence of remuneration raised conflict of interest concerns for these commenters, who feared patients would be misled into thinking the covered entity was acting solely in the patients' best interest when recommending an alternative medication or treatment. Of particular concern to these commenters was the possibility of a third party, such as a pharmaceutical company, obtaining a health care provider's patient list to market its own products or services directly to the patients under the guise of recommending an ''alternative treatment'' on behalf of the provider. Commenters argued that, even if the parties attempted to cloak the transaction in the trappings of a business associate relationship, when the remuneration flowed from the third party to the covered entity, the transaction was tantamount to selling the patient lists and ought to be considered marketing.

On the other hand, many commenters urged the Department to broaden the categories of communications that are not marketing. Several expressed concern that, under the proposal, they would be unable to send newsletters and other general circulation materials with information about health-promoting activities (*e.g.,* screenings for certain diseases) to their patients or members without an authorization. Health plans were concerned that they would be unable to send information regarding enhancements to health insurance coverage to their members and beneficiaries. They argued, among other things, that they should be excluded from the definition of ''marketing'' because these communications would be based on limited, non-clinical protected health information, and because policyholders benefit and use such information to fully evaluate the mix of coverage most appropriate to their needs. They stated that providing such information is especially important given that individual and market-wide needs, as well as benefit offerings, change over time and by statute. For example, commenters informed the Department that some States now require long-term care insurers to offer new products to existing policyholders as they are brought to market and to allow policyholders to purchase the new benefits through a formal upgrade process. These health plans were concerned that an authorization requirement for routine communications about options and enhancements would take significant time and expense. Some insurers also urged that they be allowed to market other lines of insurance to their health plan enrollees.

A number of commenters urged the Department to exclude any activity that met the definitions of ''treatment,'' ''payment,'' or ''health care operations'' from the definition of ''marketing'' so that they could freely inform customers about prescription discount card and price subsidy programs. Still others wanted the Department to broaden the treatment exception to include all health-related communications between providers and patients.

*Final Modifications.* The Department adopts the modifications to marketing substantially as proposed in the NPRM, but makes changes to the proposed definition of ''marketing'' and further clarifies one of the exclusions from the definition of ''marketing'' in response to comments on the proposal. The

definition of ''marketing'' is modified to close what commenters characterized as a loophole, that is, the possibility that covered entities, for remuneration, could disclose protected health information to a third party that would then be able to market its own products and services directly to individuals. Also, in response to comments, the Department clarifies the language in the marketing exclusion for communications about a covered entity's own products and services.

As it proposed to do, the Department eliminates the special provisions for marketing health-related products and services at § 164.514(e). Except as provided for at § 164.508(a)(3), a covered entity must have the individual's prior written authorization to use or disclose protected health information for marketing communications and will no longer be able to do so simply by meeting the disclosure and opt-out provisions, previously set forth in § 164.514(e). The Department agrees with commenters that the authorization provides individuals with more control over whether they receive marketing communications and better privacy protections for such uses and disclosures of their health information. In response to commenters who opposed this proposal, the Department does not believe that an opt-out requirement for marketing communications would provide a sufficient level of control for patients regarding their health information. Nor does the Department believe that a blanket authorization provides sufficient privacy protections for individuals. Section 164.508(c) sets forth the core elements of an authorization necessary to give individuals control of their protected health information. Those requirements give individuals sufficient information and notice regarding the type of use or disclosure of their protected health information that they are authorizing. Without such specificity, an authorization would not have meaning. Indeed, blanket marketing authorizations would be considered defective under § 164.508(b)(2).

The Department adopts the general definition of ''marketing'' with one clarification. Thus, ''marketing'' means ''to make a communication about a product or service that encourages the recipients of the communication to purchase or use the product or service.'' In removing the language referencing the purpose of the communication and substituting the term ''that encourages'' for the term ''to encourage'', the Department intends to simplify the determination of whether a communication is marketing. If, on its face, the communication encourages recipients of the communication to purchase or use the product or service, the communication is marketing. A few commenters argued for retaining the purpose of the communication as part of the definition of ''marketing'' based on their belief that the intent of the communication was a clearer and more definitive standard than the effect of the communication. The Department disagrees with these commenters. Tying the definition of ''marketing'' to the purpose of the communication creates a subjective standard that would be difficult to enforce because the intent of the communicator rarely would be documented in advance. The definition adopted by the Secretary allows the communication to speak for itself.

The Department further adopts the three categories of communications that were proposed as exclusions from the definition of ''marketing.'' Thus, the covered entity is not engaged in marketing when it communicates to individuals about: (1) The participating providers and health plans in a network, the services offered by a provider, or the benefits covered by a health plan; (2) the individual's treatment; or (3) case management or care coordination for that individual, or directions or recommendations for alternative treatments, therapies, health care providers, or settings of care to that individual. For example, a doctor that writes a prescription or refers an individual to a specialist for follow-up tests is engaging in a treatment communication and is not marketing a product or service. The Department continues to exempt from the ''marketing'' definition the same types of communications that were not marketing under the Privacy Rule as published in December 2000, but has modified some of the language to better track the terminology used in the definition of ''health care operations.'' The commenters generally supported this clarification of the language.

The Department, however, does not agree with commenters that sought to expand the exceptions from marketing for all communications that fall within the definitions of ''treatment,'' ''payment,'' or ''health care operations.'' The purpose of the exclusions from the definition of marketing is to facilitate those communications that enhance the individual's access to quality health care. Beyond these important communications, the public strongly objected to any commercial use of protected health information to attempt to sell products or services, even when the product or service is arguably health related. In light of these strong public objections, ease of administration is an insufficient justification to categorically exempt all communications about payment and health care operations from the definition of ''marketing.''

However, in response to comments, the Department is clarifying the language that excludes from the definition of ''marketing'' those communications that describe network participants and the services or benefits of the covered entity. Several commenters, particularly insurers, were concerned that the reference to a ''plan of benefits'' was too limiting and would prevent them from sending information to their enrollees regarding enhancements or upgrades to their health insurance coverage. They inquired whether the following types of communications would be permissible: enhancements to existing products; changes in deductibles/copays and types of coverage (e.g., prescription drug); continuation products for students reaching the age of majority on parental policies; special programs such as guaranteed issue products and other conversion policies; and prescription drug card programs. Some health plans also inquired if they could communicate with beneficiaries about ''one-stop shopping'' with their companies to obtain long-term care, property, casualty, and life insurance products.

The Department understands the need for covered health care providers and health plans to be able to communicate freely to their patients or enrollees about their own products, services, or benefits. The Department also understands that some of these communications are required by State or other law. To ensure that such communications may continue, the Department is broadening its policy, both of the December 2000 Privacy Rule as well as proposed in the March 2002 NPRM, to allow covered entities to use protected health information to convey information to beneficiaries and members about health insurance products offered by the covered entity that could enhance or substitute for existing health plan coverage. Specifically, the Department modifies the relevant exemption from the definition of ''marketing'' to include communications that describe ''a health-related product or service (or payment for such product or service) that is provided by, or included in a plan of benefits of, the covered entity making the communication, including communications about: the entities participating in a health care provider network or health plan network; replacement of, or enhancements to, a

health plan; and health-related products or services available only to a health plan enrollee that add value to, but are not part of, a plan of benefits.'' Thus, under this exemption, a health plan is not engaging in marketing when it advises its enrollees about other available health plan coverages that could enhance or substitute for existing health plan coverage. For example, if a child is about to age out of coverage under a family's policy, this provision will allow the plan to send the family information about continuation coverage for the child. This exception, however, does not extend to excepted benefits (described in section 2791(c)(1) of the Public Health Service Act, 42 U.S.C. 300gg–91(c)(1)), such as accident-only policies), nor to other lines of insurance (*e.g.,* it is marketing for a multi-line insurer to promote its life insurance policies using protected health information).

Moreover, the expanded language makes clear that it is not marketing when a health plan communicates about health-related products and services available only to plan enrollees or members that add value to, but are not part of, a plan of benefits. The provision of value-added items or services (VAIS) is a common practice, particularly for managed care organizations. Communications about VAIS may qualify as a communication that is about a health plan's own products or services, even if VAIS are not considered plan benefits for the Adjusted Community Rate purposes. To qualify for this exclusion, however, the VAIS must meet two conditions. First, they must be health-related. Therefore, discounts offered by Medicare+Choice or other managed care organizations for eyeglasses may be considered part of the plan's benefits, whereas discounts to attend movie theaters will not. Second, such items and services must demonstrably ''add value'' to the plan's membership and not merely be a pass-through of a discount or item available to the public at large. Therefore, a Medicare+Choice or other managed care organization could, for example, offer its members a special discount opportunity for a health/fitness club without obtaining authorizations, but could not pass along to its members discounts to a health fitness club that the members would be able to obtain directly from the health/fitness clubs.

In further response to comments, the Department has added new language to the definition of ''marketing'' to close what commenters perceived as a loophole that a covered entity could sell protected health information to another company for the marketing of that company's products or services. For example, many were concerned that a pharmaceutical company could pay a provider for a list of patients with a particular condition or taking a particular medication and then use that list to market its own drug products directly to those patients. The commenters believed the proposal would permit this to happen under the guise of the pharmaceutical company acting as a business associate of the covered entity for the purpose of recommending an alternative treatment or therapy to the individual. The Department agrees with commenters that the potential for manipulating the business associate relationship in this fashion should be expressly prohibited. Therefore, the Department is adding language that would make clear that business associate transactions of this nature are marketing. Marketing is defined expressly to include ''an arrangement between a covered entity and any other entity whereby the covered entity discloses protected health information to the other entity, in exchange for direct or indirect remuneration, for the other entity or its affiliate to make a communication about its own product or service that encourages recipients of the communication to purchase or use that product or service.'' These communications are marketing and can only occur if the covered entity obtains the individual's authorization pursuant to § 164.508. The Department believes that this provision will make express the fundamental prohibition against covered entities selling lists of patients or enrollees to third parties, or from disclosing protected health information to a third party for the marketing activities of the third party, without the written authorization of the individual. The Department further notes that manufacturers that receive identifiable health information and misuse it may be subject to action taken under other consumer protection statutes by other Federal agencies, such as the Federal Trade Commission.

The Department does not, however, agree with commenters who argued for retention of the provisions that would condition the exclusions from the ''marketing'' definition on the absence of remuneration. Except for the arrangements that are now expressly defined as ''marketing,'' the Department eliminates the conditions that communications are excluded from the definition of ''marketing'' only if they are made orally, or, if in writing, are made without any direct or indirect remuneration. The Department does not agree that the simple receipt of remuneration should transform a treatment communication into a commercial promotion of a product or service. For example, health care providers should be able to, and can, send patients prescription refill reminders regardless of whether a third party pays or subsidizes the communication. The covered entity also is able to engage a legitimate business associate to assist it in making these permissible communications. It is only in situations where, in the guise of a business associate, an entity other than the covered entity is promoting its own products using protected health information it has received from, and for which it has paid, the covered entity, that the remuneration will place the activity within the definition of ''marketing.''

In addition, the Department adopts the proposed marketing authorization provision at § 164.508(a)(3), with minor language changes to conform to the revised ''marketing'' definition. The Rule expressly requires an authorization for uses or disclosures of protected health information for marketing communications, except in two circumstances: (1) When the communication occurs in a face-to-face encounter between the covered entity and the individual; or (2) the communication involves a promotional gift of nominal value. A marketing authorization must include a statement about remuneration, if any. For ease of administration, the Department has changed the regulatory provision to require a statement on the authorization whenever the marketing ''involves'' direct or indirect remuneration to the covered entity from a third party, rather than requiring the covered entity to identify those situations where ''the marketing is expected to result in'' remuneration.

Finally, the Department clarifies that nothing in the marketing provisions of the Privacy Rule are to be construed as amending, modifying, or changing any rule or requirement related to any other Federal or State statutes or regulations, including specifically anti-kickback, fraud and abuse, or self-referral statutes or regulations, or to authorize or permit any activity or transaction currently proscribed by such statutes and regulations. Examples of such laws include the anti-kickback statute (section 1128B(b) of the Social Security Act), safe harbor regulations (42 CFR part 1001), Stark law (section 1877 of the Social Security Act) and regulations (42 CFR parts 411 and 424), and HIPAA statute on self-referral (section 1128C of the Social Security Act). The definition

of ''marketing'' is solely applicable to the Privacy Rule and the permissions granted by the Rule are only for a covered entity's use or disclosure of protected health information. In particular, although this regulation defines the term ''marketing'' to exclude communications to an individual to recommend, purchase, or use a product or service as part of the treatment of the individual or for case management or care coordination of that individual, such communication by a ''white coat'' health care professional may violate the anti-kickback statute. Similar examples for pharmacist communications with patients relating to the marketing of products on behalf of pharmaceutical companies were identified by the OIG as problematic in a 1994 Special Fraud Alert (December 19, 1994, 59 FR 65372). Other violations have involved home health nurses and physical therapists acting as marketers for durable medical equipment companies. Although a particular communication under the Privacy Rule may not require patient authorization because it is not marketing, or may require patient authorization because it is ''marketing'' as the Rule defines it, the arrangement may nevertheless violate other statutes and regulations administered by HHS, the Department of Justice, or other Federal or State agency.

*Response to Other Public Comments*

*Comment:* Some commenters recommended that the definition of ''marketing'' be broadened to read as follows: ''any communication about a product or service to encourage recipients of the communication to purchase or use the product or service or that will make the recipient aware of the product or service available for purchase or use by the recipient.'' According to these commenters, the additional language would capture marketing campaign activities to establish ''brand recognition.''

*Response:* The Department believes that marketing campaigns to establish brand name recognition of products is already encompassed within the general definition of ''marketing'' and that it is not necessary to add language to accomplish this purpose.

*Comment:* Some commenters opposed the proposed deletion of references to the covered entity as the source of the communications, in the definition of those communications that were excluded from the ''marketing'' definition. They objected to these non-marketing communications being made by unrelated third parties based on protected health information disclosed to these third parties by the covered entity, without the individual's knowledge or authorization.

*Response:* These commenters appear to have misinterpreted the proposal as allowing third parties to obtain protected health information from covered entities for marketing or other purposes for which the Rule requires an individual's authorization. The deletion of the specific reference to the covered entity does not permit disclosures to a third party beyond the disclosures already permitted by the Rule. The change is intended to be purely editorial: since the Rule applies only to covered entities, the only entities whose communications can be governed by the Rule are covered entities, and thus the reference to covered entities there was redundant. Covered entities may not disclose protected health information to third parties for marketing purposes without authorization from the individual, even if the third party is acting as the business associate of the disclosing covered entity. Covered entities may, however, use protected health information to communicate with individuals about the covered entity's own health-related products or services, the individual's treatment, or case management or care coordination for the individual. The covered entity does not need an authorization for these types of communications and may make the communication itself or use a business associate to do so.

*Comment:* Some commenters advocated for reversion to the provision in § 164.514(e) that the marketing communication identify the covered entity responsible for the communication, and argued that the covered entity should be required to identify itself as the source of the protected health information.

*Response:* As modified, the Privacy Rule requires the individual's written authorization for the covered entity to use or disclose protected health information for marketing purposes, with limited exceptions. The Department believes that the authorization process itself will put the individual sufficiently on notice that the covered entity is the source of the protected health information. To the extent that the commenter suggests that these disclosures are necessary for communications that are not ''marketing'as defined by the Rule, the Department disagrees because such a requirement would place an undue burden on necessary health-related communications.

*Comment:* Many commenters opposed the proposed elimination of the provision that would have transformed a communication exempted from marketing into a marketing communication if it was in writing and paid for by a third party. They argued that marketing should include any activity in which a covered entity receives compensation, directly or indirectly, through such things as discounts from another provider, manufacturer, or service provider in exchange for providing information about the manufacturer or service provider's products to consumers, and that consumers should be advised whenever such remuneration is involved and allowed to opt-out of future communications.

*Response:* The Department considered whether remuneration should determine whether a given activity is marketing, but ultimately concluded that remuneration should not define whether a given activity is marketing or falls under an exception to marketing. In fact, the Department believes that the provision in the December 2000 Rule that transformed a treatment communication into a marketing communication if it was in writing and paid for by a third party blurred the line between treatment and marketing in ways that would have made the Privacy Rule difficult to implement. The Department believes that certain health care communications, such as refill reminders or informing patients about existing or new health care products or services, are appropriate, whether or not the covered entity receives remuneration from third parties to pay for them. The fact that remuneration is received for a marketing communication does not mean the communication is biased or inaccurate. For the same reasons, the Department does not believe that the communications that are exempt from the definition of ''marketing'' require any special conditions, based solely on direct or indirect remuneration received by the covered entity. Requiring disclosure and opt-out conditions on these communications, as § 164.514(e) had formerly imposed on health-related marketing communications, would add a layer of complexity to the Privacy Rule that the Department intended to eliminate. Individuals, of course, are free to negotiate with covered entities for limitations on such uses and disclosures, to which the entity may, but is not required to, agree.

The Department does agree with commenters that, in limited circumstances, abuses can occur. The Privacy Rule, both as published in December 2000 and as proposed to be modified in March 2002, has always prohibited covered entities from selling protected health information to a third

party for the marketing activities of the third party, without authorization. Nonetheless, in response to continued public concern, the Department has added a new provision to the definition of ''marketing'' to prevent situations in which a covered entity could take advantage of the business associate relationship to sell protected health information to another entity for that entity's commercial marketing purposes. The Department intends this prohibition to address the potential financial conflict of interest that would lead a covered entity to disclose protected health information to another entity under the guise of a treatment exemption.

*Comment:* Commenters argued that written authorizations (opt-ins) should be required for the use of clinical information in marketing. They stated that many consumers do not want covered entities to use information about specific clinical conditions that an individual has, such as AIDS or diabetes, to target them for marketing of services for such conditions.

*Response:* The Department does not intend to interfere with the ability of health care providers or health plans to deliver quality health care to individuals. The ''marketing'' definition excludes communications for the individual's treatment and for case management, care coordination or the recommendation of alternative therapies. Clinical information is critical for these communications and, hence, cannot be used to distinguish between communications that are or are not marketing. The covered entity needs the individual's authorization to use or disclose protected health information for marketing communications, regardless of whether clinical information is to be used.

*Comment:* The proposed modification eliminated the § 164.514 requirements that permitted the use of protected health information to market health-related products and services without an authorization. In response to that proposed modification, many commenters asked whether covered entities would be allowed to make communications about ''health education'' or ''health promoting'' materials or services without an authorization under the modified Rule. Examples included communications about health improvement or disease prevention, new developments in the diagnosis or treatment of disease, health fairs, health/wellness-oriented classes or support groups.

*Response:* The Department clarifies that a communication that merely promotes health in a general manner and does not promote a specific product or service from a particular provider does not meet the general definition of ''marketing.'' Such communications may include population-based activities to improve health or reduce health care costs as set forth in the definition of ''health care operations'' at § 164.501. Therefore, communications, such as mailings reminding women to get an annual mammogram, and mailings providing information about how to lower cholesterol, about new developments in health care (e.g., new diagnostic tools), about health or ''wellness'' classes, about support groups, and about health fairs are permitted, and are not considered marketing.

*Comment:* Some commenters asked whether they could communicate with beneficiaries about government programs or government-sponsored programs such as information about SCHIP; eligibility for Medicare/Medigap (e.g., eligibility for limited, six-month open enrollment period for Medicare supplemental benefits).

*Response:* The Department clarifies that communications about government and government-sponsored programs do not fall within the definition of ''marketing.'' There is no commercial component to communications about benefits available through public programs. Therefore, a covered entity is permitted to use and disclose protected health information to communicate about eligibility for Medicare supplemental benefits, or SCHIP. As in our response above, these communications may reflect population-based activities to improve health or reduce health care costs as set forth in the definition of ''health care operations'' at § 164.501.

*Comment:* The proposed modification eliminated the § 164.514 requirements that allowed protected health information to be used and disclosed without authorization or the opportunity to opt-out, for communications contained in newsletters or similar general communication devices widely distributed to patients, enrollees, or other broad groups of individuals. Many commenters requested clarification as to whether various types of general circulation materials would be permitted under the proposed modification. Commenters argued that newsletters or similar general communication devices widely distributed to patients, enrollees, or other broad groups of individuals should be permitted without authorizations because they are ''common'' and ''serve appropriate information distribution purposes'' and, based on their general circulation, are less intrusive than other forms of communication.

*Response:* Covered entities may make communications in newsletter format without authorization so long as the content of such communications is not ''marketing,'' as defined by the Rule. The Department is not creating any special exemption for newsletters.

*Comment:* One commenter suggested that, even when authorizations are granted to disclose protected health information for a particular marketing purpose to a non-covered entity, there should also be an agreement by the third party not to re-disclose the protected health information. This same commenter also recommended that the Privacy Rule place restrictions on non-secure modes of making communications pursuant to an authorization. This commenter argued that protected health information should not be disclosed on the outside of mailings or through voice mail, unattended FAX, or other modes of communication that are not secure.

*Response:* Under the final Rule, a covered entity must obtain an individual's authorization to use or disclose protected health information for a marketing communication, with some exceptions. If an individual wanted an authorization to limit the use of the information by the covered entity, the individual could negotiate with the covered entity to make that clear in the authorization. Similarly, individuals can request confidential forms of communication, even with respect to authorized disclosures. See § 164.522(b).

*Comment:* Commenters requested that HHS provide clear guidance on what types of activities constitute a use or disclosure for marketing, and, therefore, require an authorization.

*Response:* The Department has modified the ''marketing'' definition to clarify the types of uses or disclosures of protected health information that are marketing, and, therefore, require prior authorization and those that are not marketing. The Department intends to update its guidance on this topic and address specific examples raised by commenters at that time.

*Comment:* A number of commenters wanted the Department to amend the face-to-face authorization exception. Some urged that it be broadened to include telephone, mail and other common carriers, fax machines, or the Internet so that the exception would cover communications between providers and patients that are not in person. For example, it was pointed out that some providers, such as home

delivery pharmacies, may have a direct treatment relationship, but communicate with patients through other channels. Some raised specific concerns about communicating with ''shut-ins'' and ''persons living in rural areas.'' Other commenters asked the Department to make the exception more narrow to cover only those marketing communications made by a health care provider, as opposed to by a business associate, or to cover only those marketing communications of a provider that arise from a treatment or other essential health care communication.

*Response:* The Department believes that expanding the face-to-face authorization exception to include telephone, mail, and other common carriers, fax machines or the Internet would create an exception essentially for all types of marketing communications. All providers potentially use a variety of means to communicate with their patients. The authorization exclusion, however, is narrowly crafted to permit only face-to-face encounters between the covered entity and the individual.

The Department believes that further narrowing the exception to place conditions on such communications, other than that it be face-to-face, would neither be practical nor better serve the privacy interests of the individual. The Department does not intend to police communications between doctors and patients that take place in the doctor's office. Further limiting the exception would add a layer of complexity to the Rule, encumbering physicians and potentially causing them to second-guess themselves when making treatment or other essential health care communications. In this context, the individual can readily stop any unwanted communications, including any communications that may otherwise meet the definition of ''marketing.''

2. Health Care Operations: Changes of Legal Ownership

*December 2000 Privacy Rule.* The Rule's definition of ''health care operations'' included the disclosure of protected health information for the purposes of due diligence with respect to the contemplated sale or transfer of all or part of a covered entity's assets to a potential successor in interest who is a covered entity, or would become a covered entity as a result of the transaction.

The Department indicated in the December 2000 preamble of the Privacy Rule its intent to include in the definition of health care operations the actual transfer of protected health information to a successor in interest upon a sale or transfer of its assets. (65 FR 82609.) However, the regulation itself did not expressly provide for the transfer of protected health information upon the sale or transfer of assets to a successor in interest. Instead, the definition of ''health care operations'' included uses or disclosures of protected health information only for due diligence purposes when a sale or transfer to a successor in interest is contemplated.

*March 2002 NPRM.* A number of entities expressed concern about the discrepancy between the intent as expressed in the preamble to the December 2000 Privacy Rule and the actual regulatory language. To address these concerns, the Department proposed to add language to paragraph (6) of the definition of ''health care operations'' to clarify its intent to permit the transfer of records to a covered entity upon a sale, transfer, merger, or consolidation. This proposed change would prevent the Privacy Rule from interfering with necessary treatment or payment activities upon the sale of a covered entity or its assets.

The Department also proposed to use the terms ''sale, transfer, consolidation or merger'' and to eliminate the term ''successor in interest'' from this paragraph. The Department intended this provision to apply to any sale, transfer, merger or consolidation and believed the current language may not accomplish this goal.

The Department proposed to retain the limitation that such disclosures are health care operations only to the extent the entity receiving the protected health information is a covered entity or would become a covered entity as a result of the transaction. The Department clarified that the proposed modification would not affect a covered entity's other legal or ethical obligation to notify individuals of a sale, transfer, merger, or consolidation.

*Overview of Public Comments.* The following discussion provides an overview of the public comment received on this proposal. Additional comments received on this issue are discussed below in the section entitled, ''Response to Other Public Comments.''

Numerous commenters supported the proposed modifications. Generally, these commenters claimed the modifications would prevent inconvenience to consumers, and facilitate timely access to health care. Specifically, these commenters indicated that health care would be delayed and consumers would be inconvenienced if covered entities were required to obtain individual consent or authorization before they could access health records that are newly acquired assets resulting from the sale, transfer, merger, or consolidation of all or part of a covered entity. Commenters further claimed that the administrative burden of acquiring individual permission and culling records of consumers who do not give consent would be too great, and would cause some entities to simply store or destroy the records instead. Consequently, health information would be inaccessible, causing consumers to be inconvenienced and health care to be delayed. Some commenters noted that the proposed modifications recognize the realities of business without compromising the availability or quality of health care or diminishing privacy protections one would expect in the handling of protected health information during the course of such business transactions.

Opposition to the proposed modifications was limited, with commenters generally asserting that the transfer of records in such circumstances would not be in the best interests of individuals.

*Final Modifications.* The Department agrees with the commenters that supported the proposed modifications and, therefore, adopts the modifications to the definition of health care operations. Thus, ''health care operations'' includes the sale, transfer, merger, or consolidation of all or part of the covered entity to or with another covered entity, or an entity that will become a covered entity as a result of the transaction, as well as the due diligence activities in connection with such transaction. In response to a comment, the final Rule modifies the phrase ''all or part of a covered entity'' to read ''all or part of the covered entity'' to clarify that any disclosure for such activity must be by the covered entity that is a party to the transaction.

Under the final definition of ''health care operations,'' a covered entity may use or disclose protected health information in connection with a sale or transfer of assets to, or a consolidation or merger with, an entity that is or will be a covered entity upon completion of the transaction; and to conduct due diligence in connection with such transaction. The modification makes clear it is also a health care operation to transfer records containing protected health information as part of the transaction. For example, if a pharmacy which is a covered entity buys another pharmacy which is also a covered entity, protected health information can be exchanged between the two entities for purposes of conducting due diligence, and the selling entity may

transfer any records containing protected health information to the new owner upon completion of the transaction. The new owner may then immediately use and disclose those records to provide health care services to the individuals, as well as for payment and health care operations purposes. Since the information would continue to be protected by the Privacy Rule, any other use or disclosure of the information would require an authorization unless otherwise permitted without authorization by the Rule, and the new owner would be obligated to observe the individual's rights of access, amendment, and accounting. The Privacy Rule would not interfere with other legal or ethical obligations of an entity that may arise out of the nature of its business or relationship with its customers or patients to provide such persons with notice of the transaction or an opportunity to agree to the transfer of records containing personal information to the new owner.

*Response to Other Public Comments*

*Comment:* One commenter was concerned about what obligations the parties to a transaction have regarding protected health information that was exchanged as part of a transaction if the transaction does not go through.

*Response:* The Department believes that other laws and standard business practices are adequate to address these situations and accordingly does not impose additional requirements of this type. It is standard practice for parties contemplating such transactions to enter into confidentiality agreements. In addition to exchanging protected health information, the parties to such transactions commonly exchange confidential proprietary information. It is a standard practice for the parties to these transaction to agree that the handling of all confidential information, such as proprietary information, will include ensuring that, in the event that the proposed transaction is not consummated, the information is either returned to its original owner or destroyed as appropriate. They may include protected health information in any such agreement, as they determine appropriate to the circumstances and applicable law.

3. Protected Health Information: Exclusion for Employment Records

*December 2000 Privacy Rule.* The Privacy Rule broadly defines ''protected health information'' as individually identifiable health information maintained or transmitted by a covered entity in any form or medium. The December 2000 Privacy Rule expressly excluded from the definition of ''protected health information'' only educational and other records that are covered by the Family Education Rights and Privacy Act of 1974, as amended, 20 U.S.C. 1232g. In addition, throughout the December 2000 preamble to the Privacy Rule, the Department repeatedly stated that the Privacy Rule does not apply to employers, nor does it apply to the employment functions of covered entities, that is, when they are acting in their role as employers. For example, the Department stated:

> Covered entities must comply with this regulation in their health care capacity, not in their capacity as employers. For example, information in hospital personnel files about a nurses' (sic) sick leave is not protected health information under this rule.

65 FR 82612. However, the definition of protected health information did not expressly exclude personnel or employment records of covered entities.

*March 2002 NPRM.* The Department understands that covered entities are also employers, and that this creates two potential sources of confusion about the status of health information. First, some employers are required or elect to obtain health information about their employees, as part of their routine employment activities [e.g., hiring, compliance with the Occupational Safety and Health Administration (OSHA) requirements]. Second, employees of covered health care providers or health plans sometimes seek treatment or reimbursement from that provider or health plan, unrelated to the employment relationship.

To avoid any confusion on the part of covered entities as to application of the Privacy Rule to the records they maintain as employers, the Department proposed to modify the definition of ''protected health information'' in § 164.501 to expressly exclude employment records held by a covered entity in its role as employer. The proposed modification also would alleviate the situation where a covered entity would feel compelled to elect to designate itself as a hybrid entity solely to carve out its employment functions. Individually identifiable health information maintained or transmitted by a covered entity in its health care capacity would, under the proposed modification, continue to be treated as protected health information.

The Department specifically solicited comments on whether the term ''employment records'' is clear and what types of records would be covered by the term.

In addition, as discussed in section III.C.1. below, the Department proposed to modify the definition of a hybrid entity to permit any covered entity that engaged in both covered and non-covered functions to elect to operate as a hybrid entity. Under the proposed modification, a covered entity that primarily engaged in covered functions, such as a hospital, would be allowed to elect hybrid entity status even if its only non-covered functions were those related to its capacity as an employer. Indeed, because of the absence of an express exclusion for employment records in the definition of protected health information, some covered entities may have elected hybrid entity status under the misconception that this was the only way to prevent their personnel information from being treated as protected health information under the Rule.

*Overview of Public Comments.* The following discussion provides an overview of the public comment received on this proposal. Additional comments received on this issue are discussed below in the section entitled, ''Response to Other Public Comments.''

The Department received comments both supporting and opposing the proposal to add an exemption for employment records to the definition of protected health information. Support for the proposal was based primarily on the need for clarity and certainty in this important area. Moreover, commenters supported the proposed exemption for employment records because it reinforced and clarified that the Privacy Rule does not conflict with an employer's obligation under numerous other laws, including OSHA, Family and Medical Leave Act (FMLA), workers' compensation, and alcohol and drug free workplace laws.

Those opposed to the modification were concerned that a covered entity may abuse its access to the individually identifiable health information in its employment records by using that information for discriminatory purposes. Many commenters expressed concern that an employee's health information created, maintained, or transmitted by the covered entity in its health care capacity would be considered an employment record and, therefore, would not be considered protected health information. Some of these commenters argued for the inclusion of special provisions, similar to the ''adequate separation'' requirements for disclosure of protected health information from group health plan to plan sponsor functions (§ 164.504(f)), to heighten the protection for an employee's individually identifiable health information when moving between a covered entity's

health care functions and its employer functions.

A number of commenters also suggested types of records that the Department should consider to be ''employment records'' and, therefore, excluded from the definition of ''protected health information.'' The suggested records included records maintained under the FMLA or the Americans with Disabilities Act (ADA), as well as records relating to occupational injury, disability insurance eligibility, sick leave requests and justifications, drug screening results, workplace medical surveillance, and fitness-for-duty test results. One commenter suggested that health information related to professional athletes should qualify as an employment record.

*Final Modifications.* The Department adopts as final the proposed language excluding employment records maintained by a covered entity in its capacity as an employer from the definition of ''protected health information.'' The Department agrees with commenters that the regulation should be explicit that it does not apply to a covered entity's employer functions and that the most effective means of accomplishing this is through the definition of ''protected health information.''

The Department is sensitive to the concerns of commenters that a covered entity not abuse its access to an employee's individually identifiable health information which it has created or maintains in its health care, not its employer, capacity. In responding to these concerns, the Department must remain within the boundaries set by the statute, which does not include employers per se as covered entities. Thus, we cannot regulate employers, even when it is a covered entity acting as an employer.

To address these concerns, the Department clarifies that a covered entity must remain cognizant of its dual roles as an employer and as a health care provider, health plan, or health care clearinghouse. Individually identifiable health information created, received, or maintained by a covered entity in its health care capacity is protected health information. It does not matter if the individual is a member of the covered entity's workforce or not. Thus, the medical record of a hospital employee who is receiving treatment at the hospital is protected health information and is covered by the Rule, just as the medical record of any other patient of that hospital is protected health information and covered by the Rule. The hospital may use that information only as permitted by the Privacy Rule, and in most cases will need the employee's authorization to access or use the medical information for employment purposes. When the individual gives his or her medical information to the covered entity as the employer, such as when submitting a doctor's statement to document sick leave, or when the covered entity as employer obtains the employee's written authorization for disclosure of protected health information, such as an authorization to disclose the results of a fitness for duty examination, that medical information becomes part of the employment record, and, as such, is no longer protected health information. The covered entity as employer, however, may be subject to other laws and regulations applicable to the use or disclosure of information in an employee's employment record.

The Department has decided not to add a definition of the term ''employment records'' to the Rule. The comments indicate that the same individually identifiable health information about an individual may be maintained by the covered entity in both its employment records and the medical records it maintains as a health care provider or enrollment or claims records it maintains as a health plan. The Department therefore is concerned that a definition of ''employment record'' may lead to the misconception that certain types of information are never protected health information, and will put the focus incorrectly on the nature of the information rather than the reasons for which the covered entity obtained the information. For example, drug screening test results will be protected health information when the provider administers the test to the employee, but will not be protected health information when, pursuant to the employee's authorization, the test results are provided to the provider acting as employer and placed in the employee's employment record. Similarly, the results of a fitness for duty exam will be protected health information when the provider administers the test to one of its employees, but will not be protected health information when the results of the fitness for duty exam are turned over to the provider as employer pursuant to the employee's authorization.

Furthermore, while the examples provided by commenters represent typical files or records that may be maintained by employers, the Department does not believe that it has sufficient information to provide a complete definition of employment record. Therefore, the Department does not adopt as part of this rulemaking a definition of employment record, but does clarify that medical information needed for an employer to carry out its obligations under FMLA, ADA, and similar laws, as well as files or records related to occupational injury, disability insurance eligibility, sick leave requests and justifications, drug screening results, workplace medical surveillance, and fitness-for-duty tests of employees, may be part of the employment records maintained by the covered entity in its role as an employer.

*Response to Other Public Comments*

*Comment:* One commenter requested clarification as to whether the term ''employment record'' included the following information that is either maintained or transmitted by a fully insured group health plan to an insurer or HMO for enrollment and/or disenrollment purposes: (a) the identity of an individual including name, address, birth date, marital status, dependent information and SSN; (b) the individual's choice of plan; (c) the amount of premiums/contributions for coverage of the individual; (d) whether the individual is an active employee or retired; (e) whether the individual is enrolled in Medicare.

*Response:* All of this information is protected health information when held by a fully insured group health plan and transmitted to an issuer or HMO, and the Privacy Rule applies when the group health plan discloses such information to any entity, including the plan sponsor. There are special rules in § 164.504(f) which describe the conditions for disclosure of protected health information to the plan sponsor. If the group health plan received the information from the plan sponsor, it becomes protected health information when received by the group health plan. The plan sponsor is not the covered entity, so this information will not be protected when held by a plan sponsor, whether or not it is part of the plan sponsor's ''employment record.''

*Comment:* One commenter asked for clarification as to how the Department would characterize the following items that a covered entity may have: (1) medical file kept separate from the rest of an employment record containing (a) doctor's notes; (b) leave requests; (c) physician certifications; and (d) positive hepatitis test results; (2) FMLA documentation including: (a) physician certification form; and (b) leave requests; (3) occupational injury files containing (a) drug screening; (b) exposure test results; (c) doctor's notes; and (d) medical director's notes.

*Response:* As explained above, the nature of the information does not determine whether it is an employment record. Rather, it depends on whether the covered entity obtains or creates the information in its capacity as employer or in its capacity as covered entity. An employment record may well contain some or all of the items mentioned by the commenter; but so too might a treatment record. The Department also recognizes that the employer may be required by law or sound business practice to treat such medical information as confidential and maintain it separate from other employment records. It is the function being performed by the covered entity and the purpose for which the covered entity has the medical information, not its record keeping practices, that determines whether the health information is part of an employment record or whether it is protected health information.

*Comment:* One commenter suggested that the health records of professional athletes should qualify as ''employment records.'' As such, the records would not be subject to the protections of the Privacy Rule.

*Response:* Professional sports teams are unlikely to be covered entities. Even if a sports team were to be a covered entity, employment records of a covered entity are not covered by this Rule. If this comment is suggesting that the records of professional athletes should be deemed ''employment records'' even when created or maintained by health care providers and health plans, the Department disagrees. No class of individuals should be singled out for reduced privacy protections. As noted in the preamble to the December 2000 Rule, nothing in this Rule prevents an employer, such as a professional sports team, from making an employee's agreement to disclose health records a condition of employment. A covered entity, therefore, could disclose this information to an employer pursuant to an authorization.

*B. Section 164.502—Uses and Disclosures of Protected Health Information: General Rules*

1. Incidental Uses and Disclosures

*December 2000 Privacy Rule.* The December 2000 Rule did not explicitly address incidental uses and disclosures of protected health information. Rather, the Privacy Rule generally requires covered entities to make reasonable efforts to limit the use or disclosure of, and requests for, protected health information to the minimum necessary to accomplish the intended purpose. *See* § 164.502(b). Additionally, § 164.530(c) of the Privacy Rule requires covered entities to implement appropriate administrative, technical, and physical safeguards to reasonably safeguard protected health information from any intentional or unintentional use or disclosure that violates the Rule.

Protected health information includes individually identifiable health information (with limited exceptions) in any form, including information transmitted orally, or in written or electronic form. See the definition of ''protected health information'' at § 164.501.

*March 2002 NPRM.* After publication of the Privacy Rule, the Department received a number of concerns and questions as to whether the Privacy Rule's restrictions on uses and disclosures will prohibit covered entities from engaging in certain common and essential health care communications and practices in use today. In particular, concern was expressed that the Privacy Rule establishes absolute, strict standards that would not allow for the incidental or unintentional disclosures that could occur as a by-product of engaging in these health care communications and practices. It was argued that the Privacy Rule would, in effect, prohibit such practices and, therefore, impede many activities and communications essential to effective and timely treatment of patients.

For example, some expressed concern that health care providers could no longer engage in confidential conversations with other providers or with patients, if there is a possibility that they could be overheard. Similarly, others questioned whether they would be prohibited from using sign-in sheets in waiting rooms or maintaining patient charts at bedside, or whether they would need to isolate X-ray lightboards or destroy empty prescription vials. These concerns seemed to stem from a perception that covered entities are required to prevent any incidental disclosure such as those that may occur when a visiting family member or other person not authorized to access protected health information happens to walk by medical equipment or other material containing individually identifiable health information, or when individuals in a waiting room sign their name on a log sheet and glimpse the names of other patients.

The Department, in its July 6 guidance, clarified that the Privacy Rule is not intended to impede customary and necessary health care communications or practices, nor to require that all risk of incidental use or disclosure be eliminated to satisfy its standards. The guidance promised that the Department would propose modifications to the Privacy Rule to clarify that such communications and practices may continue, if reasonable safeguards are taken to minimize the chance of incidental disclosure to others.

Accordingly, the Department proposed to modify the Privacy Rule to add a new provision at § 164.502(a)(1)(iii) which would explicitly permit certain incidental uses and disclosures that occur as a result of a use or disclosure otherwise permitted by the Privacy Rule. The proposal described an incidental use or disclosure as a secondary use or disclosure that cannot reasonably be prevented, is limited in nature, and that occurs as a by-product of an otherwise permitted use or disclosure. The Department proposed that an incidental use or disclosure be permissible only to the extent that the covered entity had applied reasonable safeguards as required by § 164.530(c), and implemented the minimum necessary standard, where applicable, as required by §§ 164.502(b) and 164.514(d).

*Overview of Public Comments.* The following discussion provides an overview of the public comment received on this proposal. Additional comments received on this issue are discussed below in the section entitled, ''Response to Other Public Comments.''

The Department received many comments on its proposal to permit certain incidental uses and disclosures, the majority of which expressed strong support for the proposal. Many of these commenters indicated that such a policy would help to ensure that essential health care communications and practices are not chilled by the Privacy Rule. A few commenters opposed the Department's proposal to permit certain incidental uses and disclosures, one of whom asserted that the burden on medical staff to take precautions not to be overheard is minimal compared to the potential harm to patients if incidental disclosures were to be considered permissible.

*Final Modifications.* In response to the overwhelming support of commenters on this proposal, the Department adopts the proposed provision at § 164.502(a)(1)(iii), explicitly permitting certain incidental uses and disclosures that occur as a by-product of a use or disclosure otherwise permitted under the Privacy Rule. As in the proposal, an incidental use or disclosure is permissible only to the extent that the covered entity has applied reasonable safeguards as

required by § 164.530(c), and implemented the minimum necessary standard, where applicable, as required by §§ 164.502(b) and 164.514(d). The Department continues to believe, as was stated in the proposed Rule, that so long as reasonable safeguards are employed, the burden of impeding such communications is not outweighed by any benefits that may accrue to individuals' privacy interests.

However, an incidental use or disclosure that occurs as a result of a failure to apply reasonable safeguards or the minimum necessary standard, where required, is not a permissible use or disclosure and, therefore, is a violation of the Privacy Rule. For example, a hospital that permits an employee to have unimpeded access to patients' medical records, where such access is not necessary for the employee to do her job, is not applying the minimum necessary standard and, therefore, any incidental use or disclosure that results from this practice would be an unlawful use or disclosure under the Privacy Rule.

In response to the few comments that opposed the proposal to permit certain incidental uses and disclosures, the Department reiterates that the Privacy Rule must not impede essential health care communications and practices. Prohibiting all incidental uses and disclosures would have a chilling effect on normal and important communications among providers, and between providers and their patients, and, therefore, would negatively affect individuals' access to quality health care. The Department does not intend with this provision to obviate the need for medical staff to take precautions to avoid being overheard, but rather, will only allow incidental uses and disclosures where appropriate precautions have been taken.

The Department clarifies, in response to a comment, that this provision applies, subject to reasonable safeguards and the minimum necessary standard, to an incidental use or disclosure that occurs as a result of any permissible use or disclosure under the Privacy Rule made to any person, and not just to incidental uses and disclosures resulting from treatment communications or only to communications among health care providers or other medical staff. For example, a provider may instruct an administrative staff member to bill a patient for a particular procedure, and may be overheard by one or more persons in the waiting room. Assuming that the provider made reasonable efforts to avoid being overheard and reasonably limited the information shared, an incidental disclosure resulting from such conversation is permissible under the Rule.

In the proposal, the Department did not address whether or not incidental disclosures would need to be included in the accounting of disclosures required by § 164.528. However, one commenter urged the Department to exclude incidental disclosures from the accounting. The Department agrees with this commenter and clarifies that covered entities are not required to include incidental disclosures in an accounting of disclosures provided to the individual pursuant to § 164.528. The Department does not believe such a requirement would be practicable; in many instances, the covered entity may not know that an incidental disclosure occurred. To make this policy clear, the Department includes an explicit exception for such disclosures to the accounting standard at § 164.528(a)(1).

*Response to Other Public Comments*

*Comment:* One commenter expressed concern that the requirement reasonably to safeguard protected health information would be problematic because any unintended use or disclosure could arguably demonstrate a failure to ''reasonably safeguard.'' This commenter requested that the Department either delete the language in § 164.530(c)(2)(ii) or modify the language to make clear that the fact that an incidental use or disclosure occurs does not imply that safeguards were not reasonable.

*Response:* The Department clarifies that the fact that an incidental use or disclosure occurs does not by itself imply that safeguards were not reasonable. However, the Department does not believe that a modification to the proposed language is necessary to express this intent. The language proposed and now adopted at § 164.530(c)(2)(ii) requires only that the covered entity reasonably safeguard protected health information to limit incidental uses or disclosures, not that the covered entity prevent all incidental uses and disclosures. Thus, the Department expects that incidental uses and disclosures will occur and permits such uses and disclosures to the extent the covered entity has in place reasonable safeguards and has applied the minimum necessary standard, where applicable.

*Comment:* Another commenter requested that the Department clarify its proposal to assure that unintended disclosures will not result in civil penalties.

*Response:* The Department's authority to impose civil monetary penalties on violations of the Privacy Rule is defined in HIPAA. Specifically, HIPAA added section 1176 to the Social Security Act, which prescribes the Secretary's authority to impose civil monetary penalties. Therefore, in the case of a violation of a disclosure provision in the Privacy Rule, a penalty may not be imposed, among other things, if the person liable for the penalty did not know and, by exercising reasonable diligence would not have known, that such person violated the provision. HIPAA also provides for criminal penalties under certain circumstances, but the Department of Justice, not this Department, has authority for criminal penalties.

*Comment:* One commenter requested that the Department clarify how covered entities should implement technical and physical safeguards when they do not yet know what safeguards the final Security Rule will require.

*Response:* Each covered entity should assess the nature of the protected health information it holds, and the nature and scope of its business, and implement safeguards that are reasonable for its particular circumstances. There should be no potential for conflict between the safeguards required by the Privacy Rule and the final Security Rule standards, for several reasons. First, while the Privacy Rule applies to protected health information in all forms, the Security Rule will apply only to electronic health information systems that maintain or transmit individually identifiable health information. Thus, all safeguards for protected health information in oral, written, or other non-electronic forms will be unaffected by the Security Rule. Second, in preparing the final Security Rule, the Department is working to ensure the Security Rule requirements for electronic information systems work ''hand in glove'' with any relevant requirements in the Privacy Rule, including § 164.530.

*Comment:* One commenter argued that while this new provision is helpful, it does not alleviate covered entities' concerns that routine practices, often beneficial for treatment, will be prohibited by the Privacy Rule. This commenter stated that, for example, specialists provide certain types of therapy to patients in a group setting, and, in some cases, where family members are also present.

*Response:* The Department reiterates that the Privacy Rule is not intended to impede common health care communications and practices that are essential in providing health care to the individual. Further, the Privacy Rule's new provision permitting certain incidental uses and disclosures is

intended to increase covered entities' confidence that such practices can continue even where an incidental use or disclosure may occur, provided that the covered entity has taken reasonable precautions to safeguard and limit the protected health information disclosed. For example, this provision should alleviate concerns that common practices, such as the use of sign-in sheets and calling out names in waiting rooms will not violate the Rule, so long as the information disclosed is appropriately limited. With regard to the commenters' specific example, disclosure of protected health information in a group therapy setting would be a treatment disclosure, and thus permissible without individual authorization. Further, § 164.510(b) generally permits a covered entity to disclose protected health information to a family member or other person involved in the individual's care. In fact, this section specifically provides that, where the individual is present during a disclosure, the covered entity may disclose protected health information if it is reasonable to infer from the circumstances that the individual does not object to the disclosure. Absent countervailing circumstances, the individual's agreement to participate in group therapy or family discussions is a good basis for such a reasonable inference. As such disclosures are permissible disclosures in and of themselves, they would not be incidental disclosures.

*Comment:* Some commenters, while in support of permitting incidental uses and disclosures, requested that the Department provide additional guidance in this area by providing additional examples of permitted incidental uses and disclosures and/or clarifying what would constitute ''reasonable safeguards.''

*Response:* The reasonable safeguards and minimum necessary standards are flexible and adaptable to the specific business needs and circumstances of the covered entity. Given the discretion covered entities have in implementing these standards, it is difficult for the Department to provide specific guidance in this area that is generally applicable to many covered entities. However, the Department intends to provide future guidance through frequently asked questions or other materials in response to specific scenarios that are raised by industry.

2. Minimum Necessary Standard

*December 2000 Privacy Rule.* The Privacy Rule generally requires covered entities to make reasonable efforts to limit the use or disclosure of, and requests for, protected health information to the minimum necessary to accomplish the intended purpose. See § 164.502(b). Protected health information includes individually identifiable health information (with limited exceptions) in any form, including information transmitted orally, or in written or electronic form. See the definition of ''protected health information'' at § 164.501. The minimum necessary standard is intended to make covered entities evaluate their practices and enhance protections as needed to limit unnecessary or inappropriate access to, and disclosures of, protected health information.

The Privacy Rule contains some exceptions to the minimum necessary standard. The minimum necessary requirements do not apply to uses or disclosures that are required by law, disclosures made to the individual or pursuant to an authorization initiated by the individual, disclosures to or requests by a health care provider for treatment purposes, uses or disclosures that are required for compliance with the regulations implementing the other administrative simplification provisions of HIPAA, or disclosures to the Secretary of HHS for purposes of enforcing this Rule. See § 164.502(b)(2).

The Privacy Rule sets forth requirements for implementing the minimum necessary standard with regard to a covered entity's uses, disclosures, and requests at § 164.514(d). A covered entity is required to develop and implement policies and procedures appropriate to the entity's business practices and workforce that reasonably minimize the amount of protected health information used, disclosed, and requested. For uses of protected health information, the policies and procedures must identify the persons or classes of persons within the covered entity who need access to the information to carry out their job duties, the categories or types of protected health information needed, and the conditions appropriate to such access. For routine or recurring requests and disclosures, the policies and procedures may be standard protocols. Non-routine requests for, and disclosures of, protected health information must be reviewed individually.

With regard to disclosures, the Privacy Rule permits a covered entity to rely on the judgment of certain parties requesting the disclosure as to the minimum amount of information that is needed. For example, a covered entity is permitted reasonably to rely on representations from a public official, such as a State workers' compensation official, that the information requested is the minimum necessary for the intended purpose. Similarly, a covered entity is permitted reasonably to rely on the judgment of another covered entity that the information requested is the minimum amount of information reasonably necessary to fulfill the purpose for which the request has been made. See § 164.514(d)(3)(iii).

*March 2002 NPRM.* The Department proposed a number of minor modifications to the minimum necessary standard to clarify the Department's intent or otherwise conform these provisions to other proposed modifications. First, the Department proposed to separate § 164.502(b)(2)(ii) into two subparagraphs (§ 164.502(b)(2)(ii) and (iii)) to eliminate confusion regarding the exception to the minimum necessary standard for uses or disclosures made pursuant to an authorization under § 164.508, and the separate exception for disclosures made to the individual. Second, to conform to the proposal to eliminate the special authorizations required by the Privacy Rule at § 164.508(d), (e), and (f), the Department proposed to exempt from the minimum necessary standard any uses or disclosures for which the covered entity had received an authorization that meets the requirements of § 164.508, rather than just those authorizations initiated by the individual.

Third, the Department proposed to modify § 164.514(d)(1) to delete the term ''reasonably ensure'' in response to concerns that the term connotes an absolute, strict standard and, therefore, is inconsistent with the Department's intent that the minimum necessary requirements be reasonable and flexible to the unique circumstances of the covered entity. In addition, the Department proposed to generally revise the language in § 164.514(d)(1) to be more consistent with the description of standards elsewhere in the Privacy Rule.

Fourth, so that the minimum necessary standard would be applied consistently to requests for, and disclosures of, protected health information, the Department proposed to add a provision to § 164.514(d)(4) to make the implementation specifications for applying the minimum necessary standard to requests for protected health information by a covered entity more consistent with the corresponding implementation specifications for disclosures. Specifically, for requests not made on a routine and recurring basis, the Department proposed to add the requirement that a covered entity must implement the minimum

necessary standard by developing and implementing criteria designed to limit its request for protected health information to the minimum necessary to accomplish the intended purpose.

*Overview of Public Comments.* The following discussion provides an overview of the public comment received on this proposal. Additional comments received on this issue are discussed below in the section entitled, ''Response to Other Public Comments.''

The Department received a number of comments on its proposal to exempt from the minimum necessary standard any use or disclosure of protected health information for which the covered entity has received an authorization that meets the requirements of § 164.508. Many commenters supported this proposal. A few commenters generally urged that the minimum necessary standard be applied to uses and disclosures pursuant to an authorization. A few other commenters appeared to misinterpret the policy in the December 2000 Rule and urged that the Department retain the minimum necessary standard for disclosures ''pursuant to an authorization other than disclosures to an individual.'' Some commenters raised specific concerns about authorizations for psychotherapy notes and the particular need for minimum necessary to be applied in these cases.

A number of commenters expressed support for the Department's statements in the preamble to the proposed Rule reinforcing that the minimum necessary standard is intended to be flexible to account for the characteristics of the entity's business and workforce, and not intended to override the professional judgment of the covered entity. Similarly, some commenters expressed support for the Department's proposal to remove the term ''reasonably ensure'' from § 164.514(d)(1). However, a few commenters expressed concerns that the proposed alternative language actually would implement a stricter standard than that included in the December 2000 Privacy Rule.

*Final Modifications.* In this final Rule, the Department adopts the proposed policy to exempt from the minimum necessary standard any uses or disclosures for which the covered entity has received an authorization that meets the requirements of § 164.508. The final modification adopts the proposal to eliminate the special authorizations that were required by the December 2000 Privacy Rule at § 164.508(d), (e), and (f). (*See* section III.E.1. of the preamble for a detailed discussion of the modifications to the authorization requirements of the Privacy Rule.) Since the only authorizations to which the minimum necessary standard applied are being eliminated in favor of a single consolidated authorization, the final Rule correspondingly eliminates the minimum necessary provisions that applied to the now-eliminated special authorizations. All uses and disclosures made pursuant to any authorization are exempt from the minimum necessary standard.

In response to commenters who opposed this proposal as a potential weakening of privacy protections or who wanted the minimum necessary requirements to apply to authorizations other than disclosures to the individual, the Department notes that nothing in the final Rule eliminates an individual's control over his or her protected health information with respect to an authorization. All authorizations must include a description of the information to be used and disclosed that identifies the information in a specific and meaningful fashion as required by § 164.508(c)(1)(i). If the individual does not wish to release the information requested, the individual has the right to not sign the authorization or to negotiate a narrower authorization with the requestor.

Additionally, in response to those commenters who raised specific concerns with respect to authorizations which request release of psychotherapy notes, the Department clarifies that the final Rule does not require a covered entity to use and disclose protected health information pursuant to an authorization. Rather, as with most other uses and disclosures under the Privacy Rule, this is only a permissible use or disclosure. If a covered health care provider is concerned that a request for an individual's psychotherapy notes is not warranted or is excessive, the provider may consult with the individual to determine whether or not the authorization is consistent with the individual's wishes.

Further, the Privacy Rule does not permit a health plan to condition enrollment, eligibility for benefits, or payment of a claim on obtaining the individual's authorization to use or disclose psychotherapy notes. Nor may a health care provider condition treatment on an authorization for the use or disclosure of psychotherapy notes. Thus, the Department believes that these additional protections appropriately and effectively protect an individual's privacy with respect to psychotherapy notes.

The final Rule also retains for clarity the proposal to separate § 164.502(b)(2)(ii) into two subparagraphs (§ 164.502(b)(2)(ii) and (iii)); commenters did not explicitly address or raise issues with this proposed clarification.

In response to concerns that the proposed language at § 164.514(d)(1) would implement a stricter standard, the Department disagrees and, therefore, adopts the proposed language. The language in § 164.514(d)(1) describes the standard: covered entities are required to meet the requirements in the implementation specifications of § 164.514(d)(2) through (d)(5). The implementation specifications describe what covered entities must do reasonably to limit uses, disclosures, and requests to the minimum necessary. Thus, the Department believes that the language in the implementation specifications is adequate to reflect the Department's intent that the minimum necessary standard is reasonable and flexible to accommodate the unique circumstances of the covered entity.

Commenters also generally did not address the Department's proposed clarification to make the implementation specifications for requests of protected health information consistent with those for disclosures of protected health information. Consequently, as commenters did not raise concerns with the proposal, this final Rule adopts the proposed provision at § 164.514(d)(4). For requests of protected health information not made on a routine and recurring basis, a covered entity must implement the minimum necessary standard by developing and implementing criteria designed to limit its request for protected health information to the minimum necessary to accomplish the intended purpose.

*Response to Other Public Comments*

*Comment:* Many commenters recommended changes to the minimum necessary standard unrelated to the proposed modifications. For example, some commenters urged that the Department exempt from the minimum necessary standard all uses of protected health information, or at least uses of protected health information for treatment purposes. Alternatively, one commenter urged that the minimum necessary standard be applied to disclosures for treatment purposes. Others requested that the Department exempt uses and disclosures for payment and health care operations from the standard, or exempt disclosures to another covered entity for such purposes. A few commenters argued that the minimum necessary standard should not apply to disclosures to another covered entity. Some urged that the minimum

necessary standard be eliminated entirely.

*Response:* The Department did not propose modifications relevant to these comments, nor did it seek comment on these issues. The proposed modifications generally were intended to address those problems or issues that presented workability problems for covered entities or otherwise had the potential to impede an individual's timely access to quality health care. Moreover, the proposed modifications to the minimum necessary standard were either minor clarifications of the Department's intent with respect to the standard or would conform the standard to other proposed modifications. The Department has, in previous guidance as well as in the preamble to the December 2000 Privacy Rule, explained its position with respect to the above concerns. The minimum necessary standard is derived from confidentiality codes and practices in common use today. We continue to believe that it is sound practice not to use or disclose private medical information that is not necessary to satisfy a request or effectively carry out a function. The privacy benefits of retaining the minimum necessary standard outweigh the burden involved with implementing the standard. The Department reiterates that position here.

Further, the Department designed the minimum necessary standard to be sufficiently flexible to accommodate the various circumstances of any covered entity. Covered entities will develop their own policies and procedures to meet this standard. A covered entity's policies and procedures may and should allow the appropriate individuals within an entity to have access to protected health information as necessary to perform their jobs with respect to the entity's covered functions. The Department is not aware of any workability issues with this standard.

With respect to disclosures to another covered entity, the Privacy Rule permits a covered entity reasonably to rely on another covered entity's request for protected health information as the minimum necessary for the intended disclosure. See § 164.514(d)(3)(iii). The Department does not believe, therefore, that a blanket exception for such disclosures is justified. The covered entity who holds the information always retains discretion to make its own minimum necessary determination.

Lastly, the Department continues to believe that the exception for disclosures to or requests by health care providers for treatment purposes is appropriate to ensure that access to timely and quality treatment is not impeded.

As the Privacy Rule is implemented, the Department will monitor the workability of the minimum necessary standard and consider proposing revisions, where appropriate, to ensure that the Privacy Rule does not hinder timely access to quality health care.

*Comment:* One commenter requested that the Department state in the preamble that the minimum necessary standard may not be used to interfere with or obstruct essential health plan payment and health care operations activities, including quality assurance, disease management, and other activities. Another commenter asked that the final Rule's preamble acknowledge that, in some cases, the minimum protected health information necessary for payment or health care operations will be the entire record. One commenter urged that the Rule be modified to presume that disclosure of a patient's entire record is justified, and that such disclosure does not require individual review, when requested for disease management purposes.

*Response:* The minimum necessary standard is not intended to impede essential treatment, payment, or health care operations activities of covered entities. Nor is the Rule intended to change the way covered entities handle their differences with respect to disclosures of protected health information. The Department recognizes that, in some cases, an individual's entire medical record may be necessary for payment or health care operations purposes, including disease management purposes. However, the Department does not believe that disclosure of a patient's entire medical record is always justified for such purposes. The Privacy Rule does not prohibit the request for, or release of, entire medical records in such circumstances, provided that the covered entity has documented the specific justification for the request or disclosure of the entire record.

*Comment:* A few commenters requested that the Department add to the regulatory text some of the statements included in the preamble to the proposed modifications. For example, commenters asked that the final Rule state that the minimum necessary standard is ''intended to be consistent with, and not override, professional judgement and standards.'' Similarly, others requested that the regulation specify that ''covered entities must implement policies and procedures based on their own assessment of what protected health information is reasonably necessary for a particular purpose, given the characteristics of their business and their workforce, and using their own professional judgment.''

*Response:* It is the Department's policy that the minimum necessary standard is intended to be consistent with, and not override, professional judgment and standards, and that covered entities must implement policies and procedures based on their own assessment of what protected health information is reasonably necessary for a particular purpose, given the characteristics of their business and their workforce. However, the Department does not believe a regulatory modification is necessary because the Department has made its policy clear not only in the preamble to the proposed modifications but also in previous guidance and in this preamble.

*Comment:* A commenter argued that the Department should exempt disclosures for any of the standard transactions as required by the Transactions Rule, when information is requested by a health plan or its business associate.

*Response:* The Department disagrees. The Privacy Rule already exempts from the minimum necessary standard data elements that are required or situationally required in any of the standard transactions (§ 164.502(b)(2)(v)). If, however, a standard transaction permits the use of optional data elements, the minimum necessary standard applies. For example, the standard transactions adopted for the outpatient pharmacy sector use optional data elements. The payer currently specifies which of the optional data elements are needed for payment of its particular pharmacy claims. The minimum necessary standard applies to the payer's request for such information. A pharmacist is permitted to rely on the payer's request for information, if reasonable to do so, as the minimum necessary for the intended disclosure.

*Comment:* A few commenters expressed concerns with respect to a covered entity's disclosures for research purposes. Specifically, one commenter was concerned that a covered entity will not accept documentation of an external IRB's waiver of authorization for purposes of reasonably relying on the request as the minimum necessary. It was suggested that the Department deem that a disclosure to a researcher based on appropriate documentation from an IRB or Privacy Board meets the minimum necessary standard.

*Response:* The Department understands commenters' concerns that covered entities may decline to

participate in research studies, but believes that the Rule already addresses this concern. The Privacy Rule explicitly permits a covered entity reasonably to rely on a researcher's documentation or the representations of an IRB or Privacy Board pursuant to § 164.512(i) that the information requested is the minimum necessary for the research purpose. This is true regardless of whether the documentation is obtained from an external IRB or Privacy Board or one that is associated with the covered entity. The preamble to the March 2002 NPRM further reinforced this policy by stating that reasonable reliance on an IRB's documentation of approval of the waiver criteria and a description of the data needed for the research as required by § 164.512(i) would satisfy a covered entity's obligations with respect to limiting the disclosure to the minimum necessary. The Department reiterates this policy here and believes that this should give covered entities sufficient confidence in accepting IRB waivers of authorization.

*Comment:* A number of commenters requested that the Department limit the amount of information that pharmacy benefits managers (PBM) may demand from pharmacies as part of their claims payment activities.

*Response:* The health plan, as a covered entity, is obligated to instruct the PBM, as its business associate acting through the business associate contract, to request only the minimum amount of information necessary to pay a claim. The pharmacist may rely on this determination if reasonable to do so, and then does not need to engage in a separate minimum necessary assessment. If a pharmacist does not agree that the amount of information requested is reasonably necessary for the PBM to fulfill its obligations, it is up to the pharmacist and PBM to negotiate a resolution of the dispute as to the amount of information needed by the PBM to carry out its obligations and that the pharmacist is willing to provide, recognizing that the PBM is not required to pay claims if it has not received the information it believes is necessary to process the claim in accordance with its procedures, including fraud prevention procedures.

The standard for electronic pharmacy claims, adopted by the Secretary in the Transactions Rule, includes optional data elements and relies on each payer to specify the data elements required for payment of its claims. Understandably, the majority of health plans require some patient identification elements in order to adjudicate claims. As the National Council for Prescription Drug Programs (NCPDP) moves from optional to required and situational data elements, the question of whether the specific element of ''patient name'' should be required or situational will be debated by the NCPDP, by the Designated Standards Maintenance Organizations, by the National Committee on Vital and Health Statistics, and ultimately will be decided in rulemaking by the Secretary.

*Comment:* One commenter requested that the minimum necessary standard be made an administrative requirement rather than a standard for uses and disclosures, to ease liability concerns with implementing the standard. The commenter stated that this change would mean that covered entities would be required to implement reasonable minimum necessary policies and procedures and would be liable if: (1) They fail to implement minimum necessary policies and procedures; (2) their policies and procedures are not reasonable; or (3) they fail to enforce their policies and procedures. The commenter further explained that health plans would be liable if their policies and procedures for requesting health information were unreasonable, but the burden of liability for the request shifts largely to the entity best suited to determine whether the amount of information requested is the minimum necessary.

*Response:* The Privacy Rule already requires covered entities to implement reasonable minimum necessary policies and procedures and to limit any use, disclosure, or request for protected health information in a manner consistent with its policies and procedures. The minimum necessary standard is an appropriate standard for uses and disclosures, and is not merely an administrative requirement. The Privacy Rule provides adequate flexibility to adopt minimum necessary policies and procedures that are workable for the covered entity, thereby minimizing a covered entity's liability concerns.

*Comment:* A number of commenters expressed concerns about application of the minimum necessary standard to disclosures for workers' compensation purposes. Commenters argued that the standard will prevent workers' compensation insurers and State administrators, as well as employers, from obtaining the information needed to pay injured workers the benefits guaranteed under the State workers' compensation system. They also argued that the minimum necessary standard could lead to fraudulent claims and unnecessary legal action in order to obtain information needed for workers' compensation purposes.

*Response:* The Privacy Rule is not intended to disrupt existing workers' compensation systems as established by State law. In particular, the Rule is not intended to impede the flow of health information that is needed by employers, workers' compensation carriers, or State officials in order to process or adjudicate claims and/or coordinate care under the workers' compensation system. To this end, the Privacy Rule at § 164.512(l) explicitly permits a covered entity to disclose protected health information as authorized by, and to the extent necessary to comply with, workers' compensation or other similar programs established by law that provide benefits for work-related injuries or illnesses without regard to fault. The minimum necessary standard permits covered entities to disclose any protected health information under § 164.512(l) that is reasonably necessary for workers' compensation purposes and is intended to operate so as to permit information to be shared for such purposes to the full extent permitted by State or other law.

Additionally, where a State or other law requires a disclosure of protected health information for workers' compensation purposes, such disclosure is permitted under § 164.512(a). A covered entity also is permitted to disclose protected health information to a workers' compensation insurer where the insurer has obtained the individual's authorization pursuant to § 164.508 for the release of such information. The minimum necessary provisions do not apply to disclosures required by law or made pursuant to authorizations. See § 164.502(b), as modified herein.

Further, the Department notes that a covered entity is permitted to disclose information to any person or entity as necessary to obtain payment for health care services. The minimum necessary provisions apply to such disclosures but permit the covered entity to disclose the amount and types of information that are necessary to obtain payment.

The Department also notes that because the disclosures described above are permitted by the Privacy Rule, there is no potential for conflict with State workers' compensation laws, and, thus, no possibility of preemption of such laws by the Privacy Rule.

The Department's review of certain States workers' compensation laws demonstrates that many of these laws address the issue of the scope of information that is available to carriers and employers. The Privacy Rule's minimum necessary standard will not create an obstacle to the type and

amount of information that currently is provided to employers, workers' compensation carriers, and State administrative agencies under these State laws. In many cases, the minimum necessary standard will not apply to disclosures made pursuant to such laws. In other cases, the minimum necessary standard applies, but permits disclosures to the full extent authorized by the workers' compensation laws. For example, Texas workers' compensation law requires a health care provider, upon the request of the injured employee or insurance carrier, to furnish records relating to the treatment or hospitalization for which compensation is being sought. Since such disclosure is required by law, it also is permissible under the Privacy Rule at § 164.512(a) and exempt from the minimum necessary standard. The Texas law further provides that a health care provider is permitted to disclose to the insurance carrier records relating to the diagnosis or treatment of the injured employee without the authorization of the injured employee to determine the amount of payment or the entitlement to payment. Since the disclosure only is permitted and not required by Texas law, the provisions at § 164.512(l) would govern to permit such disclosure. In this case, the minimum necessary standard would apply to the disclosure but would allow for information to be disclosed as authorized by the statute, that is, as necessary to ''determine the amount of payment or the entitlement to payment.''

As another example, under Louisiana workers' compensation law, a health care provider who has treated an employee related to a workers' compensation claim is required to release any requested medical information and records relative to the employee's injury to the employer or the workers' compensation insurer. Again, since such disclosure is required by law, it is permissible under the Privacy Rule at § 164.512(a) and exempt from the minimum necessary standard. The Louisiana law further provides that any information relative to any other treatment or condition shall be available to the employer or workers' compensation insurer through a written release by the claimant. Such disclosure also would be permissible and exempt from the minimum necessary standard under the Privacy Rule if the individual's written authorization is obtained consistent with the requirements of § 164.508.

The Department understands concerns about the potential chilling effect of the Privacy Rule on the workers' compensation system. Therefore, as the Privacy Rule is implemented, the Department will actively monitor the effects of the Rule on this industry to assure that the Privacy Rule does not have any unintended negative effects that disturb the existing workers' compensation systems. If the Department finds that, despite the above clarification of intent, the Privacy Rule is being misused and misapplied to interfere with the smooth operation of the workers' compensation systems, it will consider proposing modifications to the Rule to clarify the application of the minimum necessary standard to disclosures for workers' compensation purposes.

*Comment:* Another commenter urged the Department to clarify that a covered entity can reasonably rely on a determination made by a financial institution or credit card payment system regarding the minimum necessary information needed by that financial institution or payment system to complete a contemplated payment transaction.

*Response:* Except to the extent information is required or situationally required for a standard payment transaction (*see* 45 CFR 162.1601, 162.1602), the minimum necessary standard applies to a covered entity's disclosure of protected health information to a financial institution in order to process a payment transaction. With limited exceptions, the Privacy Rule does not allow a covered entity to substitute the judgment of a private, third party for its own assessment of the minimum necessary information for a disclosure. Under the exceptions in § 164.514(d)(3)(iii), a covered entity is permitted reasonably to rely on the request of another covered entity because, in this case, the requesting covered entity is itself subject to the minimum necessary standard and, therefore, required to limit its request to only that information that is reasonably necessary for the purpose. Thus, the Department does not agree that a covered entity should generally be permitted reasonably to rely on the request of a financial institution as the minimum necessary. However, the Department notes that where, for example, a financial institution is acting as a business associate of a covered entity, the disclosing covered entity may reasonably rely on a request from such financial institution, because in this situation, both the requesting and disclosing entity are subject to the minimum necessary standard.

*Comment:* A number of commenters continued to request additional guidance with respect to implementing this discretionary standard. Many expressed support for the statement in the NPRM that HHS intends to issue further guidance to clarify issues causing confusion and concern in industry, as well as provide additional technical assistance materials to help covered entities implement the provisions.

*Response:* The Department is aware of the need for additional guidance in this area and intends to provide technical assistance and further clarifications as necessary to address these concerns and questions.

3. Parents as Personal Representatives of Unemancipated Minors [1]

*December 2000 Privacy Rule.* The Privacy Rule is intended to assure that parents have appropriate access to health information about their children. By creating new Federal protections and individual rights with respect to individually identifiable health information, parents will generally have new rights with respect to the health information about their minor children. In addition, the Department intended that the disclosure of health information about a minor child to a parent should be governed by State or other applicable law.

Under the Privacy Rule, parents are granted new rights as the personal representatives of their minor children. (*See* § 164.502(g).) Generally, parents will be able to access and control the health information about their minor children. (*See* § 164.502(g)(3).)

The Privacy Rule recognizes a limited number of exceptions to this general rule. These exceptions generally track the ability under State or other applicable laws of certain minors to obtain specified health care without parental consent. For example, every State has a law that permits adolescents to be tested for HIV without the consent of a parent. These laws are created to assure that adolescents will seek health care that is essential to their own health, as well as the public health. In these exceptional cases, where a minor can obtain a particular health care service without the consent of a parent under State or other applicable law, it is the minor, and not the parent, who may exercise the privacy rights afforded to individuals under the December 2000 Privacy Rule. (*See* § 164.502(g)(3)(i) and (ii), redesignated as § 164.502(g)(3)(i)(A) and (B)).

The December 2000 Privacy Rule also allows the minor to exercise control of

[1] Throughout this section of the preamble, ''minor'' refers to an unemancipated minor and ''parent'' refers to a parent, guardian, or other person acting *in loco parentis.*

protected health information when the parent has agreed to the minor obtaining confidential treatment (*see* § 164.502(g)(3)(iii), redesignated as § 164.502(g)(3)(i)(C) in this final Rule), and allows a covered health care provider to choose not to treat a parent as a personal representative of the minor when the provider is concerned about abuse or harm to the child. (*See* § 164.502(g)(5).)

Of course, a covered provider may disclose health information about a minor to a parent in the most critical situations, even if one of the limited exceptions discussed above apply. Disclosure of such information is always permitted as necessary to avert a serious and imminent threat to the health or safety of the minor. (*See* § 164.512(j).) The Privacy Rule adopted in December 2000 also states that disclosure of health information about a minor to a parent is permitted if State law authorizes disclosure to a parent, thereby allowing such disclosure where State law determines it is appropriate. (*See* § 160.202, definition of ''more stringent.'') Finally, health information about the minor may be disclosed to the parent if the minor involves the parent in his or her health care and does not object to such disclosure. (*See* § 164.502(g)(3)(i), redesignated as § 164.502(g)(3)(i)(A), and § 164.510(b)). The parent will retain all rights concerning any other health information about his or her minor child that does not meet one of the few exceptions listed above.

*March 2002 NPRM.* After reassessing the parents and minors provisions in the Privacy Rule, the Department identified two areas in which there were unintended consequences of the Rule. First, the language regarding deference to State law, which authorizes or prohibits disclosure of health information about a minor to a parent, fails to assure that State or other law governs when the law grants a provider discretion in certain circumstances to disclose protected health information to a parent. Second, the Privacy Rule may have prohibited parental access in certain situations in which State or other law may have permitted such access.

The Department proposed changes to these standards where they did not operate as intended and did not adequately defer to State or other applicable law with respect to parents and minors. First, in order to assure that State and other applicable laws that address disclosure of health information about a minor to his or her parent govern in all cases, the Department proposed to move the relevant language about the disclosure of health information from the definition of ''more stringent'' (*see* § 160.202) to the standards regarding parents and minors (*see* § 164.502(g)(3)). This change would make it clear that State and other applicable law governs not only when a State explicitly addresses disclosure of protected health information to a parent but also when such law provides discretion to a provider. The language itself is also changed in the proposal to adapt it to the new section.

Second, the Department proposed to add a new paragraph (iii) to § 164.502(g)(3) to establish a neutral policy regarding the right of access of a parent to health information about his or her minor child under § 164.524, in the rare circumstance in which the parent is technically not the personal representative of his or her minor child under the Privacy Rule. This policy would apply particularly where State or other law is silent or unclear.

*Overview of Public Comments.* The following discussion provides an overview of the public comment received on this proposal. Additional comments received on this issue are discussed below in the section entitled, ''Response to Other Public Comments.''

The Department received a number of comments on the proposed changes to the parents and minors provisions of the Privacy Rule. Many commenters, particularly health care providers involved in provision of health care to minors, requested that the Department return to the approach under the Privacy Rule published in December 2000, because they believed that the proposed approach would discourage minors from seeking necessary health care. At a minimum, these commenters suggested that the Department clarify that discretion to grant a parent access under the proposal is limited to the covered health care provider that is providing treatment to the minor.

Supporters of the proposal asserted that the Department was moving in the right direction, but many also advocated for more parental rights. They asserted that parents have protected rights to act for their children and that the Privacy Rule interferes with these rights.

There were also some commenters that were confused by the new proposal and others that requested a Federal standard that would preempt all State laws.

*Final Modifications.* The Department will continue to defer to State or other applicable law and to remain neutral to the extent possible. However, the Department is adopting changes to the standards in the December 2000 Privacy Rule, where they do not operate as intended and are inconsistent with the Department's underlying goals. These modifications are similar in approach to the NPRM and the rationale for these changes remains the same as was stated in the NPRM. However, the Department makes some changes from the language that was proposed, in order to simplify the provisions and clarify the Department's intent.

There are three goals with respect to the parents and minors provisions in the Privacy Rule. First, the Department wants to assure that parents have appropriate access to the health information about their minor children to make important health care decisions about them, while also making sure that the Privacy Rule does not interfere with a minor's ability to consent to and obtain health care under State or other applicable law. Second, the Department does not want to interfere with State or other applicable laws related to competency or parental rights, in general, or the role of parents in making health care decisions about their minor children, in particular. Third, the Department does not want to interfere with the professional requirements of State medical boards or other ethical codes of health care providers with respect to confidentiality of health information or with the health care practices of such providers with respect to adolescent health care.

In order to honor these differing goals, the Department has and continues to take the approach of deferring to State or other applicable law and professional practice with respect to parents and minors. Where State and other applicable law is silent or unclear, the Department has attempted to create standards, implementation specifications, and requirements that are consistent with such laws and that permit States the discretion to continue to define the rights of parents and minors with respect to health information without interference from the Federal Privacy Rule.

The Department adopts two changes to the provisions regarding parents and minors in order to address unintended consequences from the December 2000 Privacy Rule and to defer to State and other law. The first change is about disclosure of protected health information to a parent and the second is about access to the health information by the parent. Disclosure is about a covered entity providing individually identifiable information to persons outside the entity, either the individual or a third party. Access is a particular type of disclosure that is the right of an individual (directly or through a personal representative) to review or

obtain a copy of his or her health information under § 164.524. This modification treats both activities similarly by deferring to State or other applicable law.

The first change, regarding disclosure of protected health information to a parent, is the same as the change proposed in the NPRM. In order to assure that State and other applicable laws that address disclosure of health information about a minor to his or her parent govern in all cases, the language in the definition of ''more stringent'' (*see* § 160.202) that addresses the disclosure of protected health information about a minor to a parent has been moved to the standards regarding parents and minors (*see* § 164.502(g)(3)). The addition of paragraphs (g)(3)(ii)(A) and (B) of § 164.502, clarify that State and other applicable law governs when such law explicitly requires, permits, or prohibits disclosure of protected health information to a parent.

In connection with moving the language, the language is changed from the December 2000 Privacy Rule in order to adapt it to the new section. Section 164.502(g)(3)(ii)(A) states that a covered entity may disclose protected health information about a minor to a parent if an applicable provision of State or other law permits or requires such disclosure. By adopting this provision, the Department makes clear that nothing in the regulation prohibits disclosure of health information to a parent if, and to the extent that, State or other law permits or requires such disclosure. The Privacy Rule defers to such State or other law and permits covered entities to act in accordance to such law. Section 164.502(g)(3)(ii)(B) states that a covered entity may not disclose protected health information about a minor to a parent if an applicable provision of State or other law prohibits such disclosure. Again, regardless of how the Privacy Rule would operate in the absence of explicit State or other law, if such law prohibits the disclosure of protected health information about a minor to a parent, so does the Privacy Rule. The revision also clarifies that deference to State or other applicable law includes deference to established case law as well as explicit provisions in statutes or regulations that permit, require, or prohibit particular disclosures.

The second change, regarding access to protected health information, also reflects the same policy as proposed in the NPRM. There are two provisions that refer to access, in order to clarify the Department's intent in this area. The first is where there is an explicit State or other law regarding parental access, and the second is where State or other law is silent or unclear, which is often the case with access.

Like the provisions regarding disclosure of protected health information to a parent, the final Rule defers to State or other applicable law regarding a parent's access to health information about a minor. The change assures that State or other applicable law governs when the law explicitly requires, permits, or prohibits access to protected health information about a minor to a parent. This includes deference to established case law as well as an explicit provision in a statute or regulation. This issue is addressed in paragraphs (g)(3)(ii)(A) and (B) of § 164.502 with the disclosure provisions discussed above.

In addition to the provision regarding explicit State access laws, the Department recognizes that the Privacy Rule creates a right of access that previously did not exist in most States. Most States do not have explicit laws in this area. In order to address the limited number of cases in which the parent is not the personal representative of the minor because one of the exceptions in the parents and minors provisions are met (*see* § 164.502(g)(3)(i)(A), (B), or (C)), the Department adds a provision, § 164.502(g)(3)(ii)(C), similar to a provision proposed in the NPRM, that addresses those situations in which State and other law about parental access is not explicit. Under this provision, a covered entity may provide or deny access to a parent provided that such discretion is permitted by State or other law. This new paragraph would assure that the Privacy Rule would not prevent a covered entity from providing access to a parent if the covered entity would have been able to provide this access under State or other applicable law. The new paragraph would also prohibit access by a parent if providing such access would violate State or other applicable law.

It is important to note that this provision regarding access to health information about a minor in cases in which State and other laws are silent or unclear will not apply in the majority of cases because, typically, the parent will be the personal representative of his or her minor child and will have a right of access to the medical records of his or her minor children under the Privacy Rule. This provision only applies in cases in which the parent is not the personal representative under the Privacy Rule.

In response to comments by health care providers, the final modifications also clarify that, the discretion to provide or deny access to a parent under § 164.502(g)(3)(ii)(C) only may be exercised by a licensed health care professional, in the exercise of professional judgment. This is consistent with the policy described in the preamble to the NPRM, is similar to the approach in the access provisions in § 164.524(a)(3), and furthers the Department's interest in balancing the goals of providing appropriate information to parents and of assuring that minors obtain appropriate access to health care. This decision should be made by a health care professional, who is accustomed to exercising professional judgment. A health plan may also exercise such discretion if the decision is made by a licensed health care provider.

The Department takes no position on the ability of a minor to consent to treatment and no position on how State or other law affects privacy between the minor and parent. Where State or other law is unclear, covered entities should continue to conduct the same analysis of such law as they do now to determine if access is permissible or not. Because the Privacy Rule defers to State and other law in the area of parents and minors, the Department assumes that the current practices of health care providers with respect to access by parents and confidentiality of minor's records are consistent with State and other applicable law, and, therefore, can continue under the Privacy Rule.

Parental access under this section would continue to be subject to any limitations on activities of a personal representative in § 164.502(g)(5) and § 164.524(a)(2) and (3). In cases in which the parent is not the personal representative of the minor and State or other law does not require parental access, this provision does not provide a parent a right to demand access and does not require a covered entity to provide access to a parent. Furthermore, nothing in these modifications shall affect whether or not a minor would have a right to access his or her records. That is, a covered entity's exercise of discretion to not grant a parent access does not affect the right of access the minor may have under the Privacy Rule. A covered entity may deny a parent access in accordance with State or other law and may be required to provide access to the minor under the Privacy Rule.

These changes also do not affect the general provisions, explained in the section ''December 2000 Privacy Rule'' above, regarding parents as personal representatives of their minor children or the exceptions to this general rule, where parents would not be the

personal representatives of their minor children.

These changes adopted in this Rule provide States with the option of clarifying the interaction between their laws regarding consent to health care and the ability of parents to have access to the health information about the care received by their minor children in accordance with such laws. As such, this change should more accurately reflect current State and other laws and modifications to such laws.

*Response to Other Public Comments*

*Comment:* Some commenters urged the Department to retain the approach to parents and minors that was adopted in December 2000. They claimed that the NPRM approach would seriously undermine minors' willingness to seek necessary medical care. Other commenters advocated full parental access to health information about their minor children, claiming that the Privacy Rule interferes with parents' rights.

*Response:* We believe the approach adopted in the final Rule strikes the right balance between these concerns. It defers to State law or other applicable law and preserves the status quo to the greatest extent possible.

*Comment:* Health care providers generally opposed the changes to the parents and minors provisions claiming that they would eliminate protection of a minor's privacy, and therefore, would decrease the willingness of adolescents to obtain necessary health care for sensitive types of health care services. They also argued that the NPRM approach is inconsistent with State laws that give minors the right to consent to certain health care because the purpose of these laws is to provide minors with confidential health care.

*Response:* Issues related to parents' and minors' rights with respect to health care are best left for the States to decide. The standards regarding parents and minors are designed to defer to State law in this area. While we believe that there is a correlation between State laws that grant minors the authority to consent to treatment and confidentiality of the information related to such treatment, our research has not established that these laws bar parental access to such health information under all circumstances. Therefore, to act in a manner consistent with State law, the approach adopted in this Final Rule is more flexible than the standards adopted in December 2000, in order to assure that the Privacy Rule does not preclude a provider from granting access to a parent if this is permissible under State law. However, this new standard would not permit activity that would be impermissible under State law.

Some State or other laws may state clearly that a covered entity must provide a parent access to the medical records of his or her minor child, even when the minor consents to the treatment without the parent. In this case, the covered entity must provide a parent access, subject to the access limitations in the Privacy Rule at § 164.524(a)(2) and (3). Other laws may state clearly that a covered entity must not provide a parent access to their minor child's medical records when the minor consents to the treatment without the parent. In this case, the covered entity would be precluded from granting access to the parent. If the State or other law clearly provides a covered entity with discretion to grant a parent access, then the covered entity may exercise such discretion, to the extent permitted under such other law.

If State law is silent or unclear on its face, then a covered entity would have to go through the same analysis as it would today to determine if such law permitted, required, or prohibited providing a parent with access to a minor's records. That analysis may involve review of case law, attorney general opinions, legislative history, etc. If such analysis showed that the State would permit an entity to provide a parent access to health information about a minor child, and under the Privacy Rule, the parent would not be the personal representative of the minor because of one of the limited exceptions in § 164.502(g)(3)(i), then the covered entity may exercise such discretion, based on the professional judgment of a licensed health care provider, to choose whether or not to provide the parent access to the medical records of his or her minor child. If, as the commenters suggest, a State consent law were interpreted to prohibit such access, then such access is prohibited under the Privacy Rule as well.

*Comment:* One commenter asserted that the Privacy Rule inappropriately erects barriers between parents and children. Specifically, the commenter stated that § 164.502(g)(5) delegates to private entities government power to decide whether a child may be subjected to abuse or could be endangered. The commenter also stated that the access provisions in § 164.502(g)(3) would erect barriers where State law is silent or unclear.

*Response:* The Department does not agree that the Privacy Rule erects barriers between a parent and a minor child because the relevant standards are intended to defer to State law. Health care providers have responsibilities under other laws and professional standards to report child abuse to the appropriate authorities and to use professional discretion to protect the child's welfare in abuse situations. Similarly the Privacy Rule permits (but does not require) the provider to use professional discretion to act to protect a child she believes is being abused. If the Privacy Rule were to mandate that a provider grant a parent access to a medical record in abuse situations, as the commenter suggests, this would be a change from current law. In addition, the Privacy Rule does not allow a denial of parental access to medical records if State or other law would require such access.

*Comment:* Commenters continue to raise preemption issues. A few commenters called for preemption of all State law in this area. Others stated that there should be one standard, not 50 standards, controlling disclosure of protected health information about a minor to a parent and that the NPRM approach would burden regional and national health care providers. Others urged preemption of State laws that are less protective of a minor's privacy, consistent with the general preemption provisions.

*Response:* The Department does not want to interfere with a State's role in determining the appropriate rights of parents and their minor children. The claim that the Privacy Rule introduces 50 standards is inaccurate. These State standards exist today and are not created by the Privacy Rule. Our approach has been, and continues to be, to defer to State and other applicable law in this area.

*Comment:* One commenter requested the Privacy Rule state that good faith compliance with the Privacy Rule is an affirmative defense to enforcement of contrary laws ultimately determined to be more stringent than the Rule, or that it provide specific guidance on which State laws conflict with or are more stringent than the Privacy Rule.

*Response:* The Privacy Rule cannot dictate how States enforce their own privacy laws. Furthermore, guidance on whether or not a State law is preempted would not be binding on a State interpreting its own law.

*Comment:* Some commenters remain concerned that a parent will not get information about a child who receives care in an emergency without the consent of the parent and that the provisions in § 164.510(b) are not sufficient.

*Response:* As we have stated in previous guidance, a provider generally can discuss all the health information

about a minor child with his parent, because the parent usually will be the personal representative of the child. This is true, under the Privacy Rule, even if the parent did not provide consent to the treatment because of the emergency nature of the health care. A parent may be unable to obtain such information in limited circumstances, such as when the minor provided consent for the treatment in accordance with State law or the treating physician suspects abuse or neglect or reasonably believes that releasing the information to the parent will endanger the child.

*Comment:* A couple of commenters were concerned that the provisions regarding confidential communications conflict with the Fair Debt Collection Practices Act (FDCPA), which allows collection agencies to contact the party responsible for payment of the debt, be it the spouse or parent (of a minor) of the individual that incurred the debt, and share information that supports the incurrence and amount of the debt. They feared that the Privacy Rule would no longer allow collection agencies to continue this practice.

*Response:* Our analysis of the relevant provisions of the Privacy Rule and the FDCPA does not indicate any conflicts between the two laws. An entity that is subject to the FDCPA and the Privacy Rule (or that must act consistent with the Privacy Rule as a business associate of the covered entity) should be able to comply with both laws, because the FDCPA permits an entity to exercise discretion to disclose information about one individual to another.

The FDCPA allows debt collectors to communicate with the debtor's spouse or parent if the debtor is a minor. The provisions of the FDCPA are permissive rather than required.

Generally, the Privacy Rule permits covered entities to use the services of debt collectors as the use of such services to obtain payment for the provision of health care comes within the definition of ''payment.'' The Privacy Rule generally does not identify to whom information can be disclosed when a covered entity is engaged in its own payment activities. Therefore, if a covered entity or a debt collector, as a business associate of a covered entity, needs to disclose protected health information to a spouse or a parent, the Privacy Rule generally would not prevent such disclosure. In these cases where the Privacy Rule would permit disclosure to a parent or spouse, there should be no concern with the interaction with the FDCPA.

However, there are some circumstances in which the Privacy Rule may prohibit a disclosure to a parent or a spouse for payment purposes. For example, under § 164.522(a), an individual has the right to request restrictions to the disclosure of health information for payment. A provider or health plan may choose whether or not to agree to the request. If the covered entity agreed to a restriction, the covered entity would be bound by that restriction and would not be permitted to disclose the individual's health information in violation of that agreement. Also, § 164.522(b) generally requires covered entities to accommodate reasonable requests by individuals to receive communications of protected health information by alternative means or at alternative locations. However, the covered entity may condition the accommodation on the individual providing information on how payment will be handled. In both of these cases, the covered entity has means for permitting disclosures as permitted by the FDCPA. Therefore, these provisions of the Privacy Rule need not limit options available under the FDCPA. However, if the agreed-to restrictions or accommodation for confidential communications prohibit disclosure to a parent or spouse of an individual, the covered entity, and the debt collector as a business associate of the covered entity, would be prohibited from disclosing such information under the Privacy Rule. In such case, because the FDCPA would provide discretion to make a disclosure, but the Privacy Rule would prohibit the disclosure, a covered entity or the debt collector as a business associate of a covered entity would have to exercise discretion granted under the FDCPA in a way that complies with the Privacy Rule. This means not making the disclosure.

### *C. Section 164.504—Uses and Disclosures: Organizational Requirements*

#### 1. Hybrid Entities

*December 2000 Privacy Rule.* The Privacy Rule, as published in December 2000, defined covered entities that primarily engage in activities that are not ''covered functions,'' that is, functions that relate to the entity's operation as a health plan, health care provider, or health care clearinghouse, as hybrid entities. *See* 45 CFR 164.504(a). Examples of hybrid entities were: (1) corporations that are not in the health care industry, but that operate on-site health clinics that conduct the HIPAA standard transactions electronically; and (2) insurance carriers that have multiple lines of business that include both health insurance and other insurance lines, such as general liability or property and casualty insurance.

Under the December 2000 Privacy Rule, a hybrid entity was required to define and designate those parts of the entity that engage in covered functions as one or more health care component(s). A hybrid entity also was required to include in the health care component(s) any other components of the entity that support the covered functions in the same way such support may be provided by a business associate (e.g., an auditing component). The health care component was to include such ''business associate'' functions for two reasons: (1) It is impracticable for the entity to contract with itself; and (2) having to obtain an authorization for disclosures to such support components would limit the ability of the hybrid entity to engage in necessary health care operations functions. In order to limit the burden on hybrid entities, most of the requirements of the Privacy Rule only applied to the health care component(s) of the entity and not to the parts of the entity that do not engage in covered functions.

The hybrid entity was required to create adequate separation, in the form of firewalls, between the health care component(s) and other components of the entity. Transfer of protected health information held by the health care component to other components of the hybrid entity was a disclosure under the Privacy Rule and was allowed only to the same extent such a disclosure was permitted to a separate entity.

In the preamble to the December 2000 Privacy Rule, the Department explained that the use of the term ''primary'' in the definition of a ''hybrid entity'' was not intended to operate with mathematical precision. The Department further explained that it intended a common sense evaluation of whether the covered entity mostly operates as a health plan, health care provider, or health care clearinghouse. If an entity's primary activity was a covered function, then the whole entity would have been a covered entity and the hybrid entity provisions would not have applied. However, if the covered entity primarily conducted non-health activities, it would have qualified as a hybrid entity and would have been required to comply with the Privacy Rule with respect to its health care component(s). *See* 65 FR 82502.

*March 2002 NPRM.* Since the publication of the final Rule, concerns were raised that the policy guidance in the preamble was insufficient so long as the Privacy Rule itself limited the hybrid entity provisions to entities that primarily conducted non-health related activities. In particular, concerns were

raised about whether entities, which have the health plan line of business as the primary business and an excepted benefits line, such as workers' compensation insurance, as a small portion of the business, qualified as hybrid entities. There were also concerns about how ''primary'' was to be defined, if it was not a mathematical calculation, and how an entity would know whether or not it was a hybrid entity based on the guidance in the preamble.

As a result of these comments, the Department proposed to delete the term ''primary'' from the definition of ''hybrid entity'' in § 164.504(a) and permit any covered entity that is a single legal entity and that performs both covered and non-covered functions to choose whether or not to be a hybrid entity for purposes of the Privacy Rule. Under the proposal, any covered entity could be a hybrid entity regardless of whether the non-covered functions represent the entity's primary functions, a substantial function, or even a small portion of the entity's activities. In order to be a hybrid entity under the proposal, a covered entity would have to designate its health care component(s). If the covered entity did not designate any health care component(s), the entire entity would be a covered entity and, therefore, subject to the Privacy Rule. Since the entire entity would be the covered entity, § 164.504(c)(2) requiring firewalls between covered and non-covered portions of hybrid entities would not apply.

The Department explained in the preamble to the proposal that there are advantages and disadvantages to being a hybrid entity. Whether or not the advantages outweigh the disadvantages would be a decision for each covered entity that qualified as a hybrid entity, taking into account factors such as how the entity was organized and the proportion of the entity that must be included in the health care component.

The Department also proposed to simplify the definition of ''health care component'' in § 164.504(a) to make clear that a health care component is whatever the covered entity designates as the health care component, consistent with the provisions regarding designation in proposed § 164.504(c)(3)(iii). The Department proposed to move the specific language regarding which components make up a health care component to the implementation specification that addresses designation of health care components at § 164.504(c)(3)(iii). At § 164.504(c)(3)(iii), the Department proposed that a health care component could include: (1) Components of the covered entity that engage in covered functions, and (2) any component that engages in activities that would make such component a business associate of a component that performs covered functions, if the two components were separate legal entities. In addition, the Department proposed to make clear at § 164.504(c)(3)(iii) that a hybrid entity must designate as a health care component(s) any component that would meet the definition of ''covered entity'' if it were a separate legal entity.

There was some ambiguity in the December 2000 Privacy Rule as to whether a health care provider that does not conduct electronic transactions for which the Secretary has adopted standards (*i.e.,* a non-covered health care provider) and which is part of a larger covered entity was required to be included in the health care component. To clarify this issue, the proposal also would allow a hybrid entity the discretion to include in its health care component a non-covered health care provider component. Including a non-covered health care provider in the health care component would subject the non-covered provider to the Privacy Rule. Accordingly, the Department proposed a conforming change in § 164.504(c)(1)(ii) to make clear that a reference to a ''covered health care provider'' in the Privacy Rule could include the functions of a health care provider who does not engage in electronic transactions, if the covered entity chooses to include such functions in the health care component.

The proposal also would permit a hybrid entity to designate otherwise non-covered portions of its operations that provide services to the covered functions, such as parts of the legal or accounting divisions of the entity, as part of the health care component, so that protected health information could be shared with such functions of the entity without business associate agreements or individual authorizations. The proposal would not require that the covered entity designate entire divisions as in or out of the covered component. Rather, it would permit the covered entity to designate functions within such divisions, such as the functions of the accounting division that support health insurance activities, without including those functions that support life insurance activities. The Department proposed to delete as unnecessary and redundant the related language in paragraph (2)(ii) of the definition of ''health care component'' in the Privacy Rule that requires the ''business associate'' functions include the use of protected health information.

*Overview of Public Comments.* The following discussion provides an overview of the public comment received on this proposal. Additional comments received on this issue are discussed below in the section entitled, ''Response to Other Public Comments.''

The Department received relatively few comments on its proposal regarding hybrid entities. A number of comments supported the proposal, appreciative of the added flexibility it would afford covered entities in their compliance efforts. For example, some drug stores stated that the proposal would provide them with the flexibility to designate health care components, whereas under the December 2000 Rule, these entities would have been required to subject their entire business, including the ''front end'' of the store which is not associated with dispensing prescription drugs, to the Privacy Rule's requirements.

Some health plans and other insurers also expressed strong support for the proposal. These comments, however, seemed to be based on a misinterpretation of the uses and disclosures the proposal actually would permit. These commenters appear to assume that the proposal would allow information to flow freely between non-covered and covered functions in the same entity, if that entity chose not to be a hybrid entity. For example, commenters explained that they interpreted the proposal to mean that a multi-line insurer which does not elect hybrid entity status would be permitted to share protected health information between its covered lines and its otherwise non-covered lines. It was stated that such latitude would greatly enhance multi-line insurers' ability to detect and prevent fraudulent activities and eliminate barriers to sharing claims information between covered and non-covered lines of insurance where necessary to process a claim.

Some commenters opposed the Department's hybrid entity proposal, stating that the proposal would reduce the protections afforded under the Privacy Rule and would be subject to abuse. Commenters expressed concerns that the proposal would allow a covered entity with only a small health care component to avoid the extra protections of creating firewalls between the health care component and the rest of the organization. Moreover, one of the commenters stated that the proposal could allow a covered entity that is primarily performing health care functions to circumvent the requirements of the Rule for a large part of its operations by designating itself a hybrid and excluding from the health

care component a non-covered health care provider function, such as a free nurse advice line that does not bill electronically. In addition, it was stated that the ambiguous language in the proposal could potentially be construed as allowing a hybrid entity to designate only the business associate-like functions as the health care component, and exclude covered functions. The commenter urged the Department to clarify that a hybrid entity must, at a minimum, designate a component that performs covered functions as a health care component, and that a health care provider cannot avoid having its treatment component considered a health care component by relying on a billing department to conduct its standard electronic transactions. These commenters urged the Department to retain the existing policy by requiring those organizations whose primary functions are not health care to be hybrid entities and to institute firewall protections between their health care and other components.

*Final Modifications.* After consideration of the comments, the Department adopts in the final Rule the proposed approach to provide covered entities that otherwise qualify the discretion to decide whether to be a hybrid entity. To do so, the Department eliminates the term ''primary'' from the definition of ''hybrid entity'' at § 164.504(a). Any covered entity that otherwise qualifies (*i.e.,* is a single legal entity that performs both covered and non-covered functions) and that designates health care component(s) in accordance with § 164.504(c)(3)(iii) is a hybrid entity. A hybrid entity is required to create adequate separation, in the form of firewalls, between the health care component(s) and other components of the entity. Transfer of protected health information held by the health care component to other components of the hybrid entity continues to be a disclosure under the Privacy Rule, and, thus, allowed only to the same extent such a disclosure is permitted to a separate entity.

Most of the requirements of the Privacy Rule continue to apply only to the health care component(s) of a hybrid entity. Covered entities that choose not to designate health care component(s) are subject to the Privacy Rule in their entirety.

The final Rule regarding hybrid entities is intended to provide a covered entity with the flexibility to apply the Privacy Rule as best suited to the structure of its organization, while maintaining privacy protections for protected health information within the organization. In addition, the policy in the final Rule simplifies the Privacy Rule and makes moot any questions about what ''primary'' means for purposes of determining whether an entity is a hybrid entity.

The final Rule adopts the proposal's simplified definition of ''health care component,'' which makes clear that a health care component is what the covered entity designates as the health care component. The Department makes a conforming change in § 164.504(c)(2)(ii) to reflect the changes to the definition of ''health care component.'' The final Rule at § 164.504(c)(3)(iii) requires a health care component to include a component that would meet the definition of a ''covered entity'' if it were a separate legal entity. The Department also modifies the language of the final Rule at § 164.504(c)(3)(iii) to clarify that only a component that performs covered functions, and a component to the extent that it performs covered functions or activities that would make such component a business associate of a component that performs covered functions if the two components were separate legal entities, may be included in the health care component. ''Covered functions'' are defined at § 164.501 as ''those functions of a covered entity the performance of which makes the entity a health plan, health care provider, or health care clearinghouse.''

As in the proposal, the Department provides a hybrid entity with some discretion as to what functions may be included in the health care component in two ways. First, the final Rule clarifies that a hybrid entity may include in its health care component a non-covered health care provider component. Accordingly, the Department adopts the proposed conforming change to § 164.504(c)(1)(ii) to make clear that a reference to a ''covered health care provider'' in the Privacy Rule may include the functions of a health care provider who does not engage in electronic transactions for which the Secretary has adopted standards, if the covered entity chooses to include such functions in the health care component. A hybrid entity that chooses to include a non-covered health care provider in its health care component is required to ensure that the non-covered health care provider, as well as the rest of the health care component, is in compliance with the Privacy Rule.

Second, the final Rule retains the proposed policy to provide hybrid entities with discretion as to whether or not to include business associate-like divisions within the health care component. It is not a violation of the Privacy Rule to exclude such divisions from the health care component. However, a disclosure of protected health information from the health care component to such other division that is not part of the health care component is the same as a disclosure outside the covered entity. Because an entity cannot have a business associate contract with itself, such a disclosure likely will require individual authorization.

The Department clarifies, in response to comments, that a health care provider cannot avoid being a covered entity and, therefore, part of a health care component of a hybrid entity just by relying on a billing department to conduct standard transactions on its behalf. A health care provider is a covered entity if standard transactions are conducted on his behalf, regardless of whether the provider or a business associate (or billing department within a hybrid entity) actually conducts the transactions. In such a situation, however, designating relevant parts of the business associate division as part of the health care component would facilitate the conduct of health care operations and payment.

Also in response to comments, the Department clarifies that even if a covered entity does not choose to be a hybrid entity, and therefore is not required to erect firewalls around its health care functions, the entity still only is allowed to use protected health information as permitted by the Privacy Rule, for example, for treatment, payment, and health care operations. Additionally, the covered entity is still subject to minimum necessary restrictions under §§ 164.502 and 164.514(d), and, thus, must have policies and procedures that describe who within the entity may have access to the protected health information. Under these provisions, workforce members may be permitted access to protected health information only as necessary to carry out their duties with respect to the entity's covered functions. For example, the health insurance line of a multi-line insurer is not permitted to share protected health information with the life insurance line for purposes of determining eligibility for life insurance benefits or any other life insurance purposes absent an individual's written authorization. However, the health insurance line of a multi-line insurer may share protected health information with another line of business pursuant to § 164.512(a), if, for example, State law requires an insurer that receives a claim under one policy to share that information with other lines of insurance to determine if the event also may be payable under

another insurance policy. Furthermore, the health plan may share information with another line of business if necessary for the health plan's coordination of benefits activities, which would be a payment activity of the health plan.

Given the above restrictions on information flows within the covered entity, the Department disagrees with those commenters who raised concerns that the proposed policy would weaken the Rule by eliminating the formal requirement for ''firewalls.'' Even if a covered entity does not designate health care component(s) and, therefore, does not have to establish firewalls to separate its health care function(s) from the non-covered functions, the Privacy Rule continues to restrict how protected health information may be used and shared within the entity and who gets access to the information.

Further, the Department does not believe that allowing a covered entity to exclude a non-covered health care provider component from its health care component will be subject to abuse. Excluding health care functions from the health care component has significant implications under the Rule. Specifically, the Privacy Rule treats the sharing of protected health information from a health care component to a non-covered component as a disclosure, subject to the same restrictions as a disclosure between two legally separate entities. For example, if a covered entity decides to exclude from its health care component a non-covered provider, the health care component is then restricted from disclosing protected health information to that provider for any of the non-covered provider's health care operations, absent an individual's authorization. *See* § 164.506(c). If, however, the non-covered health care provider function is not excluded, it would be part of the health care component and that information could be used for its operations without the individual's authorization.

*Response to Other Public Comments*

*Comment:* A number of academic medical centers expressed concern that the Privacy Rule prevents them from organizing for compliance in a manner that reflects the integration of operations between the medical school and affiliated faculty practice plans and teaching hospitals. These commenters stated that neither the proposal nor the existing Rule would permit many academic medical centers to designate themselves as either a hybrid or affiliated entity, since the components of each must belong to a single legal entity or share common ownership or control. These commenters also explained that a typical medical school would not appear to qualify as an organized health care arrangement (OHCA) because it does not engage in any of the requisite joint activities, for example, quality assessment and improvement activities, on behalf of the covered entity. It was stated that it is essential that there not be impediments to the flow of information within an academic medical center. These commenters, therefore, urged that the Department add a definition of ''academic medical center'' to the Privacy Rule and modify the definition of ''common control'' to explicitly apply to the components of an academic medical center, so as to ensure that academic medical centers qualify as affiliated entities for purposes of the Rule.

*Response:* The Department does not believe that a modification to include a special rule for academic medical centers is warranted. The Privacy Rule's organizational requirements at § 164.504 for hybrid entities and affiliated entities, as well as the definition of ''organized health care arrangement'' in § 164.501, provide covered entities with much flexibility to apply the Rule's requirements as best suited to the structure of their businesses. However, in order to maintain privacy protections, the Privacy Rule places appropriate conditions on who may qualify for such organizational options, as well as how information may flow within such constructs. Additionally, if the commenter is suggesting that information should flow freely between the covered and non-covered functions within an academic medical center, the Department clarifies that the Privacy Rule restricts the sharing of protected health information between covered and non-covered functions, regardless of whether the information is shared within a single covered entity or a hybrid entity, or among affiliated covered entities or covered entities participating in an OHCA. Such uses and disclosures may only be made as permitted by the Rule.

*Comment:* A few commenters expressed concern with respect to governmental hybrid entities having to include business associate-like divisions within the health care component or else being required to obtain an individual's authorization for disclosures to such division. It was stated that this concept does not take into account the organizational structures of local governments and effectively forces such governmental hybrid entities to bring those components that perform business associate type functions into their covered component. Additionally, a commenter stated that this places an undue burden on local government by essentially requiring that functions, such as auditor/controller or county counsel, be treated as fully covered by the Privacy Rule in order to minimize otherwise considerable risk. Commenters, therefore, urged that the Department allow a health care component to enter into a memorandum of understanding (MOU) or other agreement with the business associate division within the hybrid entity. Alternatively, it was suggested that a governmental hybrid entity be permitted to include in its notice of privacy practices the possibility that information may be shared with other divisions within the same government entity for specific purposes.

*Response:* The Department clarifies that a covered entity which chooses to include its business associate division within the health care component may only do so to the extent such division performs activities on behalf of, or provides services to, the health care component. That same division's activities with respect to non-covered activities may not be included. To clarify this point, the Department modified the proposed language in § 164.504(c)(3)(iii) to provide that a health care component may only include a component to the extent that it performs covered functions or activities that would make such component a business associate of a component that performs covered functions if the two components were separate legal entities. For example, employees within an accounting division may be included within the health care component to the extent that they provide services to such component. However, where these same employees also provide services to non-covered components of the entity, their activities with respect to the health care component must be adequately separated from their other non-covered functions.

While the Department does not believe that a MOU between governmental divisions within a hybrid entity may be necessary given the above clarification, the Department notes that a governmental hybrid entity may elect to have its health care component enter into a MOU with its business associate division, provided that such agreement is legally binding and meets the relevant requirements of § 164.504(e)(3) and (e)(4). Such agreement would eliminate the need for the health care component to include the business associate division or for obtaining the

individual's authorization to disclose to such division.

Additionally, the Department encourages covered entities to develop a notice of privacy practices that is as specific as possible, which may include, for a government hybrid entity, a statement that information may be shared with other divisions within the government entity as permitted by the Rule. However, the notice of privacy practices is not an adequate substitute for, as appropriate, a memorandum of understanding; designation of business associate functions as part of a health care component; or alternatively, conditioning disclosures to such business associate functions on individuals' authorizations.

*Comment:* One commenter requested a clarification that a pharmacy-convenience store, where the pharmacy itself is a separate enclosure under supervision of a licensed pharmacist, is not a hybrid entity.

*Response:* The Department clarifies that a pharmacy-convenience store, if a single legal entity, is permitted, but not required, to be a hybrid entity and designate the pharmacy as the health care component. Alternatively, such an entity may choose to be a covered entity in its entirety. However, if the pharmacy and the convenience store are separate legal entities, the convenience store is not a covered entity simply by virtue of sharing retail space with the covered pharmacy.

*Comment:* Another commenter stated that the Rule implies that individual providers, once covered, are covered for all circumstances even if they are employed by more than one entity—one sending transactions electronically but not the other—or if the individual provider changes functions or employment and no longer electronically transmits standard transactions. This commenter asked that either the Rule permit an individual provider to be a hybrid entity (recognizing that there are times when an individual provider may be engaging in standard transactions, and other times when he is not), or that the definition of a ''covered entity'' should be modified so that individual providers are themselves classified as covered entities only when they are working as individuals.

*Response:* A health care provider is not a covered entity based on his being a workforce member of a health care provider that conducts the standard transactions. Thus, a health care provider may maintain a separate uncovered practice (if he does not engage in standard transactions electronically in connection with that practice), even though the provider may also practice at a hospital which may be a covered entity. However, the Rule does not permit an individual provider to use hybrid entity status to eliminate protections on information when he is not conducting standard transactions. If a health care provider conducts standard transactions electronically on his own behalf, then the protected health information maintained or transmitted by that provider is covered, regardless of whether the information is actually used in such transactions.

*Comment:* One commenter requested a clarification that employers are not hybrid entities simply because they may be the plan sponsor of a group health plan.

*Response:* The Department clarifies that an employer is not a hybrid entity simply because it is the plan sponsor of a group health plan. The employer/plan sponsor and group health plan are separate legal entities and, therefore, do not qualify as a hybrid entity. Further, disclosures from the group health plan to the plan sponsor are governed specifically by the requirements of § 164.504(f).

*Comment:* A few commenters asked the Department to permit a covered entity with multiple types of health care components to tailor notices to address the specific privacy practices within a component, rather than have just one generic notice for the entire covered entity.

*Response:* Covered entities are allowed to provide a separate notice for each separate health care component, and are encouraged to provide individuals with the most specific notice possible.

2. Group Health Plan Disclosures of Enrollment and Disenrollment Information to Plan Sponsors

*December 2000 Privacy Rule.* The Department recognized the legitimate need of plan sponsors and employers to access health information held by group health plans in order to carry out essential functions related to the group health plan. Therefore, the Privacy Rule at § 164.504(f) permits a group health plan, and health insurance issuers or HMOs with respect to the group health plan, to disclose protected health information to a plan sponsor provided that, among other requirements, the plan documents are amended appropriately to reflect and restrict the plan sponsor's uses and disclosures of such information. The Department further determined that there were two situations in which protected health information could be shared between the group health plan and the plan sponsor without individual authorization or an amendment to the plan documents. First, § 164.504(f) permits the group health plan to share summary health information (as defined in § 164.504(a)) with the plan sponsor. Second, a group health plan is allowed to share enrollment or disenrollment information with the plan sponsor without amending the plan documents as required by § 164.504(f). As explained in the preamble to the December 2000 Privacy Rule, a plan sponsor is permitted to perform enrollment functions on behalf of its employees without meeting the requirements of § 164.504(f), as such functions are considered outside of the plan administration functions. However, the second exception was not stated in the regulation text.

*March 2002 NPRM.* The ability of group health plans to disclose enrollment or disenrollment information without amending the plan documents was addressed only in the preamble to the Privacy Rule. The absence of a specific provision in the regulation text caused many entities to conclude that plan documents would need to be amended for enrollment and disenrollment information to be exchanged between plans and plan sponsors. To remedy this misunderstanding and make its policy clear, the Department proposed to add an explicit exception at § 164.504(f)(1)(iii) to clarify that group health plans (or health insurance issuers or HMOs with respect to group health plans, as appropriate) are permitted to disclose enrollment or disenrollment information to a plan sponsor without meeting the plan document amendment and other related requirements.

*Overview of Public Comments.* The following discussion provides an overview of the public comment received on this proposal. Additional comments received on this issue are discussed below in the section entitled, ''Response to Other Public Comments.''

Commenters in general supported the proposed modification. Some supported the proposal because it was limited to information about whether an individual is participating or enrolled in a group health plan and would not permit the disclosure of any other protected health information. Others asserted that the modification is a reasonable approach because enrollment and disenrollment information is needed by plan sponsors for payroll and other employment reasons.

*Final Modifications.* The Department adopts the modification to § 164.504(f)(1)(iii) essentially as proposed. Thus, a group health plan, or

a health insurance issuer or HMO acting for a group health plan, may disclose to a plan sponsor information on whether the individual is participating in the group health plan, or is enrolled in or has disenrolled from a health insurance issuer or HMO offered by the plan. This disclosure can be made without amending the plan documents. In adopting the modification as a final Rule, the Department deletes the phrase ''to the plan sponsor'' that appeared at the end of the proposed new provision, as mere surplusage.

As a result of the modification, summary health information and enrollment and disenrollment information are treated consistently. Under § 164.504(f), as modified, group health plans can share summary health information and enrollment or disenrollment information with plan sponsors without having to amend the plan documents. Section 164.520(a) provides that a fully insured group health plan does not need to comply with the Privacy Rule's notice requirements if the only protected health information it creates or receives is summary health information and/or information about individuals' enrollment in, or disenrollment from, a health insurer or HMO offered by the group health plan. Similarly, in § 164.530(k), the Department exempts fully insured group health plans from many of the administrative requirements in that section if the only protected health information held by the group health plan is summary health information and/or information about individuals' enrollment in, or disenrollment from, a health insurer or HMO offered by the group health plan. Such consistency will simplify compliance with the Privacy Rule.

*Response to Other Public Comments*

*Comment:* One commenter stated that there needs to be protection for health information given to group health plans on enrollment forms. In particular, this commenter suggested that the Department include a definition of ''enrollment'' or ''disenrollment'' information that specifies that medical information, such as past or present medical conditions and doctor or hospital visits, is not enrollment information, but rather is individually identifiable health information, and therefore, subject to the Privacy Rule's protections.

*Response:* Individually identifiable health information received or created by the group health plan for enrollment purposes is protected health information under the Privacy Rule. The modification to § 164.504(f) being adopted in this rulemaking does not affect this policy. The Privacy Rule does not define the information that may be transmitted for enrollment and disenrollment purposes. Rather, the Department in the Transactions Rule has adopted a standard transaction for enrollment and disenrollment in a health plan. That standard (ASC X12N 834, Benefit Enrollment and Maintenance, Version 4010, May 2000, Washington Publishing Company) specifies the required and situationally required data elements to be transmitted as part of such a transaction. While the standard enrollment and disenrollment transaction does not include any substantial clinical information, the information provided as part of the transaction may indicate whether or not tobacco use, substance abuse, or short, long-term, permanent, or total disability is relevant, when such information is available. However, the Department clarifies that, in disclosing or maintaining information about an individual's enrollment in, or disenrollment from, a health insurer or HMO offered by the group health plan, the group health plan may not include medical information about the individual above and beyond that which is required or situationally required by the standard transaction and still qualify for the exceptions for enrollment and disenrollment information allowed under the Rule.

*Comment:* Several commenters recommended that enrollment and disenrollment information specifically be excluded from the definition of ''protected health information.'' They argued that this change would be warranted because enrollment and disenrollment information do not include health information. They further argued that such a change would help alleviate confusion surrounding the application of the Privacy Rule to employers.

*Response:* We disagree that enrollment and disenrollment information should be excluded from the definition of ''protected health information.'' Enrollment and disenrollment information fall under the statutory definition of ''individually identifiable health information,'' since it is received or created by a health plan, identifies an individual, and relates to the past, present, or future payment for the provision of health care to an individual. As such, the Department believes there is no statutory basis to exclude such information from the definition of ''protected health information.'' The Department believes that the exception to the requirement for group health plans to amend plan documents that has been added to the Privacy Rule for enrollment and disenrollment information balances the legitimate need that plan sponsors have for enrollment and disenrollment information against the individual's right to have such information kept private and confidential.

*Comment:* Given that, under § 164.504(f)(2), plan sponsors agree not to use or further disclose protected health information other than as permitted or required by plan documents or ''required by law,'' one commenter requested that the definition of ''required by law'' set forth at § 164.501 should be revised to reflect that it applies not only to covered entities, but also to plan sponsors who are required to report under OSHA or similar laws.

*Response:* The Department agrees and has made a technical correction to the definition of ''required by law'' in § 164.501 to reflect that the definition applies to a requirement under law that compels any entity, not just a covered entity, to make a use or disclosure of protected health information.

*D. Section 164.506—Uses and Disclosures for Treatment, Payment, and Health Care Operations*

1. Consent

*December 2000 Privacy Rule.* Treatment and payment for health care are core functions of the health care industry, and uses and disclosures of individually identifiable health information for such purposes are critical to the effective operation of the health care system. Health care providers and health plans must also use individually identifiable health information for certain health care operations, such as administrative, financial, and legal activities, to run their businesses and to support the essential health care functions of treatment and payment. Equally important are health care operations designed to maintain and improve the quality of health care. In developing the Privacy Rule, the Department balanced the privacy implications of uses and disclosures for treatment, payment, and health care operations and the need for these core activities to continue. The Department considered the fact that many individuals expect that their health information will be used and disclosed as necessary to treat them, bill for treatment, and, to some extent, operate the covered entity's health care business. Given public expectations with respect to the use or disclosure of information for such activities and so as not to interfere with an individual's

access to quality health care or the efficient payment for such health care, the Department's goal is, and has always been, to permit these activities to occur with little or no restriction.

Consistent with this goal, the Privacy Rule published in December 2000 generally provided covered entities with permission to use and disclose protected health information as necessary for treatment, payment, and health care operations. For certain health care providers that have direct treatment relationships with individuals, such as many physicians, hospitals, and pharmacies, the December 2000 Privacy Rule required such providers to obtain an individual's written consent prior to using or disclosing protected health information for these purposes. The Department designed consent as a one-time, general permission from the individual, which the individual would have had the right to revoke. A health care provider could have conditioned treatment on the receipt of consent. Other covered entities also could have chosen to obtain consent but would have been required to follow the consent standards if they opted to do so.

The consent requirement for health care providers with direct treatment relationships was a significant change from the Department's initial proposal published in November 1999. At that time, the Department proposed to permit all covered entities to use and disclose protected health information to carry out treatment, payment, and health care operations without any requirement that the covered entities obtain an individual's consent for such uses and disclosures, subject to a few limited exceptions. Further, the Department proposed to prohibit covered entities from obtaining an individual's consent for uses and disclosures of protected health information for these purposes, unless required by other applicable law.

The transition provisions of the Privacy Rule permit covered health care providers that were required to obtain consent to use and disclose protected health information they created or received prior to the compliance date of the Privacy Rule for treatment, payment, or health care operations if they had obtained consent, authorization, or other express legal permission to use or disclose such information for any of these purposes, even if such permission did not meet the consent requirements of the Privacy Rule.

*March 2002 NPRM.* The Department heard concerns about significant practical problems that resulted from the consent requirements in the Privacy Rule. Covered entities and others provided numerous examples of obstacles that the consent provisions would pose to timely access to health care. These examples extended to various types of providers and various settings. The most troubling, pervasive problem was that health care providers would not have been able to use or disclose protected health information for treatment, payment, or health care operations purposes prior to their initial face-to-face contact with the patient, something which is routinely done today to provide patients with timely access to quality health care. A list of some of the more significant examples and concerns are as follows:

- Pharmacists would not have been able to fill a prescription, search for potential drug interactions, determine eligibility, or verify coverage before the individual arrived at the pharmacy to pick up the prescription if the individual had not already provided consent under the Privacy Rule.
- Hospitals would not have been able to use information from a referring physician to schedule and prepare for procedures before the individual presented at the hospital for such procedure, or the patient would have had to make a special trip to the hospital to sign the consent form.
- Providers who do not provide treatment in person may have been unable to provide care because they would have had difficulty obtaining prior written consent to use protected health information at the first service delivery.
- Emergency medical providers were concerned that, if a situation was urgent, they would have had to try to obtain consent to comply with the Privacy Rule, even if that would be inconsistent with appropriate practice of emergency medicine.
- Emergency medical providers were also concerned that the requirement that they attempt to obtain consent as soon as reasonably practicable after an emergency would have required significant efforts and administrative burden which might have been viewed as harassing by individuals, because these providers typically do not have ongoing relationships with individuals.
- Providers who did not meet one of the consent exceptions were concerned that they could have been put in the untenable position of having to decide whether to withhold treatment when an individual did not provide consent or proceed to use information to treat the individual in violation of the consent requirements.
- The right to revoke a consent would have required tracking consents, which could have hampered treatment and resulted in large institutional providers deciding that it would be necessary to obtain consent at each patient encounter instead.
- The transition provisions would have resulted in significant operational problems, and the inability to access health records would have had an adverse effect on quality activities, because many providers currently are not required to obtain consent for treatment, payment, or health care operations.
- Providers that are required by law to treat were concerned about the mixed messages to patients and interference with the physician-patient relationship that would have resulted because they would have had to ask for consent to use or disclose protected health information for treatment, payment, or health care operations, but could have used or disclosed the information for such purposes even if the patient said ''no.''

As a result of the large number of treatment-related obstacles raised by various types of health care providers that would have been required to obtain consent, the Department became concerned that individual fixes would be too complex and could possibly overlook important problems. Instead, the Department proposed an approach designed to protect privacy interests by affording patients the opportunity to engage in important discussions regarding the use and disclosure of their health information through the strengthened notice requirement, while allowing activities that are essential to quality health care to occur unimpeded (see section III.H. of the preamble for a discussion of the strengthened notice requirements).

Specifically, the Department proposed to make the obtaining of consent to use and disclose protected health information for treatment, payment, or health care operations more flexible for all covered entities, including providers with direct treatment relationships. Under this proposal, health care providers with direct treatment relationships with individuals would no longer be required to obtain an individual's consent prior to using and disclosing information about him or her for treatment, payment, and health care operations. They, like other covered entities, would have regulatory permission for such uses and disclosures.

The NPRM included provisions to permit covered entities to obtain consent for uses and disclosures of protected health information for treatment, payment, or health care

operations, if they wished to do so. These provisions would grant providers complete discretion in designing this process. These proposed changes were partnered, however, by the proposal to strengthen the notice provisions to require direct treatment providers to make good faith efforts to obtain a written acknowledgment of receipt of the notice. The intent was to preserve the opportunity to raise questions about the entity's privacy policies that the consent requirements previously provided.

*Overview of Public Comments.* The following discussion provides an overview of the public comment received on this proposal. Additional comments received on this issue are discussed below in the section entitled, ''Response to Other Public Comments.''

The vast majority of commenters addressed the consent proposal. Most comments fell into three basic categories: (1) Many comments supported the NPRM approach to eliminate the consent requirement; (2) many comments urged the Department to require consent, but make targeted fixes to address workability issues; and (3) some comments urged the Department to strengthen the consent requirement.

The proposed approach of eliminating required consent and making obtaining of consent permissible, at the entity's discretion, was supported by many covered entities that asserted that it would provide the appropriate balance among access to quality health care, administrative burden, and patient privacy. Many argued that the appropriate privacy protections were preserved by strengthening the notice requirement. This approach was also supported by the NCVHS.

The comments received in response to the NPRM continued to raise the issues and obstacles described above, and others. For example, in addition to providing health care services to patients, hospices often provide psychological and emotional support to family members. These consultations often take place long distance and would likely be considered treatment. The consent requirement would make it difficult, or impossible in some circumstances, for hospices to provide these important services to grieving family members on a timely basis. Comments explained that the consent provisions in the Rule pose significant obstacles to oncologists as well. Cancer treatment is referral-based. Oncologists often obtain information from other doctors, hospital, labs, etc., speak with patients by telephone, identify treatment options, and develop preliminary treatment plans, all before the initial patient visit. The prior consent requirement would prevent all of these important preliminary activities before the first patient visit, which would delay treatment in cases in which such delay cannot be tolerated.

Other commenters continued to strongly support a consent requirement, consistent with their views expressed during the comment period in March 2001. Some argued that the NPRM approach would eliminate an important consumer protection and that such a ''radical'' approach to fixing the workability issues was not required. They recommended a targeted approach to fixing each problem, and suggested ways to fix each unintended consequence of the consent requirement, in lieu of removing the requirement to obtain consent.

A few commenters argued for reinstating a consent requirement, but making it similar to the proposal for acknowledgment of notice by permitting flexibility and including a ''good faith'' standard. They also urged the Department to narrow the definition of health care operations and require that de-identified information be used where possible for health care operations.

Finally, a few commenters continued to assert that consent should be strengthened by applying it to more covered entities, requiring it to be obtained more frequently, or prohibiting the conditioning of treatment on the obtaining of consent.

*Final Modifications.* The Department continues to be concerned by the multitude of comments and examples demonstrating that the consent requirements would result in unintended consequences that would impede the provision of health care in many critical circumstances. We are also concerned that other such unintended consequences may exist which have yet to be brought to our attention. The Department would not have been able to address consent issues arising after publication of this Rule until at least a year had passed from this Rule's publication date due to statutory limitations on the timing of modifications. The Department believes in strong privacy protections for individually identifiable health information, but does not want to compromise timely access to quality health care. The Department also understands that the opportunity to discuss privacy practices and concerns is an important component of privacy, and that the confidential relationship between a patient and a health care provider includes the patient's ability to be involved in discussions and decisions related to the use and disclosure of protected health information about him or her.

A review of the comments showed that almost all of the commenters that discussed consent acknowledged that there are unintended consequences of the consent requirement that would interfere with treatment. These comments point toward two potential approaches to fixing these problems. The Department could address these problems by adopting a single solution that would address most or all of the concerns, or could address these problems by adopting changes targeted to each specific problem that was brought to the attention of the Department. One of the goals in making changes to the Privacy Rule is to simplify, rather than add complexity to, the Rule. Another goal is to assure that the Privacy Rule does not hamper necessary treatment. For both of these reasons, the Department is concerned about adopting different changes for different issues related to consent and regulating to address specific examples that have been brought to its attention. Therefore, the options that the Department most seriously considered were those that would provide a global fix to the consent problems. Some commenters provided global options other than the proposed approach. However, none of these would have resolved the operational problems created by a mandatory consent.

The Department also reviewed State laws to understand how they approached uses and disclosures of health information for treatment, payment, or health care operations purposes. Of note was the California Confidentiality of Medical Information Act. Cal. Civ. Code § 56. This law permits health care providers and health plans to disclose health information for treatment, payment, and certain types of health care operations purposes without obtaining consent of the individual. The California HealthCare Foundation conducted a medical privacy and confidentiality survey in January 1999 that addressed consumer views on confidentiality of medical records. The results showed that, despite the California law that permitted disclosures of health information without an individual's consent, consumers in California did not have greater concerns about confidentiality than other health care consumers. This is true with respect to trust of providers and health plans to keep health information private and confidential and the level of access to health information that providers and health plans have.

The Department adopts the approach that was proposed in the NPRM, because it is the only one that resolves the operational problems that have been identified in a simple and uniform manner. First, this Rule strengthens the notice requirements to preserve the opportunity for individuals to discuss privacy practices and concerns with providers. (See section III.H. of the preamble for the related discussion of modifications to strengthen the notice requirements.) Second, the final Rule makes the obtaining of consent to use and disclose protected health information for treatment, payment, or health care operations optional on the part of all covered entities, including providers with direct treatment relationships. A health care provider that has a direct treatment relationship with an individual is not required by the Privacy Rule to obtain an individual's consent prior to using and disclosing information about him or her for treatment, payment, and health care operations. They, like other covered entities, have regulatory permission for such uses and disclosures. The fact that there is a State law that has been using a similar model for years provides us confidence that this is a workable approach.

Other rights provided by the Rule are not affected by this modification. Although covered entities will not be required to obtain an individual's consent, any uses or disclosures of protected health information for treatment, payment, or health care operations must still be consistent with the covered entity's notice of privacy practices. Also, the removal of the consent requirement applies only to consent for treatment, payment, and health care operations; it does not alter the requirement to obtain an authorization under § 164.508 for uses and disclosures of protected health information not otherwise permitted by the Privacy Rule or any other requirements for the use or disclosure of protected health information. The Department intends to enforce strictly the requirement for obtaining an individual's authorization, in accordance with § 164.508, for uses and disclosure of protected health information for purposes not otherwise permitted or required by the Privacy Rule. Furthermore, individuals retain the right to request restrictions, in accordance with § 164.522(a). This allows individuals and covered entities to enter into agreements to restrict uses and disclosures of protected health information for treatment, payment, and health care operations that are enforceable under the Privacy Rule.

Although consent for use and disclosure of protected health information for treatment, payment, and health care operations is no longer mandated, this Final Rule allows covered entities to have a consent process if they wish to do so. The Department heard from many commenters that obtaining consent was an integral part of the ethical and other practice standards for many health care professionals. It, therefore, does not prohibit covered entities from obtaining consent.

This final Rule allows covered entities that choose to have a consent process complete discretion in designing that process. Prior comments have informed the Department that one consent process and one set of principles will likely be unworkable. Covered entities that choose to obtain consent may rely on industry practices to design a voluntary consent process that works best for their practice area and consumers, but they are not required to do so.

This final Rule effectuates these changes in the same manner as proposed by the NPRM. The consent provisions in § 164.506 are replaced with a new provision at § 164.506(a) that provides regulatory permission for covered entities to use or disclose protected health information for treatment, payment, and health care operations. A new provision is added at § 164.506(b) that permits covered entities to obtain consent if they choose to, and makes clear any such consent process does not override or alter the authorization requirements in § 164.508. Section 164.506(b) includes a small change from the proposed version to make it clearer that authorizations are still required by referring directly to authorizations under § 164.508.

Additionally, this final Rule includes a number of conforming modifications, identical to those proposed in the NPRM, to accommodate the new approach. The most substantive corresponding changes are at §§ 164.502 and 164.532. Section 164.502(a)(1) provides a list of the permissible uses and disclosures of protected health information, and refers to the corresponding section of the Privacy Rule for the detailed requirements. The provisions at §§ 164.502(a)(1)(ii) and (iii) that address uses and disclosures of protected health information for treatment, payment, and health care operations are collapsed into a single provision, and the language is modified to eliminate the consent requirement.

The references in § 164.532 to § 164.506 and to consent, authorization, or other express legal permission obtained for uses and disclosures of protected health information for treatment, payment, and health care operations prior to the compliance date of the Privacy Rule are deleted. The proposal to permit a covered entity to use or disclose protected health information for these purposes without consent or authorization would apply to any protected health information held by a covered entity whether created or received before or after the compliance date. Therefore, transition provisions are not necessary.

This final Rule also includes conforming changes to the definition of ''more stringent'' in § 160.202; the text of § 164.500(b)(1)(v), §§ 164.508(a)(2)(i) and (b)(3)(i), and § 164.520(b)(1)(ii)(B); the introductory text of §§ 164.510 and 164.512, and the title of § 164.512 to eliminate references to required consent.

*Response to Other Public Comments*

*Comment:* There were three categories of commenters with respect to the Rule's general approach to consent-those that supported the changes proposed in the NPRM provisions, those that requested targeted changes to the consent requirement, and those that requested that the consent requirement be strengthened.

Many commenters supported the NPRM approach to consent, making consent to use or disclose protected health information for treatment, payment, and health care operations voluntary for all covered entities. These commenters said that this approach provided flexibility for covered entities to address consent in a way that is consistent with their practices. These commenters also stated that the NPRM approach assured that the Privacy Rule would not interfere with or delay necessary treatment.

Those that advocated retaining a consent requirement stated that the NPRM approach would undermine trust in the health care system and that requiring consent before using or disclosing protected health information shows respect for the patient's autonomy, underscores the need to inform the patient of the risks and benefits of sharing protected health information, and makes it possible for the patient to make an informed decision. Many of these commenters suggested that the consent requirement be retained and that the problems raised by consent be addressed through targeted changes or guidance for each issue.

Some suggestions targeted to specific problems were: (1) Fix the problems

related to filling prescriptions by treating pharmacists as providers with indirect treatment relationships or by deeming a prescription to serve as an implied consent; and (2) allow certain uses and disclosures prior to first patient encounter. Some of these commenters argued that certain issues could be addressed through guidance on other provisions in the Rule, rather than a change in the regulation. For example, they suggested that guidance could explain that physicians who take phone calls for one another are part of an organized health care arrangement, or could provide technical assistance about revocations on consent by identifying when a covered entity has taken action in reliance on a consent.

Other suggestions were more general. They included suggestions that the Department: (1) Substitute a good faith effort requirement for the current provisions; (2) provide regulatory permission for certain uses and disclosures of protected heath information prior to first service delivery; (3) permit oral consent with documentation; (4) retain a consent requirement for disclosures, but not uses; (5) retain a consent requirement for payment and operations, but not treatment uses and disclosures; (6) allow individuals to opt out of the consent requirement; (7) allow the consent to apply to activities of referred-to providers, and (8) retain the consent requirement but add flexibility, not exceptions.

The third group of commenters requested that the consent requirement be strengthened. Some requested that the Privacy Rule not permit conditioning of treatment or enrollment on consent for multiple uses and disclosures. Others requested that the consent requirement be extended to covered entities other than providers with direct treatment relationships, such as health plans. Some commenters also asked that the consent be time-limited or be required more frequently, such as at each service delivery.

*Response:* The Department recognizes that there are some benefits to the consent requirement and has considered all options to preserve the consent requirement while fixing the problems it raises. After examining each of these options, we do not believe that any would address all of the issues that were brought to the Department's attention during the comment process or would be the best approach for regulating this area. For example, the suggestion to treat pharmacists as indirect treatment providers would not be consistent with the current regulatory definition of that term and would not have addressed other referral situations. This approach was also rejected by some pharmacists who view themselves as providing treatment directly to individuals. The suggestion to allow certain uses and disclosures prior to first patient encounter would not address concerns of tracking consents, use of historical data for quality purposes, or the concerns of emergency treatment providers.

The Department desired a global approach to resolving the problems raised by the prior consent requirement, so as not to add additional complexity to the Privacy Rule or apply different standards to different types of direct treatment providers. This approach is consistent with the basic goal of the Rule to provide flexibility as necessary for the standards to work for all sectors of the health care industry.

More global approaches suggested were carefully considered, but each had some flaw or failed to address all of the treatment-related concerns brought to our attention. For example, those who suggested that the Rule be modified to require a good faith effort to obtain consent at first service delivery failed to explain how that approach would provide additional protection than the approach we proposed. The Department also decided against eliminating the consent requirement only for uses and disclosures for treatment, or only for uses of protected health information but not for disclosures, because these options fall short of addressing all of the problems raised. Scheduling appointments and surgeries, and conducting many pre-admission activities, are health care operations activities, not treatment. Retaining the consent requirement for payment would be problematic because, in cases where a provider, such as a pharmacist or hospital, engages in a payment activity prior to face-to-face contact with the individual, it would prohibit the provider from contacting insurance companies to obtain pre-certification or to verify coverage.

Similarly, the suggestion to limit the prior consent requirement to disclosures and not to uses would not have addressed all of the problems raised by the consent requirements. Many of the basic activities that occur before the initial face-to-face meeting between a provider and an individual involve disclosures as well as uses. Like the previous approach, this approach also would prohibit pharmacists and hospitals from contacting insurance companies to obtain pre-certification or verify coverage if they did not have the individual's prior consent to disclose the protected health information for payment. It also would prohibit a provider from contacting another provider to ask questions about the medical record and discuss the patient's condition, because this would be a disclosure and would require consent.

There was a substantial amount of support from commenters for the approach taken in the NPRM. The Department continues to believe that this approach makes the most sense and meets the goals of not interfering with access to quality health care and of providing a single standard that works for the entire health care industry. Therefore, the Department has adopted the approach proposed in the NPRM.

*Comment:* Some commenters asserted that eliminating the consent requirement would be a departure from current medical ethical standards that protect patient confidentiality and common law and State law remedies for breach of confidentiality that generally require or support patient consent prior to disclosing patient information for any reason. Another commenter was concerned that the removal of the consent requirement from the Privacy Rule will become the de facto industry standard and supplant professional ethical duties to obtain consent for the use of protected health information.

*Response:* The Privacy Rule provides a floor of privacy protection. State laws that are more stringent remain in force. In order not to interfere with such laws and ethical standards, this Rule permits covered entities to obtain consent. Nor is the Privacy Rule intended to serve as a ''best practices'' standard. Thus, professional standards that are more protective of privacy retain their vitality.

*Comment:* Some commenters requested that, if the Department adopts the NPRM approach to eliminate the consent requirement for uses and disclosures of protected health information for treatment, payment, or health care operations, the definition of ''health care operations'' should also be narrowed to protect individual expectations of privacy.

*Response:* We disagree. As stated in the preamble to the December 2000 Privacy Rule, the Department believes that narrowing the definition of ''health care operations'' will place serious burdens on covered entities and impair their ability to conduct legitimate business and management functions.

*Comment:* Some commenters requested that the regulation text state more specifically that a voluntary consent cannot substitute for an authorization when an authorization is otherwise required under the Privacy Rule.

*Response:* The Department agrees and modifies the regulation text, at § 164.506(b)(2), to make this clear. As stated in the preamble to the NPRM, the Department intends to enforce strictly the requirement for obtaining an individual's authorization, in accordance with § 164.508, for uses and disclosures of protected health information for purposes not otherwise permitted or required by the Privacy Rule. A consent obtained voluntarily would not be sufficient to permit a use or disclosure which, under the Privacy Rule, requires an authorization or is otherwise expressly conditioned under the Rule. For example, a consent under § 164.506 could not be obtained in lieu of an authorization required by § 164.508 or a waiver of authorization by an IRB or Privacy Board under § 164.512(i) to disclose protected health information for research purposes.

*Comment:* Some commenters requested that, if the Department decides to allow consent on a voluntary basis, the Privacy Rule include requirements for those covered entities that voluntarily choose to obtain consents.

*Response:* The goal of the NPRM approach was to enhance flexibility for covered entities by allowing them to design a consent process that best matches their needs. The Department learned over the past year that no single consent process works for all covered entities. In addition, the Department wants to encourage covered entities to adopt a consent process, and is concerned that by prescribing particular rules, it would discourage some covered entities from doing so.

*Comment:* Some commenters asserted that the consent requirement provides individuals with control because providers may not opt to withhold treatment if a patient refuses consent only for the use or disclosure of protected health information for health care operations.

*Response:* These commenters may not fully understand the consent requirements in the December 2000 Rule. That requirement did not allow separate consents for use of protected health information for treatment, payment, and health care operations. The only way to allow use of protected health information for treatment but not for health care operations purposes would have been to invoke the right to request restrictions (§ 164.522(a)); the provider could agree or not agree to restrict use and disclosure of protected health information for health care operations. That is also how the Rule will work with these modifications. The Department is not modifying the right to request restrictions.

*Comment:* Some commenters were confused about the relationship between the proposed changes to the consent provisions and State law. Some were concerned that the Privacy Rule would override State consent laws which provide stronger protections for medical and psychotherapeutic privacy.

*Response:* The Privacy Rule does not weaken the operation of State laws that require consent to use or disclose health information. The Privacy Rule permits a covered entity to obtain consent to use or disclose health information, and, therefore, presents no barrier to the entity's ability to comply with State law requirements.

*Comment:* One commenter suggested that the consent requirement be retained to protect victims of domestic violence.

*Response:* The Department understands the concerns that the Privacy Rule not endanger victims of domestic violence, but we do not believe that eliminating the consent requirement will do so. The Department believes that the provisions that provide real protections to victims of domestic violence in how information is used or disclosed for treatment, payment, and health care operations, are provisions that allow an individual to object to disclosure of directory information and of protected health information to family members or friends involved in the individual's care (*see* § 164.510), that provide an individual the right to request restrictions (*see* § 164.522(a)), and that grant an individual the right to request confidential communications (*see* § 164.522(b)). These provisions are not affected by the changes in this final Rule.

*Comment:* One commenter asserted that written consent represents a signed agreement between the provider and patient regarding the manner in which covered entities will use and disclose health information in the future, and that the removal of this requirement would shift ''ownership'' of records from patients to doctors and corporate entities.

*Response:* The Department disagrees with this position. Our research indicates that a signed consent form is most typically treated as a waiver of rights by a patient and not as a binding agreement between a provider and a patient. Further, many States have laws assigning the ownership of records, apart from any consent requirements. The Privacy Rule does not address, and is not intended to affect, existing laws governing the ownership of health records.

*Comment:* A few commenters claimed that the signed notice of a provider's privacy policy is meaningless if the individual has no right to withhold consent and the NPRM approach would reinforce the fact that individuals have no say in how their health information is used or disclosed.

*Response:* The Department disagrees. The individual's options under the consent requirement established by the Privacy Rule published in December 2000 and the voluntary consent and strengthened notice provisions adopted by this Rule are the same. Under the previous Rule, a patient who disagreed with the covered entity's information practices as stated in the notice could withhold consent and not receive treatment, or could sign the consent form and obtain treatment despite concerns about the information practices. The patient could request that the provider restrict the use and/or disclosure of the information. Under the Rule as modified, a patient who disagrees with the covered entity's information practices as stated in the notice, can choose not to receive treatment from that provider, or can obtain treatment despite concerns about the information practices. The patient can request that the provider restrict the use and/or disclosure of the information. The result, for the patient, is the same.

*Comment:* One commenter requested clarification with respect to the effect of a revocation of voluntary consent and whether agreed-to restrictions must be honored.

*Response:* The final Rule is silent as to how a covered entity handles the revocation of a voluntary consent under § 164.506(b)(1). The Rule provides the covered entity that chooses to adopt a consent process discretion to design the process that works for that entity.

The change to the consent provision in the Privacy Rule does not affect the right of an individual under § 164.522(a) to request restrictions to a use or disclosure of protected health information. While a covered entity is not required to agree to such restrictions, it must act in accordance with any restriction it does agree to. Failure of a covered entity to act in accordance with an agreed-to restriction is a violation of the Rule.

*Comment:* Commenters asked the Department to rename consent to ''consent for information use'' to reduce confusion with consent for treatment.

*Response:* In order to clear up confusion between informed consent for treatment, which is addressed by State law, and consent to use or disclose protected health information under the

Privacy Rule, we changed the title of § 164.506(b) from ''Consent permitted'' to ''Consent for uses and disclosures of information permitted.'' The Privacy Rule does not affect informed consent for treatment.

*Comment:* A few commenters requested that the Department modify the regulation to state that de-identified information should be used for health care operations where possible.

*Response:* The Department continues to encourage covered entities to use de-identified information wherever possible. As the Department has made this position clear in the preambles to both the December 2000 Privacy Rule and the March 2002 NPRM, as well as in this preamble, we do not believe that it is necessary to modify the regulation to include such language. Further, the minimum necessary requirements, under §§ 164.502(b)(2) and 164.514(d), already require a covered entity to make reasonable efforts to limit protected health information used for health care operations and other purposes to the minimum necessary to accomplish the intended purpose, which may, in some cases, be de-identified information.

*Comment:* One commenter requested that the Privacy Rule state that consent is not required for provider-to-provider communications.

*Response:* Prior to these final modifications, the consent requirements of the Privacy Rule would have required a provider to obtain written consent to disclose protected health information to another provider for treatment purposes—which could have interfered with an individual's ability to obtain timely access to quality care. This is one reason the Department has eliminated the consent requirement for treatment, payment, and health care operations. Providers will not need a patient's consent to consult with other providers about the treatment of a patient. However, if a provider is disclosing protected health information to another provider for purposes other than treatment, payment, or health care operations, an authorization may be required under § 164.508 (*e.g.*, generally, disclosures for clinical trials would require an authorization).

*Comment:* One commenter asserted that, without a consent requirement, nothing will stop a health plan from demanding a patient's mental health records as a condition of payment for physical therapy.

*Response:* The Department does not agree that the former consent requirement is the relevant standard with respect to the activities of the health plan that concern the commenter. Rather, the Transactions Rule and the minimum necessary standard of the Privacy Rule prescribe and limit the health information that may be disclosed as part of payment transactions between health plans and health care providers. Although a health plan may request additional information to process a specific claim, in addition to the required and situational elements under the Transactions Rule, the request must comply with the Privacy Rule's minimum necessary requirements. In this example, the health plan can only request mental health records if they are reasonably necessary for the plan to process the physical therapy claim.

2. Disclosures for Treatment, Payment, or Health Care Operations of Another Entity

*December 2000 Privacy Rule.* The Privacy Rule permits a covered entity to use and disclose protected health information for treatment, payment, or health care operations. For treatment purposes, the Rule generally allows protected health information to be shared without restriction. The definition of ''treatment'' incorporates the necessary interaction of more than one entity. In particular, the definition of ''treatment'' includes the coordination and management of health care among health care providers or by a health care provider with a third party, consultations between health care providers, and referrals of a patient for health care from one health care provider to another. As a result, covered entities are permitted to disclose protected health information for treatment purposes regardless of to whom the disclosure is made, as well as to disclose protected health information for the treatment activities of another health care provider.

However, for payment and health care operations, the Privacy Rule, as published in December 2000, generally limited a covered entity's uses and disclosures of protected health information to those that were necessary for its own payment and health care operations activities. This limitation was explicitly stated in the December 2000 preamble discussions of the definitions of ''payment'' and ''health care operations.'' 65 FR 82490, 82495. The Privacy Rule also provided that a covered entity must obtain authorization to disclose protected health information for the payment or health care operations of another entity. The Department intended these requirements to be consistent with individuals' privacy expectations. *See* 45 CFR 164.506(a)(5) and 164.508(e).

*March 2002 NPRM.* Since the publication of the December 2000 Rule, a number of commenters raised specific concerns with the restriction that a covered entity may not disclose protected health information for another entity's payment and health care operations activities, absent an authorization. These commenters presented a number of examples where such a restriction would impede the ability of certain entities to obtain reimbursement for health care, to conduct certain quality assurance or improvement activities, such as accreditation, or to monitor fraud and abuse.

With regard to payment, for example, the Department heard concerns of ambulance service providers who explained that they normally receive the information they need to obtain payment for their treatment services from the hospital emergency departments to which they transport their patients. They explained that it is usually not possible for the ambulance service provider to obtain such information directly from the individual, nor is it always practicable or feasible for the hospital to obtain the individual's authorization to provide payment information to the ambulance service provider. This disclosure of protected health information from the hospital to the ambulance service provider was not permitted under the December 2000 Privacy Rule without an authorization from the patient, because it was a disclosure by the hospital for the payment activities of the ambulance service provider.

Commenters also were concerned about situations in which covered entities outsource their billing, claims, and reimbursement functions to accounts receivable management companies. These collectors often attempt to recover payments from a patient on behalf of multiple health care providers. Commenters were concerned that the Privacy Rule would prevent these collectors, as business associates of multiple providers, from using a patient's demographic information received from one provider to facilitate collection for another provider's payment.

With regard to health care operations, the Department also received comments about the difficulty that the Privacy Rule would place on health plans trying to obtain information needed for quality assessment activities. Health plans informed the Department that they need to obtain individually identifiable health information from health care providers for the plans' quality-related activities, accreditation, and performance measures, such as Health Plan Employer Data and Information Set

(HEDIS). Commenters explained that the information provided to plans for payment purposes (*e.g.*, claims or encounter information) may not be sufficient for quality assessment or accreditation purposes.

The NCVHS, in response to public testimony on this issue at its August 2001 hearing, also recommended that the Department amend the Privacy Rule to allow for uses and disclosures for quality-related activities among covered entities, without the individual's written authorization.

Based on these concerns, the Department proposed to modify § 164.506 to permit a covered entity to disclose protected health information for the payment activities of another covered entity or any health care provider, and also for certain types of health care operations of another covered entity. The proposal would broaden the uses and disclosures that are permitted without authorization as part of treatment, payment, and health care operations so as not to interfere inappropriately with access to quality and effective health care, while limiting this expansion in order to continue to protect the privacy expectations of the individual.

Specifically, the Department proposed the following. First, the Department proposed to add to § 164.506(c)(1) language stating that a covered entity may use or disclose protected health information for its own treatment, payment, or health care operations without prior permission.

Second, the Department proposed to include language in § 164.506(c)(2) to clarify its intent that a covered entity may share protected health information for the treatment activities of another health care provider. For example, a primary care provider who is a covered entity under the Privacy Rule may send a copy of an individual's medical record to a specialist who needs the information to treat the same individual, whether or not that specialist is also a covered entity. No authorization would be required.

Third, the Department proposed to include language in § 164.506(c)(3) to permit a covered entity to disclose protected health information to another covered entity or any health care provider for the payment activities of that entity. The Department recognized that not all health care providers who need protected health information to obtain payment are covered entities, and, therefore, proposed to allow disclosures of protected health information to both covered and non-covered health care providers. In addition, the Department proposed a conforming change to delete the word ''covered'' in paragraph (1)(ii) of the definition of ''payment,'' to permit disclosures to non-covered providers for their payment activities.

The Department also proposed to limit disclosures under this provision to those health plans that are covered by the Privacy Rule. However, the Department solicited comment on whether plans that are not covered by the Privacy Rule would be able to obtain the protected health information that they need for payment purposes.

Fourth, in § 164.506(c)(4), the Department proposed to permit a covered entity to disclose protected health information about an individual to another covered entity for specified health care operations purposes of the covered entity that receives the information, provided that both entities have a relationship with the individual. This proposed expansion was limited in a number of ways. The proposal would permit such disclosures only for the activities described in paragraphs (1) and (2) of the definition of ''health care operations,'' as well as for health care fraud and abuse detection and compliance programs (as provided for in paragraph (4) of the definition of ''health care operations''). The activities that fall into paragraphs (1) and (2) of the definition of ''health care operations'' include quality assessment and improvement activities, population-based activities relating to improving health or reducing health care costs, case management, conducting training programs, and accreditation, certification, licensing, or credentialing activities. The Department proposed this limitation because it recognized that ''health care operations'' is a broad term and that individuals are less aware of the business-related activities that are part of health care operations than they are of treatment- or payment-related activities. In addition, many commenters and the NCVHS focused their comments on covered entities' needs to share protected health information for quality-related health care operations activities. The proposed provision was intended to allow information to flow from one covered entity to another for activities important to providing quality and effective health care.

The proposal would have applied only to disclosures of protected health information to other covered entities. By limiting such disclosures to those entities that are required to comply with the Privacy Rule, the Department intended to ensure that the protected health information remained protected. The Department believed that this would create the appropriate balance between meeting an individual's privacy expectations and meeting a covered entity's need for information for quality-related health care operations.

Further, such disclosures would be permitted only to the extent that each entity has, or had, a relationship with the individual who is the subject of the information being disclosed. Where the relationship between the individual and the covered entity has ended, a disclosure of protected health information about the individual would be allowed only if related to the past relationship. The Department believed that this limitation would be necessary in order to further protect the privacy expectations of the individual.

The proposal made clear that these provisions would not eliminate a covered entity's responsibility to apply the Privacy Rule's minimum necessary provisions to both the disclosure of and request for protected health information for payment and health care operations purposes. In addition, the proposal strongly encouraged the use of de-identified information, wherever feasible.

While the Department stated that it believed it had struck the right balance with respect to the proposed modification for disclosures for health care operations, the Department was aware that the proposal could pose barriers to disclosures for quality-related health care operations to health plans and health care providers that are not covered entities, or to entities that do not have a relationship with the individual. Therefore, the preamble referred commenters to the Department's request for comment on an approach that would permit for any health care operations purposes the disclosure of protected health information that does not contain direct identifiers, subject to a data use or similar agreement.

In addition, related to the above modifications and in response to comments evidencing confusion on this matter, the Department also proposed to clarify that covered entities participating in an organized health care arrangement (OHCA) may share protected health information for the health care operations of the OHCA (§ 164.506(c)(5)). The Department also proposed to remove the language regarding OHCAs from the definition of ''health care operations'' as unnecessary because such language now would appear in § 164.506(c)(5).

*Overview of Public Comments.* The following discussion provides an overview of the public comment received on this proposal. Additional

comments received on this issue are discussed below in the section entitled, ''Response to Other Public Comments.''

The Department received a number of comments on its proposal to permit a covered entity to disclose protected health information for the payment and health care operations activities of other entities.

Most of the commenters who addressed the Department's proposed clarification regarding treatment expressed support for the clarification. Also, the majority of commenters supported, either wholly or in part, the Department's proposal to expand the payment and health care operations disclosures that would be permitted.

Most commenters generally were supportive of the Department's proposed approach regarding disclosures for payment. A number of commenters stated that the proposed expansion is important to facilitate coordination of benefits for many patients who have multiple sources of payment for prescription drugs. One commenter, however, requested that the Department narrow its proposed language to address only those problems specifically described in the preamble, that is, payment issues faced by ambulance providers and collection agencies that are business associates of multiple health care providers. This commenter stated that, at the very least, covered entities should be required to obtain assurances from non-covered providers, prior to disclosure of protected health information, that the recipient will not use protected health information for any other purpose or disclose it to others. Another commenter remarked that the proposal to limit disclosures only to another covered entity or any health care provider may impede disclosures to reinsurers that are not covered entities.

While most commenters supported expanding disclosures for health care operations, many requested that the Department modify the proposal in a number of ways. For example, a number of health plans and others requested that the Department eliminate the condition that both covered entities have a relationship with the individual. Some of these commenters explained that such a restriction would impede some fraud and abuse activities, credentialing investigations, and quality assurance research and outcome studies. Some commenters asked that the Department clarify that the condition that both covered entities have a relationship with the individual would not be limited to a current relationship, but also would include a past relationship with the individual.

In addition, many commenters requested that the Department expand the proposed provision to allow for disclosures for any type of health care operation of another covered entity, or at least additional activities beyond those specified in the proposal. Some health plans commented that they may need information from a health care provider in order for the health plan to resolve member or internal grievances, provide customer service, arrange for legal services, or conduct medical review or auditing activities. A number of commenters requested that the proposal be expanded to allow for disclosures for another covered entity's underwriting or premium rating.

Some commenters also requested that the Department expand the provision to allow for disclosures to non-covered entities. In particular, a number of these commenters urged that the Department allow disclosures to non-covered insurers for fraud and abuse purposes. Some of these commenters specifically requested that the Department allow for disclosures to affiliated entities or non-health care components of the covered entity for purposes of investigating fraud and abuse. A few commenters requested that the Rule allow for disclosures to a non-covered health care provider for that provider's operations. For example, it was explained that an independent emergency services provider, who is not a covered entity and who often asks for outcome information on patients it has treated and transported to a facility because it wants to improve care, would be unable to obtain such information absent the individual's authorization.

Some commenters were generally opposed to the proposed expansion of the disclosures permitted under the Rule for health care operations purposes, viewing the proposal as a weakening of the Privacy Rule. One of these commenters urged the Department to implement a targeted solution allowing disclosures for only those activities specifically identified as problematic in the preamble, instead of allowing disclosures for all activities that fall within certain paragraphs within the definition of ''health care operations.''

*Final Modifications.* In this final Rule, the Department adopts its proposal to allow covered entities to disclose protected health information for the treatment, payment, and certain health care operations purposes of another entity. Specifically, the final Rule at § 164.506(c):

(1) States that a covered entity may use or disclose protected health information for its own treatment, payment, or health care operations.

(2) Clarifies that a covered entity may use or disclose protected health information for the treatment activities of any health care provider.

(3) Permits a covered entity to disclose protected health information to another covered entity or any health care provider for the payment activities of the entity that receives the information.

(4) Permits a covered entity to disclose protected health information to another covered entity for the health care operations activities of the entity that receives the information, if each entity either has or had a relationship with the individual who is the subject of the information, the protected health information pertains to such relationship, and the disclosure is:

(i) For a purpose listed in paragraphs (1) or (2) of the definition of ''health care operations,'' which includes quality assessment and improvement activities, population-based activities relating to improving health or reducing health care costs, case management and care coordination, conducting training programs, and accreditation, licensing, or credentialing activities; or

(ii) For the purpose of health care fraud and abuse detection or compliance.

(5) Clarifies that a covered entity that participates in an organized health care arrangement may disclose protected health information about an individual to another covered entity that participates in the organized health care arrangement for any health care operations activities of the organized health care arrangement.

Based on the comments received, the Department believes that the above provisions strike the appropriate balance between meeting an individual's privacy expectations and meeting a covered entity's need for information for reimbursement and quality purposes. The Department also clarifies that disclosures pursuant to the above provisions may be made to or by a business associate of a covered entity.

In § 164.506(c)(2), in response to a comment, the Department deletes the word ''another'' before ''health care provider'' to eliminate any implication that the disclosing entity must also be a health care provider.

With respect to payment, the majority of commenters were supportive of the Department's proposal. In response to those commenters who expressed support for the proposal because it would facilitate coordination of benefits, the Department clarifies that the definition of ''payment'' in the

Privacy Rule allows for uses and disclosures necessary for coordination of benefits. The new language may, however, reinforce that uses and disclosures for such purposes are permitted under the Rule.

The Department does not believe, as suggested by one commenter, that a targeted approach, one that would address only the problems raised by the ambulance providers and collection agencies, is a practical solution to these problems. The Department believes that these problems may apply in other situations. For example, an indirect treatment provider, such as a pathologist, may need to obtain health coverage information about an individual for billing purposes from the hospital to which the pathologist provided services. If the Department addressed only these discrete scenarios in this final modification, each additional similar problem that arises would require another rulemaking, which would, in and of itself, create a problem because the Department can change a standard only once per year. In addition, by creating special rules to address multiple, distinct circumstances, the Department would have created a substantially more complicated policy for covered entities to follow and implement.

The suggestion that the Department require a covered entity to obtain assurances from non-covered providers, prior to disclosure of protected health information for payment purposes, that the recipient will not use protected health information for any other purpose or disclose it to others, similarly would add a layer of complexity to payment disclosures. Such a requirement would encumber these communications and may interfere with the ability of non-covered health care providers to be paid for treatment they have provided. Moreover, the Privacy Rule requires a covered entity to apply the minimum necessary standard to disclosures for a non-covered provider's payment purposes. Thus, a non-covered provider will receive only the minimum information reasonably necessary for such purposes. Accordingly, the Department believes the final Rule appropriately and practically addresses the issue.

In response to the comment that the proposal may impede disclosures to reinsurers who are not covered entities, the Department clarifies that disclosures to obtain payment under a contract for reinsurance explicitly are permitted as part of the definition of ''payment,'' regardless of whether the reinsurer is a covered entity. Similarly, disclosures for the purposes of ceding, securing, or placing a contract for reinsurance of risk relating to claims for health care are explicitly permitted as part of the definition of ''health care operations,'' also without regard to whether the reinsurer is a covered entity. *See* the definitions of ''payment'' and ''health care operations'' in § 164.501.

With respect to disclosures for the health care operations of another covered entity, the Department continues to believe that the condition that both entities have a relationship with the individual is appropriate to balance an individual's privacy expectations with a covered entity's need for the information. The Department clarifies that a covered entity, prior to making a disclosure allowed under this requirement, is permitted to communicate with another covered entity as necessary to determine if this condition has been met. Additionally, in response to comments, the Department adds language to § 164.506(c)(4) to make clear that the condition that both covered entities have a relationship with the individual is not limited to a current relationship. Where the relationship between the covered entity and the individual has ended, a disclosure of protected health information about the individual is permitted to the extent the disclosure is related to the past relationship. For example, the final Rule would permit a health care provider to disclose protected health information to a health plan for HEDIS purposes, even if the individual no longer was covered by the health plan, provided that the period for which information is needed overlaps with the period for which the individual was enrolled in the health plan.

In response to commenters who were concerned that this condition would impede certain health care operations activities where the covered entity may not have a relationship with the individual, the Department notes that the new limited data set provisions in § 164.514(e) are intended to provide a mechanism for disclosures of protected health information for quality and other health care operations where the covered entity requesting the information does not have a relationship with the individual. Under those provisions, the final modifications permit a covered entity to disclose protected health information, with direct identifiers removed, for any health care operations activities of the entity requesting the information, subject to a data use agreement. Additionally, as clarified by § 164.506(c)(5), covered entities that participate in an OHCA may share protected health information for the health care operations of the OHCA, without the condition that each covered entity have a relationship with the individual who is the subject of the information. The Department believes that such provisions provide adequate avenues for covered entities to obtain the information they need for health care operations activities, without eliminating appropriate privacy protections and conditions on such disclosures.

The Department also was not persuaded by the comments that the proposal should be broadened to allow disclosures for other types of health care operations activities, such as resolution of internal grievances, customer service, or medical review or auditing activities. The Department believes that the provisions at § 164.506(c)(5), which permit covered entities that participate in an OHCA to share information for any health care operations activities of the OHCA, adequately provides for such disclosures. For example, a health plan and the health care providers in its network that participate as part of the same OHCA are permitted to share information for any of the activities listed in the definition of ''health care operations.'' The Department understands the need for entities participating in these joint arrangements to have shared access to information for health care operations purposes and intended the OHCA provisions to provide for such access. Where such a joint arrangement does not exist and fully identifiable health information is needed, one covered entity may disclose protected health information for another covered entity's health care operations pursuant to an individual's authorization as required by § 164.508. In addition, as described above, a covered entity also may disclose protected health information as part of a limited data set, with direct identifiers removed, for such purposes, as permitted by § 164.514(e).

With respect to underwriting and premium rating, a few commenters raised similar concerns that the Department's proposal to expand the disclosures permitted under health care operations would not allow for the disclosures between a health insurance issuer and a group health plan, or the agent or broker as a business associate of the plan, needed to perform functions related to supplementing or replacing insurance coverage, such as to solicit bids from prospective issuers. The Department clarifies that, if more than summary health information is needed for this purpose, paragraphs (3), (4), and (5) of the definition of ''organized health

care arrangement'' may permit the disclosure. These provisions define the arrangements between group health plans and their health insurance issuers or HMOs as OHCAs, which are permitted to share information for each other's health care operations. Such disclosures also may be made to a broker or agent that is a business associate of the health plan. The Department clarifies that the OHCA provisions also permit the sharing of protected health information between such entities even when they no longer have a current relationship, that is, when a group health plan needs protected health information from a former issuer. The Department, therefore, does not believe that a broadening of the provisions under § 164.506(c)(4), to allow disclosures of protected health information for other types of health care operations activities, is warranted.

The final Rule also adopts the condition proposed in the NPRM that disclosures for these health care operations may be made only to another covered entity. The Department continues to consider such a condition necessary to appropriately balance an individual's privacy interests with entities' needs for the information. The Department was not convinced by the commenters who urged that this condition needed to be eliminated to allow for disclosures to non-covered health care providers or third parties. The Department believes that permitting disclosures of protected health information to a non-covered provider for that provider's treatment and payment purposes is warranted and appropriate so as not to impede such core activities. However, given that an individual's health information will no longer be protected when it is disclosed to a non-covered provider, the Department does not consider disclosures for a non-covered provider's health care operations to warrant similar consideration under the Rule. Moreover, this final Rule at § 164.514(e) permits a covered entity to disclose a limited data set, with direct identifiers removed, to a non-covered provider for any of the provider's health care operations purposes, without individual authorization.

Also, the Department believes that expanding the provision to allow disclosures to a third party for any of the third party's business operations would severely weaken the Privacy Rule and essentially negate the need for individual authorization. With respect to those commenters who urged the Department to permit disclosures to non-health care components of a hybrid entity or to an affiliated entity for the purposes of investigating fraud and abuse, the Department's position is that disclosures to a non-health care component within a hybrid entity or to a non-covered affiliated entity present the same privacy risks as do disclosures to a non-covered entity. The Privacy Rule, therefore, permits such disclosures only to the same extent the disclosures are permitted to a separate entity. This policy is further explained in section III.C.1. regarding hybrid entities.

Lastly, the Department believes that the final Rule does in fact implement a targeted solution to the problems previously identified by commenters, by allowing disclosures for only quality-related and fraud and abuse activities. The Department does not believe further limiting such disclosures to only certain activities within paragraphs (1) and (2) of the definition of ''health care operations'' is practical or appropriate. The Department is aware of the important role that these quality-related activities play in ensuring that individuals have access to quality health care. Covered entities have a legitimate need for protected health information in order to conduct these quality activities, regardless of whether such information is used for HEDIS purposes or for training. Moreover, as described above, the final Rule retains a number of conditions on such disclosures that serve to protect an individual's privacy interests and expectations. In addition, the Privacy Rule requires that the minimum necessary standard be applied to both covered entities' requests for and disclosures of protected health information for such purposes.

*Response to Other Public Comments*

*Comment:* One commenter urged that the Department permit disclosures among participants in an OHCA only when their privacy notices (or any joint notice they issue) informs individuals of this possibility.

*Response:* The Privacy Rule requires the joint notice of an OHCA to reflect the fact that the notice covers more than one covered entity and that, if applicable, the covered entities participating in the OHCA will share protected health information with each other, as necessary to carry out treatment, payment, or health care operations relating to the OHCA. *See* § 164.520(d). Where the participants of an OHCA choose to have separate notices, such notices must reflect and describe in sufficient detail the particular uses and disclosures that each covered entity may make to place the individual on notice. This detail should include disclosures to other members of an OHCA, where appropriate.

*Comment:* Another commenter requested clarification as to whether a covered entity (such as an HMO) is permitted to disclose protected health information for payment and health care operations both to the group health plan and to the plan's third party administrator or plan sponsor. The commenter stated that it was not clear from the proposal whether a covered entity could share protected health information directly with another covered entity's business associate.

*Response:* The Department clarifies that, if the Rule permits a covered entity to share protected health information with another covered entity, the covered entity is permitted to disclose protected health information directly to a business associate acting on behalf of that other covered entity. This is true with respect to all of the Rule's provisions. Also, an HMO may disclose protected health information to a group health plan, or a third party administrator that is a business associate of the plan, because the relationship between the HMO and the group health plan is defined as an OHCA for purposes of the Rule. See § 164.501, definition of ''organized health care arrangement.'' The group health plan (or the HMO with respect to the group health plan) may disclose protected health information to a plan sponsor in accordance with § 164.504(f).

*Comment:* Several commenters requested that the Department expand the definition of ''payment'' to include disclosures to a responsible party. Additionally, these commenters urged that the Department permit covered entities (and their business associates) to use and disclose protected health information as permitted by other law, rather than only as required by law. These commenters were concerned that the Privacy Rule would impede the ability of first-party billing companies, collection agencies, and accounts receivable management companies to continue to bill and communicate, on behalf of a health care provider, with the responsible party on an account when that person is different from the individual to whom health care services were provided; report outstanding receivables owed by the responsible party on an account to a credit reporting agency; and perform collection litigation services.

*Response:* The Department does not believe a modification to the definition of ''payment'' is necessary. The Privacy Rule permits a covered entity, or a business associate acting on behalf of a covered entity (*e.g.,* a collection agency),

to disclose protected health information as necessary to obtain payment for health care, and does not limit to whom such a disclosure may be made. See the definition of ''payment'' in § 164.501. Therefore, a collection agency, as a business associate of a covered entity, is permitted to contact persons other than the individual to whom health care is provided as necessary to obtain payment for such services.

Regarding the commenters' concerns about collection or payment activities otherwise permitted by law, the Department clarifies that the Privacy Rule permits covered entities to use and disclose protected health information as required by other law, or as permitted by other law provided that such use or disclosure does not conflict with the Privacy Rule. For example, the Privacy Rule permits a collection agency, as a business associate of a covered health care provider, to use and disclose protected health information as necessary to obtain reimbursement for health care services, which could include disclosures of certain protected health information to a credit reporting agency, or as part of collection litigation. See the definition of ''payment'' in § 164.501.

The Department notes, however, that a covered entity, and its business associate through its contract, is required to reasonably limit the amount of information disclosed for such purposes to the minimum necessary, where applicable, as well as abide by any reasonable requests for confidential communications and any agreed-to restrictions as required by the Privacy Rule.

*Comment:* One commenter asked that the Department clarify that disclosure by an eye doctor to confirm a contact prescription received by a mail-order contact company is treatment.

*Response:* The Department agrees that disclosure of protected health information by an eye doctor to a distributor of contact lenses for the purpose of confirming a contact lens prescription is treatment and is permissible under § 164.506. In relevant part, treatment is defined by the Privacy Rule as ''the provision, coordination, or management of health care and related services by one or more health care providers, including the coordination or management of health care by a health care provider with a third party * * *'' Health care is defined, in part, as ''care, services, or supplies related to the health of an individual. Health care includes * * * Sale or dispensing of a drug, device, equipment, or other item in accordance with a prescription.'' Therefore, the dispensing of contact lenses based on a prescription is health care and the disclosure of protected health information by a provider to confirm a prescription falls within the provision, coordination, or management of health care and related services and is a treatment activity.

*E. Uses and Disclosures for Which Authorization Is Required*

1. Restructuring Authorization

*December 2000 Privacy Rule.* The Privacy Rule requires individual authorization for uses and disclosures of protected health information for purposes that are not otherwise permitted or required under the Rule. To ensure that authorizations are informed and voluntary, the Rule prohibits, with limited exceptions, covered entities from conditioning treatment, payment, or eligibility for benefits or enrollment in a health plan, on obtaining an authorization. The Rule also permits, with limited exceptions, individuals to revoke an authorization at any time. Additionally, the Rule sets out core elements that must be included in any authorization. These elements are intended to provide individuals with the information they need to make an informed decision about giving their authorization. This information includes specific details about the use or disclosure, and provides the individual fair notice about his or her rights with respect to the authorization and the potential for the information to be redisclosed. Additionally, the authorization must be written in plain language so individuals can read and understand its contents. The Privacy Rule required that authorizations provide individuals with additional information for specific circumstances under the following three sets of implementation specifications: In § 164.508(d), for authorizations requested by a covered entity for its own uses and disclosures; in § 164.508(e), for authorizations requested by a covered entity for another entity to disclose protected health information to the covered entity requesting the authorization to carry out treatment, payment, or health care operations; and in § 164.508(f), for authorizations requested by a covered entity for research that includes treatment of the individual.

*March 2002 NPRM.* Various issues were raised regarding the authorization requirements. Commenters claimed the authorization provisions were too complex and confusing. They alleged that the different sets of implementation specifications were not discrete, creating the potential for the implementation specifications for specific circumstances to conflict with the required core elements. Some covered entities were confused about which authorization requirements they should implement in any given circumstance. Also, although the Department intended to permit insurers to obtain necessary protected health information during contestability periods under State law, the Rule did not provide an exception to the revocation provision when other law provides an insurer the right to contest an insurance policy.

To address these issues, the Department proposed to simplify the authorization provisions by consolidating the implementation specifications into a single set of criteria under § 164.508(c), thus eliminating paragraphs (d), (e), and (f) which contained separate implementation specifications. Under the proposal, paragraph (c)(1) would require all authorizations to contain the following core elements: (1) A description of the information to be used or disclosed, (2) the identification of the persons or class of persons authorized to make the use or disclosure of the protected health information, (3) the identification of the persons or class of persons to whom the covered entity is authorized to make the use or disclosure, (4) a description of each purpose of the use or disclosure, (5) an expiration date or event, (6) the individual's signature and date, and (7) if signed by a personal representative, a description of his or her authority to act for the individual. The proposal also included new language to clarify that when individuals initiate an authorization for their own purposes, the purpose may be described as ''at the request of the individual.''

In the NPRM, the Department proposed that § 164.508(c)(2) require authorizations to contain the following required notifications: (1) A statement that the individual may revoke the authorization in writing, and either a statement regarding the right to revoke and instructions on how to exercise such right or, to the extent this information is included in the covered entity's notice, a reference to the notice, (2) a statement that treatment, payment, enrollment, or eligibility for benefits may not be conditioned on obtaining the authorization if such conditioning is prohibited by the Privacy Rule, or, if conditioning is permitted by the Privacy Rule a statement about the consequences of refusing to sign the authorization, and (3) a statement about the potential for the protected health information to be redisclosed by the recipient.

Also under the proposal, covered entities would be required to obtain an authorization to use or disclose protected health information for marketing purposes, and to disclose in such authorizations any direct or indirect remuneration the covered entity would receive from a third party as a result of obtaining or disclosing the protected health information. The other proposed changes regarding marketing are discussed in section III.A.1. of the preamble.

The NPRM proposed a new exception to the revocation provision at § 164.508(b)(5)(ii) for authorizations obtained as a condition of obtaining insurance coverage when other law gives the insurer the right to contest the policy. Additionally, the Department proposed that the exception to permit conditioning payment of a claim on obtaining an authorization be deleted, since the proposed provision to permit the sharing of protected health information for the payment activities of another covered entity or a health care provider would eliminate the need for an authorization in such situations.

Finally, the Department proposed modifications at § 164.508(a)(2)(i)(A), (B), and (C), to clarify its intent that the proposed provisions for sharing protected health information for the treatment, payment, or health care operations of another entity would not apply to psychotherapy notes.

There were a number of proposed modifications concerning authorizations for research purposes. Those modifications are discussed in section III.E.2. of the preamble.

*Overview of Public Comments.* The following discussion provides an overview of the public comment received on this proposal. Additional comments received on this issue are discussed below in the section entitled, ''Response to Other Public Comments.''

There was overwhelming support for the proposed modifications. Overall, supporters were of the opinion that the consolidation and simplification would promote efficiency, simplify compliance, and reduce confusion. Many commenters claimed the changes would eliminate barriers to quality health care. Some commenters claimed the proposed modifications would make the authorization process easier for both providers and individuals, and one commenter said they would make authorizations easier to read and understand. A number of commenters stated the changes would not have adverse consequences for individuals, and one commenter noted the proposal would preserve the opportunity for individuals to give a meaningful authorization.

However, some of the proponents suggested the Department go further to ease the administrative burden of obtaining authorizations. Some urged the Department to eliminate some of the required elements which they perceived as unnecessary to protect privacy, while others suggested that covered entities should decide which elements were relevant in a given situation. Some commenters urged the Department to retain the exception to the prohibition on conditioning payment of a claim on obtaining an authorization. These commenters expressed fear that the voluntary consent process and/or the right to request restrictions on uses and disclosures for treatment, payment, or health care operations might prevent covered entities from disclosing protected health information needed for payment purposes, or providers may be reluctant to cooperate in disclosures for payment purposes based on inadequately drafted notices.

Comments were divided on the proposed requirement to disclose remuneration in marketing authorizations. Recommendations ranged from requiring the disclosure of remuneration on all authorizations, to eliminating the requirement altogether.

*Final Modifications.* In the final modifications, the Department adopts the changes proposed in the NPRM. Since the modifications to the authorization provision are comprehensive, the Department is publishing this section in its entirety so that it will be easier to use and understand. Therefore, the preamble addresses all authorization requirements, and not just those that were modified.

In § 164.508(a), covered entities are required to obtain an authorization for uses and disclosures of protected health information, unless the use or disclosure is required or otherwise permitted by the Rule. Covered entities may use only authorizations that meet the requirements of § 164.508(b), and any such use or disclosure will be lawful only to the extent it is consistent with the terms of such authorization. Thus, a voluntary consent document will not constitute a valid permission to use or disclose protected health information for a purpose that requires an authorization under the Rule.

Although the requirements regarding uses and disclosures of psychotherapy notes are not changed substantively, the Department made minor changes to the language in paragraph (a)(2) to clarify that a covered entity may not use or disclose psychotherapy notes for purposes of another covered entity's treatment, payment, or health care operations without obtaining the individual's authorization. However, covered entities may use and disclose psychotherapy notes, without obtaining individual authorization, to carry out its own limited treatment, payment, or health care operations as follows: (1) Use by the originator of the notes for treatment, (2) use or disclosure for the covered entity's own training programs for its mental health professionals, students, and trainees, and (3) use or disclosure by the covered entity to defend itself in a legal action or other proceeding brought by the individual.

Section 164.508(a)(3) requires covered entities to obtain an authorization to use or disclose protected health information for marketing purposes, with two exceptions. The authorization requirements for marketing and the comments received on these provisions are discussed in detail in section III.A.1. of the preamble.

If the marketing involves any direct or indirect remuneration to the covered entity from a third party, the authorization must state that fact. The comments on this requirement also are discussed in section III.A.1. of the preamble. However, a statement concerning remuneration is not a required notification for other authorizations. Such a statement was never required for all authorizations and the Department believes it would be most meaningful for consumers on authorizations for uses and disclosures of protected health information for marketing purposes. Some commenters urged the Department to require remuneration statements on research authorizations. The Department has not done so because the complexity of such arrangements would make it difficult to define what constitutes remuneration in the research context. Moreover, to require covered entities to disclose remuneration by a third party on authorizations for research would go beyond the requirements imposed in the December 2000 Rule, which did not require such a disclosure on authorizations obtained for the research of a third party. The Department believes that concerns regarding financial conflicts of interest that arise in research are not limited to privacy concerns, but also are important to the objectivity of research and to protecting human subjects from harm. Therefore, in the near future, the Department plans to issue guidance for the research community on this important topic.

Pursuant to § 164.508(b)(1), an authorization is not valid under the Rule unless it contains all of the

required core elements and notification statements, which are discussed below. Covered entities may include additional, non-required elements so long as they are not inconsistent with the required elements and statements. The language regarding defective authorizations in § 164.508(b)(2) is not changed substantively. However, some changes are made to conform this paragraph to modifications to other parts of the authorization provision, as well as other sections of the Rule. An authorization is not valid if it contains any of the following defects: (1) The expiration date has passed or the expiration event has occurred, and the covered entity is aware of the fact, (2) any of the required core elements or notification statements are omitted or incomplete, (3) the authorization violates the specifications regarding compounding or conditioning authorizations, or (4) the covered entity knows that material information in the authorization is false.

In § 164.508(b)(3) regarding compound authorizations, the requirements for authorizations for purposes other than research are not changed. That is, authorizations for use or disclosure of psychotherapy notes may be combined only with another authorization for the use or disclosure of psychotherapy notes. Other authorizations may be combined, unless a covered entity has conditioned the provision of treatment, payment, enrollment in a health plan, or eligibility for benefits on one of the authorizations. A covered entity generally may not combine an authorization with any other type of document, such as a notice of privacy practices or a written voluntary consent. However, there are exceptions for research authorizations, which are discussed in section III.E.2. of the preamble.

Section 164.508(b)(4) prohibits the conditioning of treatment, payment, enrollment in a health plan, or eligibility for benefits on obtaining an authorization, with a few exceptions. The exceptions to this requirement for research-related treatment, eligibility for benefits and enrollment in a health plan, and health care solely for creating protected health information for disclosure to a third party are not changed. Moreover, the Department eliminates the exception to the prohibition on conditioning payment of a claim on obtaining an authorization. Although some insurers urged that this conditioning authority be retained to provide them with more collection options, the Department believes this authorization is no longer necessary because we are adding a new provision in § 164.506 that permits covered entities to disclose protected health information for the payment purposes of another covered entity or health care provider. Therefore, that exception has been eliminated.

Section 164.508(b)(5) provides individuals the right to revoke an authorization at any time in writing. The two exceptions to this right are retained, but with some modification. An individual may not revoke an authorization if the covered entity has acted in reliance on the authorization, or if the authorization was obtained as a condition of obtaining insurance coverage and other law gives the insurer the right to contest the claim or the policy itself. The Department adopts the proposed modification to the latter exception so that insurers can exercise the right to contest an insurance policy under other law. Public comment was generally supportive of this proposed modification.

Section 164.508(b)(6) requires covered entities to document and retain authorizations as required under § 164.530(j). This requirement is not changed.

The different sets of implementation criteria are consolidated into one set of criteria under § 164.508(c), thus eliminating the confusion and uncertainty associated with different requirements for specific circumstances. Covered entities may use one authorization form for all purposes. The Department adopts in paragraph (c)(1), the following core elements for a valid authorization: (1) A description of the information to be used or disclosed, (2) the identification of the persons or class of persons authorized to make the use or disclosure of the protected health information, (3) the identification of the persons or class of persons to whom the covered entity is authorized to make the use or disclosure, (4) a description of each purpose of the use or disclosure, (5) an expiration date or event, (6) the individual's signature and date, and (7) if signed by a personal representative, a description of his or her authority to act for the individual. An authorization that does not contain all of the core elements does not meet the requirements for a valid authorization. The Department intends for the authorization process to provide individuals with the opportunity to know and understand the circumstances surrounding a requested authorization.

To further protect the privacy interests of individuals, when individuals initiate an authorization for their own purposes, the purpose may be stated as ''at the request of the individual.'' Other changes to the core elements pertain to authorizations for research, and are discussed in section III.E.2. of the preamble.

Also, under § 164.508(c)(2), an authorization is not valid unless it contains all of the following: (1) A statement that the individual may revoke the authorization in writing, and either a statement regarding the right to revoke, and instructions on how to exercise such right or, to the extent this information is included in the covered entity's notice, a reference to the notice, (2) a statement that treatment, payment, enrollment, or eligibility for benefits may not be conditioned on obtaining the authorization if such conditioning is prohibited by the Privacy Rule or, if conditioning is permitted, a statement about the consequences of refusing to sign the authorization, and (3) a statement about the potential for the protected health information to be redisclosed by the recipient. Although the notification statements are not included in the paragraph on core elements an authorization is not valid unless it contains both the required core elements, and all of the required statements. This is the minimum information the Department believes is needed to ensure individuals are fully informed of their rights with respect to an authorization and to understand the consequences of authorizing the use or disclosure. The required statements must be written in a manner that is adequate to place the individual on notice of the substance of the statements.

In response to comments, the Department clarifies that the statement regarding the potential for redisclosure does not require an analysis of the risk for redisclosure, but may be a general statement that the health information may no longer be protected by the Privacy Rule once it is disclosed by the covered entity. Others objected to this statement because individuals might be hesitant to sign an authorization if they knew their protected health information could be redisclosed and no longer protected by the Rule. In response, the Department believes that individuals need to know about the consequences of authorizing the disclosure of their protected health information. As the commenter recognized, the potential for redisclosure may, indeed, be an important factor in an individual's decision to give or deny a requested authorization.

Others suggested that the statement regarding redisclosure should be omitted when an authorization is obtained only for a use, since such a statement would be confusing and

inappropriate when the covered entity maintains the information. Similarly, some commenters were concerned that the statement may be misleading where the recipient of the information, although not a covered entity, will keep the information confidential. In response, the Department clarifies that, while a general statement would suffice, a covered entity has the discretion to provide a more definitive statement where appropriate. Thus, the covered entity requesting an authorization for its own use of protected health information may provide assurances that the information will remain subject to the Privacy Rule. Similarly, if a third party, such as a researcher, is seeking an authorization for research, the statement may refer to the privacy protections that the researcher will provide for the data.

Under § 164.508(c)(3), authorizations must be written in plain language so that individuals can understand the information contained in the form, and thus be able to make an informed decision about whether to give the authorization. A few commenters urged the Department to keep the plain language requirement as a core element of a valid authorization. Under the December 2000 Rule, the plain language requirement was not a requisite for a valid authorization. Nevertheless, under both the December 2000 Rule and the final modifications, authorizations must be written in plain language. The fact that the plain language requirement is not a core element does not diminish its importance or effect, and the failure to meet this requirement is a violation of the Rule.

Finally, under § 164.508(c)(4), covered entities who seek an authorization are required to provide the individual with a copy of the signed authorization form.

*Response to Other Public Comments*

*Comment:* A number of commenters specifically expressed support of the proposed authorization requirement for marketing, and urged the Department to adopt the requirement. However, one commenter claimed that requiring authorizations for marketing would reduce hospitals' ability to market their programs and services effectively in order to compete in the marketplace, and that obtaining, storing, and maintaining marketing authorizations would be too burdensome.

*Response:* In light of the support in the comments, the Department has adopted the proposed requirement for an authorization before a covered entity may use or disclose protected health information for marketing. However, the commenter is mistaken that this requirement will interfere with a hospital's ability to promote its own program and services within the community. First, such broad-based marketing is likely taking place without resort to protected health information, through dissemination of information about the hospital through community-wide mailing lists. Second, under the Privacy Rule, a communication is not marketing if a covered entity is describing its own products and services. Therefore, nothing in the Rule will inhibit a hospital from competing in the marketplace by communicating about its programs and services.

*Comment:* One commenter suggested that authorizations for marketing should clearly indicate that they are comprehensive and may contain sensitive protected health information.

*Response:* The Department treats all individually identifiable health information as sensitive and equally deserving of protections under the Privacy Rule. The Rule requires all authorizations to contain the specified core elements to ensure individuals are given the information they need to make an informed decision. One of the core elements for all authorizations is a clear description of the information that is authorized to be used or disclosed in specific and meaningful terms. The authorization process provides the individual with the opportunity to ask questions, negotiate how their information will be used and disclosed, and ultimately to control whether these uses and disclosures will be made.

*Comment:* Several commenters urged the Department to retain the existing structure of the implementation specifications, whereby the notification statements about the individual's right to revoke and the potential for redisclosure are ''core elements.'' It was argued that this information is essential to an informed decision. One of the commenters claimed that moving them out of the core elements and only requiring a statement adequate to put the person on notice of the information would increase uncertainty, and that these two elements are too important to risk inadequate explanation.

*Response:* The Department agrees that the required notification statements are essential information that a person needs in order to make an informed decision about authorizing the use or disclosure of protected health information. Individuals need to know what rights they have with respect to an authorization, and how they can exercise those rights. However, separating the core elements and notification statements into two different subparagraphs does not diminish the importance or effect of the notification statements. The Department clarifies that both the core elements and the notification statements are required, and both must be included for an authorization to be valid.

*Comment:* Several commenters urged the Department to eliminate unnecessary authorization contents. They argued the test should be whether the person needs the information to protect his or her privacy, and cited the disclosure of remuneration by a third party as an example of unnecessary content, alleging that the disclosure of remuneration is not relevant to protecting privacy. One commenter suggested that covered entities should be given the flexibility to decide which contents are applicable in a given situation.

*Response:* The Department believes the core elements are all essential information. Individuals need to know this information to make an informed decision about giving the authorization to use or disclose their protected health information. Therefore, the Department believes all of the core elements are necessary content in all situations. The Department does not agree that the remuneration statement required on an authorization for uses and disclosures of an individual's protected health information for marketing purposes is not relevant to protecting privacy. Individuals exercise control over the privacy of their protected health information by either giving or denying an authorization, and remuneration from a third party to the covered entity for obtaining an authorization for marketing is an important factor in making that choice.

*Comment:* One commenter suggested that covered entities should not be required to state on an authorization a person's authority to act on an individual's behalf, and they should be trusted to require such identification or proof of legal authority when the authorization is signed. The commenter stated that this requirement only increases administrative burden for covered entities.

*Response:* The Department does not agree. The authorization requirement is intended to give individuals some control over uses and disclosures of protected health information that are not otherwise permitted or required by the Rule. Therefore, the Rule requires that covered entities verify and document a person's authority to sign an authorization on an individual's behalf, since that person is exercising the individual's control of the information. Furthermore, the Department understands that it is a

current industry standard to verify and document a person's authority to sign any legal permission on another person's behalf. Thus, the requirement should not result in any undue administrative burden for covered entities.

*Comment:* One commenter suggested that the Department should require authorizations to include a complete list of entities that will use and share the information, and that the individual should be notified periodically of any changes to the list so that the individual can provide written authorization for the changes.

*Response:* It may not always be feasible or practical for covered entities to include a comprehensive list of persons authorized to use and share the information disclosed pursuant to an authorization. However, individuals may discuss this option with covered entities, and they may refuse to sign an authorization that does not meet their expectations. Also, subject to certain limitations, individuals may revoke an authorization at any time.

*Comment:* One commenter asked for clarification that a health plan may not condition a provider's participation in the health plan on seeking authorization for the disclosure of psychotherapy notes, arguing that this practice would coerce providers to request, and patients to provide, an authorization to disclose psychotherapy notes.

*Response:* The Privacy Rule does not permit a health plan to condition enrollment, eligibility for benefits, or payment of a claim on obtaining the individual's authorization to use or disclose psychotherapy notes. Nor may a health care provider condition treatment on an authorization for the use or disclosure of psychotherapy notes. In a situation such as the one described by the commenter, the Department would look closely at whether the health plan was attempting to accomplish indirectly that which the Rule prohibits. These prohibitions are to ensure that the individual's permission is wholly voluntary and informed with regard to such an authorization. To meet these standards, in the circumstances set forth in the comment, the Department would expect the provider subject to such a requirement by the health plan to explain to the individual in very clear terms that, while the provider is required to ask, the individual remains free to refuse to authorize the disclosure and that such refusal will have no effect on either the provision of treatment or the individual's coverage under, and payment of claims by, the health plan.

*Comment:* A few commenters suggested the Department should allow covered entities to combine an authorization with other documents, such as the notice acknowledgment, claiming it would reduce administrative burden and paperwork, as well as reduce patient confusion and waiting times, without compromising privacy protections.

*Response:* The Department disagrees that combining an authorization with other documents, such as the notice acknowledgment, would be less confusing for individuals. To the contrary, the Department believes that combining unrelated documents would be more confusing. However, the Rule does permit an authorization to be combined with other authorizations so long as the provision of treatment, payment, enrollment in a health plan or eligibility for benefits is not conditioned on obtaining any of the authorizations, and the authorization is not for the use or disclosure of psychotherapy notes.

Also, authorizations must contain the same information, whether it is a separate document or combined with another document; and the individual must be given the opportunity to read and discuss that information. Combining an authorization with routine paperwork diminishes individuals' ability to make a considered and informed judgment to permit the use or disclosure of their medical information for some other purpose.

*Comment:* One commenter stated that the requirement for covered entities to use only authorizations that are valid under the Rule must be an unintended result of the Rule, because covered entities would have to use only valid authorizations when requesting information from non-covered entities. The commenter did not believe the Department intended this requirement to apply with respect to non-covered entities, and gave the example of dental health plans obtaining protected health information in connection with paper claims submitted by dental offices. The commenter requested clarification that health plans may continue to use authorization forms currently in use for all claims submitted by non-covered entities.

*Response:* The commenter misapprehends the Rule's requirements. The requirements apply to uses and disclosure of protected health information by covered entities. In the example provided, where a health plan is requesting additional information in support of a claim for payment by a non-covered health care provider, the health plan is not required to use an authorization. The plan does not need the individual's authorization to use protected health information for payment purposes, and the non-covered health care provider is not subject to any of the Rule's requirements. Therefore, the exchange of information may occur as it does today. The Department notes that, based on the modifications regarding consent adopted in this rulemaking, neither a consent nor an authorization would be required in this example even if the health care provider was also a covered entity.

*Comment:* Several commenters urged the Department to add a transition provision to permit hospitals to use protected health information in already existing databases for marketing and outreach to the communities they serve. Commenters claimed that these databases are important assets that would take many years to rebuild, and hospitals may not have an already existing authorization or other express legal permission for such use of the information. They contended that, without a transition provision, these databases would become useless under the Rule. Commenters suggested the Department should adopt an ''opt out'' provision that would allow continued use of these databases to initially communicate with the persons listed in the database; at that time, they could obtain authorization for future communications, thus providing a smooth transition.

*Response:* Covered entities are provided a two-year period in which to come into compliance with the Privacy Rule. One of the purposes of the compliance period is to allow covered entities sufficient time to undertake actions such as those described in the comment (obtaining the legal permissions that would permit databases to continue to operate after the compliance date). An additional transition period for these activities has not been justified by the commenters. However, the Department notes that a covered entity is permitted to use the information in a database for communications that are either excepted from or that do not meet the definition of ''marketing'' in § 164.501, without individual authorization. For example, a hospital may use protected health information in an existing database to distribute information about the services it provides, or to distribute a newsletter with general health or wellness information that does not promote a particular product or service.

2. Research Authorizations

*December 2000 Privacy Rule.* The Privacy Rule requires covered entities to obtain an individual's voluntary and informed authorization before using or disclosing protected health information for any purpose that is not otherwise permitted or required under the Rule. Uses and disclosures of protected health information for research purposes are subject to the same authorization requirements as uses and disclosures for other purposes. However, for research that includes treatment of the individual, the December 2000 Privacy Rule prescribed special authorization requirements at § 164.508(f). The December 2000 Privacy Rule, at § 164.508(b)(5), also permitted individuals to revoke their authorization at any time, with limited exceptions. Further, the December 2000 Privacy Rule prohibited the combining of the authorization for the use or disclosure of existing protected health information with any other legal permission related to the research study.

*March 2002 NPRM.* Several of those who commented on the December 2000 Privacy Rule argued that certain authorization requirements in § 164.508 were unduly complex and burdensome as applied to research uses and disclosures. In particular, several commenters favored eliminating the Rule's specific provisions at § 164.508(f) for authorizations for uses and disclosures of protected health information for research that includes treatment of the individual. The Department also heard from several provider groups who argued in favor of permitting covered entities to combine all of the research authorizations required by the Privacy Rule with the informed consent to participate in the research. Commenters also noted that the Rule's requirement for an ''expiration date or event that relates to the individual or the purpose of the use or disclosure'' runs counter to the needs of research databases and repositories that are often retained indefinitely.

In response to these concerns, the Department proposed to a number of modifications to simplify the authorization requirements both generally, and in certain circumstances, as they specifically applied to uses and disclosures of protected health information for research. In particular, the Department proposed a single set of authorization requirements for all uses and disclosures, including those for research purposes. This proposal would eliminate the additional authorization requirements for the use and disclosure of protected health information created for research that includes treatment of the individual. Consistent with this proposed change, the Department further proposed to modify the requirements prohibiting the conditioning of authorizations at § 164.508(b)(4)(i) to remove the reference to § 164.508(f).

In addition, the Department proposed that the Privacy Rule permit an authorization for the use or disclosure of protected health information to be combined with any other legal permission related to the research study, including another authorization or consent to participate in the research.

Finally, the Department proposed to provide explicitly that the statement, ''end of a research study,'' or similar language be sufficient to meet the requirement for an expiration date in § 164.508(c)(1)(v). Additionally, the Department proposed that the statement ''none'' or similar language be sufficient to meet this provision if the authorization was for a covered entity to use or disclose protected health information for the creation or maintenance of a research database or repository.

*Overview of Public Comments.* The following discussion provides an overview of the public comment received on this proposal. Additional comments received on this issue are discussed below in the section entitled, ''Response to Other Public Comments.''

The vast majority of commenters were very supportive of the proposed revisions to the Rule's provisions for research authorizations. However, the Department did hear from several commenters that the Privacy Rule's requirement for an expiration date or event should be eliminated for all research uses and disclosures of protected health information, not just for uses and disclosures for the creation or maintenance of a research database or repository, as was proposed in the NPRM. These commenters were concerned that the Privacy Rule would prohibit important uses and disclosures of protected health information after the termination of a research project, such as the reporting of research results to the Food and Drug Administration (FDA) for an FDA investigational new drug application, unless the covered entity obtained another patient authorization. In addition, several of these commenters cited confusion in defining repositories and databases. Some of these commenters stated that an individual who authorizes information to be used for an indeterminate time most likely expects and intends for the information to be used and disclosed if needed well into the future, regardless of whether or not the research involves the use or disclosure of protected health information for the creation or maintenance of a database or repository.

Several commenters responded to the Department's request for comments on how to appropriately limit uses and disclosures following revocation of an authorization, while preserving the integrity of the research. The NPRM attempted to clarify that ''even though a revocation will prevent a covered entity from further disclosing protected health information for research purposes, the exception to this requirement is intended to allow for certain continued uses of information as appropriate to preserve the integrity of the research study.'' However, the NPRM further stated that ''if covered entities were permitted to continue using or disclosing protected health information for the research project even after an individual had revoked his or her authorization, this would undermine the primary objective of the authorization requirements to be a voluntary, informed choice of the individual.'' Several commenters were concerned and confused by the NPRM's statements. In particular, the Department received comments urging that the regulation permit covered entities to use and disclose research data already obtained, even after an individual has withdrawn his or her authorization. These commenters suggested that once a subject has authorized the use and disclosure of protected health information for research and the covered entity has relied on the authorization, the covered entity must retain the ability to use or disclose the subject's pre-withdrawal information for purposes consistent with the overall research. One commenter argued that it would be inadequate for the reliance exception at § 164.508(b)(5) to be interpreted to permit continued uses of the individual's information as appropriate only to account for an individual's withdrawal from the study. In this commenter's opinion, most research would call for the continued use of protected health information obtained prior to an individual's revocation of their authorization to safeguard statistical validity and truly to preserve the integrity of human research.

*Final Modifications.* The Department agrees with the commenters that supported the NPRM's proposed simplification of authorizations for research uses and disclosures of protected health information and, therefore, adopts the modifications to these provisions as proposed in the NPRM. The final Rule requires a single

set of authorization requirements for all uses and disclosures, including those for research purposes, and permits an authorization for the use or disclosure of protected health information to be combined with any other legal permission related to the research study, including another authorization or consent to participate in the research.

In addition, in response to commenters' concerns that the Rule would prohibit important uses and disclosures of protected health information after the termination of a research project, the final Rule eliminates the requirement for an expiration date for all uses and disclosures of protected health information for research purposes, not only for the creation and maintenance of a research database or repository. The Department agrees that the line between research repositories and databases in particular, and research data collection in general, is sometimes arbitrary and unclear. If the authorization for research uses and disclosures of protected health information does not have an expiration date, the final Rule at § 164.508(c)(1)(v), requires that this fact be stated on the authorization form. Patients continue to control whether protected health information about them may be used or disclosed for research, since the authorization must include an expiration date or event, or a statement that the authorization will have no expiration date. In addition, patients will be permitted to revoke their authorization at any time during the research project, except as specified under § 164.508(b)(5). However, the Department notes that researchers may choose to include, and covered entities may choose to require, an expiration date when appropriate.

Although the final Rule does not modify the revocation provision at § 164.508(b)(5), in response to commenters' concerns, the Department clarifies that this provision permits covered entities to continue using and disclosing protected health information that was obtained prior to the time the individual revoked his or her authorization, as necessary to maintain the integrity of the research study. An individual may not revoke an authorization to the extent the covered entity has acted in reliance on the authorization. For research uses and disclosures, this reliance exception at § 164.508(b)(5)(i) permits the continued use and disclosure of protected health information already obtained pursuant to a valid authorization to the extent necessary to preserve the integrity of the research study. For example, the reliance exception would permit the continued use and disclosure of protected health information to account for a subject's withdrawal from the research study, as necessary to incorporate the information as part of a marketing application submitted to the FDA, to conduct investigations of scientific misconduct, or to report adverse events. However, the reliance exception would not permit a covered entity to continue disclosing additional protected health information to a researcher or to use for its own research purposes information not already gathered at the time an individual withdraws his or her authorization. The Department believes that this clarification of the Rule will minimize the negative effects on research caused by participant withdrawal and will allow for important continued uses and disclosures to occur, while maintaining privacy protections for research subjects.

*Response to Other Public Comments*

*Comment:* In opposition to the March 2002 NPRM, one commenter suggested prohibiting the combining of authorization forms with an informed consent when the covered entity disclosing the protected health information is not otherwise participating in research. The commenter argued that the NPRM would allow covered entities to receive more information than necessary to fulfill a patient's authorization request, such as information about the particular type or purpose of the study itself, and could, thereby, violate the patient's privacy.

*Response:* The Department acknowledges the concern raised by these commenters; however, prohibiting the combination of authorization forms with an informed consent reduces the flexibility proposed in the March 2002 NPRM. Since the final modifications permit—but do not require—such combining of forms, the Department has decided to leave it to the discretion of researchers or the IRBs to determine whether the combining of authorization forms and consent forms for research would be appropriate for a particular research study.

*Comment:* Some commenters supported retaining the December 2000 Privacy Rule requirement that a description of the extent to which protected health information will be used or disclosed for treatment, payment, or health care operations be included in an authorization to use or disclose protected health information for a research study that includes treatment of individuals. These commenters argued that an individual's ability to make informed decisions requires that he or she know how research information will and will not be used and disclosed.

*Response:* The Department agrees with the majority of the commenters who were in support of the March 2002 NPRM proposal to eliminate the additional authorization requirements for research that includes treatment, and has adopted these proposed modifications in the final Rule. Retaining the distinction between research that involves treatment and research that does not would require overly subjective decisions without providing commensurate privacy protections for individuals. However, the Department notes that it may sometimes be advisable for authorization forms to include a statement regarding how protected health information obtained for a research study will be used and disclosed for treatment, payment, and health care operations, if such information would assist individuals in making informed decisions about whether or not to provide their authorization for a research study.

*Comment:* One commenter argued that expiration dates should be included on authorizations and that extensions should be required for all research uses and disclosures made after the expiration date or event has passed.

*Response:* The Department disagrees. We have determined that an expiration date or event would not always be feasible or desirable for some research uses and disclosures of protected health information. By allowing for no expiration date, the final Rule permits without separate patient authorization important disclosures even after the ''termination of the research project'' that might otherwise be prohibited. However, the final Rule contains the requirement that the patient authorization specify if the authorization would not have an expiration date or event. Therefore, patients will have this information to make an informed decision about whether to sign the authorization.

*Comment:* Another commenter suggested permitting covered entities/researchers to continue using or disclosing protected health information even after a revocation of the initial authorization but only if an IRB or Privacy Board approved the continuation. This commenter argued that such review by an IRB or Privacy Board would protect privacy, while permitting continued uses and disclosures of protected health information for important purposes.

*Response:* As stated above, the Department agrees that it may sometimes be necessary to continue using and disclosing protected health information even after an individual has revoked his or her authorization in order to preserve the integrity of a research study. Therefore, the Department has clarified that the reliance exception at § 164.508(b)(5)(i) would permit the continued use and disclosure of protected health information already obtained pursuant to a valid authorization to the extent necessary to preserve the integrity of the research study. A requirement for documentation of IRB or Privacy Board review and approval of the continued use or disclosure of protected health information after an individual's authorization had been revoked could protect patient privacy. However, the Department believes that the additional burden on the IRB or Privacy Board could be substantial, and is not warranted at this time.

*Comment:* A commenter requested clarification that the ''reliance exception'' does not permit covered entities as researchers to continue analyzing data once an individual has revoked his or her authorization.

*Response:* As discussed above, the Department disagrees with this comment. Patient privacy must be balanced against other public goods, such as research and the risk of compromising such research projects if researchers could not continue to use such data. The Department determined that permitting continued uses and disclosures of protected health information already obtained to protect the integrity of research, even after an individual's authorization has been revoked, would pose minimal privacy risk to individuals without compromising research.

*Comment:* Several commenters suggested permitting the proposed authorization requirement for a ''description of each purpose of the requested use or disclosure'' at § 164.508 to be sufficiently broad to encompass future unspecified research. These commenters argued that this option would reduce the burden for covered entities and researchers by permitting covered entities to use or disclose protected health information for re-analysis without having to obtain an additional authorization from the individual. Some discussed the possibility that burden for patients would also be reduced because they would not have to provide additional authorizations. These commenters also argued that such a provision would more directly align the Rule with the Common Rule, which permits broad informed consent for secondary studies if the IRB deems the original informed consent to be adequate.

*Response:* The Department disagrees with broadening the required ''description of the purpose of the use or disclosure'' because of the concern that patients would lack necessary information to make an informed decision. In addition, unlike the Common Rule, the Privacy Rule does not require IRB or Privacy Board review of research uses and disclosures made with individual authorization. Therefore, instead of IRBs or Privacy Boards reviewing the adequacy of existing patient authorizations, covered entities would be left to decide whether or not the initial authorization was broad enough to cover subsequent research analyses. Furthermore, it should be noted that patient authorization would not be required for such re-analysis if, with respect to the re-analysis, the covered entity obtains IRB or Privacy Board waiver of such authorization as required by § 164.512(i). For these reasons, the Department has decided to retain the requirement that each purpose of the requested use or disclosure described in the authorization form be research study specific. However, the Department understands that, in the past, some express legal permissions and informed consents have not been study-specific and sometimes authorize the use or disclosure of information for future unspecified research. Furthermore, some IRB-approved waivers of informed consent have been for future unspecified research. Therefore, the final Rule at § 164.532 permits covered entities to rely on an express legal permission, informed consent, or IRB-approved waiver of informed consent for future unspecified research, provided the legal permission, informed consent or IRB-approved waiver was obtained prior to the compliance date.

*Comment:* Several commenters suggested retaining the authorization element requiring a statement regarding ''the potential for information disclosed pursuant to the authorization to be subject to redisclosure by the recipient and no longer protected by this Rule'' but with one addition. This addition would state that ''researchers could only use or disclose the protected health information for purposes approved by the IRB or as required by law or regulation.'' These commenters argued that this would be clearer to participants and would prevent the misconception that their information would not be protected by any confidentiality standards.

*Response:* The Department recognizes the concern of the commenters seeking to supplement the requirement, but points out that, although the final Rule will not require this addition, it is permissible to include such a statement in the authorization. In addition, since the Privacy Rule does not require IRB or Privacy Board review of research uses and disclosures made with patient authorization, the Department determined that adding the commenters' suggestion to the final Rule would be inappropriate. Section III.E.1. above provides further discussion of this provision.

*F. Section 164.512—Uses and Disclosures for Which Authorization or Opportunity To Agree or Object Is Not Required*

1. Uses and Disclosures Regarding FDA-Regulated Products and Activities

*December 2000 Privacy Rule.* The Privacy Rule permits covered entities to disclose protected health information without consent or authorization for public health purposes. Generally, these disclosures may be made to public health authorities, as well as to contractors and agents of public health authorities. However, in recognition of the essential role of drug and medical device manufacturers and other private persons in carrying out the Food and Drug Administration's (FDA) public health mission, the December 2000 Privacy Rule permitted covered entities to make such disclosures to a person who is subject to the jurisdiction of the FDA, but only for the following specified purposes: (1) To report adverse events, defects or problems, or biological product deviations with respect to products regulated by the FDA (if the disclosure is made to the person required or directed to report such information to the FDA); (2) to track products (if the disclosure is made to the person required or directed to report such information to the FDA); (3) for product recalls, repairs, or replacement; and (4) for conducting post-marketing surveillance to comply with FDA requirements or at the direction of the FDA.

*March 2002 NPRM.* The Department heard a number of concerns about the scope of the disclosures permitted for FDA-regulated products and activities and the failure of the Privacy Rule to reflect the breadth of the public health activities currently conducted by private sector entities subject to the jurisdiction of the FDA on a voluntary basis. These commenters claimed the Rule would constrain important public health surveillance and reporting activities by

impeding the flow of needed information to those subject to the jurisdiction of the FDA. For instance, there were concerns that the Rule would have a chilling effect on current voluntary reporting practices. The FDA gets the vast majority of information concerning problems with FDA-regulated products, including drugs, medical devices, biological products, and food indirectly through voluntary reports made by health care providers to the manufacturers. These reports are critically important to public health and safety. The December 2000 Rule permitted such disclosures only when made to a person ''required or directed'' to report the information to the FDA or to track the product. The manufacturer may or may not be required to report such problems to the FDA, and the covered entities who make these reports are not in a position to know whether the recipient of the information is so obligated. Consequently, many feared that this uncertainty would cause covered entities to discontinue their practices of voluntary reporting of adverse events related to FDA-regulated products or entities.

Some covered entities also expressed fears of the risk of liability should they inadvertently report the information to a person who is not subject to the jurisdiction of the FDA or to the wrong manufacturer. Hence, they urged the Department to provide a ''good-faith'' safe harbor to protect covered entities from enforcement actions arising from unintentional violations of the Privacy Rule.

A number of commenters, including some subject to the jurisdiction of the FDA, suggested that it is not necessary to disclose identifiable health information for some or all of these public health purposes, that identifiable health information is not reported to the FDA, and that information without direct identifiers (such as name, mailing address, phone number, social security number, and email address) is sufficient for post-marketing surveillance purposes.

The Rule is not intended to discourage or prevent adverse event reporting or otherwise disrupt the flow of essential information that the FDA and persons subject to the jurisdiction of the FDA need in order to carry out their important public health activities. Therefore, the Department proposed some modifications to the Rule to address these issues in the NPRM. Specifically, the Department proposed to remove from §§ 164.512(b)(1)(iii)(A) and (B) the phrase ''if the disclosure is made to a person required or directed to report such information to the Food and Drug Administration'' and to remove from subparagraph (D) the phrase ''to comply with requirements or at the direction of the Food and Drug Administration.'' In lieu of this language, the Department proposed to describe at the outset the public health purposes for which disclosures may be made. The proposed language read: ''A person subject to the jurisdiction of the Food and Drug Administration (FDA) with respect to an FDA-regulated product or activity for which that person has responsibility, for the purpose of activities related to the quality, safety or effectiveness of such FDA-regulated product or activity.''

The proposal retained the specific activities identified in paragraphs (A), (B), (C), and (D) as examples of common FDA purposes for which disclosures would be permitted, but eliminated the language that would have made this listing the only activities for which such disclosures would be allowed. These activities include reporting of adverse events and other product defects, the tracking of FDA-regulated products, enabling product recalls, repairs, or replacement, and conducting post-marketing surveillance. Additionally, the Department proposed to include ''lookback'' activities in paragraph (C), which are necessary for tracking blood and plasma products, as well as quarantining tainted blood or plasma and notifying recipients of such tainted products.

In addition to these specific changes, the Department solicited comments on whether a limited data set should be required or permitted for some or all public health purposes, or if a special rule should be developed for public health reporting. The Department also requested comments as to whether the proposed modifications would be sufficient, or if additional measures, such as a good-faith safe harbor, would be needed for covered entities to continue to report vital information concerning FDA-regulated products or activities on a voluntary basis.

*Overview of Public Comments.* The following discussion provides an overview of the public comment received on this proposal. Additional comments received on this issue are discussed below in the section entitled, ''Response to Other Public Comments.''

The proposed changes received wide support. The overwhelming majority of commenters urged the Department to adopt the proposed changes, claiming it would reduce the chilling effect that the Rule would otherwise have on current voluntary reporting practices, which are an important means of identifying adverse events, defects, and other problems regarding FDA-regulated products. Several commenters further urged the Department to provide a good-faith safe harbor to allay providers' fears of inadvertently violating the Rule, stating that covered entities would otherwise be reluctant to risk liability to make these important public health disclosures.

A few commenters opposed the proposed changes, expressing concern that the scope of the proposal was too broad. They were particularly concerned that including activities related to ''quality'' or ''effectiveness'' would create a loophole for manufacturers to obtain and use protected health information for purposes the average person would consider unrelated to public health or safety, such as using information to market products to individuals. Some of these commenters said the Department should retain the exclusive list of purposes and activities for which such disclosures may be made, and some urged the Department to retain the ''required or directed'' language, as it creates an essential nexus to a government authority or requirement. It was also suggested that the chilling effect on reporting of adverse events could be counteracted by a more targeted approach. Commenters were also concerned that the proposal would permit disclosure of much more protected health information to non-covered entities that are not obligated by the Rule to protect the privacy of the information. Comments regarding use of a limited data set for public health disclosures are discussed in section III.G.1. of the preamble.

*Final Modifications.* In the final modifications, the Department adopts the language proposed in the NPRM. Section 164.512(b)(1)(iii), as modified, permits covered entities to disclose protected health information, without authorization, to a person subject to the jurisdiction of the FDA with respect to an FDA-regulated product or activity for which that person has responsibility, for the purpose of activities related to the quality, safety, or effectiveness of such FDA-regulated product or activity. Such purposes include, but are not limited to, the following activities and purposes listed in subparagraphs (A) through (D): (1) To collect or report adverse events (or similar activities regarding food or dietary supplements), product defects or problems (including problems with the use or labeling of a product), or biological product deviations, (2) to track FDA-regulated products, (3) to enable product recalls, repairs, or replacement, or for lookback (including locating and notifying persons who have

received products that have been withdrawn, recalled, or are the subject of lookback), and (4) to conduct post-marketing surveillance.

The Department believes these modifications are necessary to remove barriers that could prevent or chill the continued flow of vital information between health care providers and manufacturers of food, drugs, medical and other devices, and biological products. Health care providers have been making these disclosures to manufacturers for many years, and commenters opposed to the proposal did not cite any examples of abuses of information disclosed for such purposes. Furthermore, both the individuals who are the subjects of the information and the general public benefit from these disclosures, which are an important means of identifying and dealing with FDA-regulated products on the market that potentially pose a health or safety threat. For example, FDA learns a great deal about the safety of a drug after it is marketed as a result of voluntary adverse event reports made by covered entities to the product's manufacturer. The manufacturer is required to submit these safety reports to FDA, which uses the information to help make the product safer by, among other things, adding warnings or changing the product's directions for use. The modifications provide the necessary assurances to covered entities that such voluntary reporting may continue.

Although the list of permissible disclosures is no longer exclusive, the Department disagrees with commenters that asserted the modifications permit virtually unlimited disclosures for FDA purposes. As modified, such disclosures must still be made to a person subject to the jurisdiction of the FDA. The disclosure also must relate to FDA-regulated products or activities for which the person using or receiving the information has responsibility, and be made only for activities related to the safety, effectiveness, or quality of such FDA-regulated product or activity. These terms are terms of art with commonly accepted and understood meanings in the FDA context, meanings of which providers making such reports are aware. This limits the possibility that FDA-regulated manufacturers and entities will able to abuse this provision to obtain information to which they would otherwise not be entitled.

Moreover, § 164.512(b)(1) specifically limits permissible disclosures to those made for public health activities and purposes. While a disclosure related to the safety, quality or effectiveness of an FDA-regulated product is a permissible disclosure, the disclosure also must be for a ''public health'' activity or purpose. For example, it is not permissible under § 164.512(b)(1)(iii) for a covered entity to disclose protected health information to a manufacturer to allow the manufacturer to evaluate the effectiveness of a marketing campaign for a prescription drug. In this example, although the disclosure may be related to the effectiveness of an FDA-regulated activity (the advertising of a prescription drug), the disclosure is made for the commercial purposes of the manufacturer rather than for a public health purpose.

A disclosure related to a ''quality'' defect of an FDA-regulated product is also permitted. For instance, the public health exception permits a covered entity to contact the manufacturer of a product to report drug packaging quality defects. However, this section does not permit all possible reports from a covered entity to a person subject to FDA jurisdiction about product quality. It would not be permissible for a provider to furnish a manufacturer with a list of patients who prefer a different flavored cough syrup over the flavor of the manufacturer's product. Such a disclosure generally would not be for a public health purpose. However, a disclosure related to the flavor of a product would be permitted under this section if the covered entity believed that a difference in the product's flavor indicated, for example, a possible manufacturing problem or suggested that the product had been tampered with in a way that could affect the product's safety.

The Department clarifies that the types of disclosures that covered entities are permitted to make to persons subject to FDA jurisdiction are those of the type that have been traditionally made over the years. These reports include, but are not limited to, those made for the purposes identified in paragraphs (A)–(D) of § 164.512(b)(1)(iii) of this final Rule.

Also, the minimum necessary standard applies to public health disclosures, including those made to persons subject to the jurisdiction of the FDA. There are many instances where a report about the quality, safety, or effectiveness of an FDA-regulated product can be made without disclosing protected health information. Such may be the case with many adverse drug events where it is important to know what happened but it may not be important to know to whom. However, in other circumstances, such as device tracking or blood lookback, it is essential for the manufacturer to have identifying patient information in order to carry out its responsibilities under the Food, Drug, and Cosmetic Act. Therefore, identifiable health information can be disclosed for these purposes, consistent with the minimum necessary standard.

As the Department stated in the preamble of the NPRM, ''a person'' subject to the jurisdiction of the FDA does not mean that the disclosure must be made to a specific individual. The Food, Drug, and Cosmetic Act defines ''person'' to include an individual, partnership, corporation, and association. Therefore, covered entities may continue to disclose protected health information to the companies subject to FDA's jurisdiction that have responsibility for the product or activity. Covered entities may identify responsible companies by using information obtained from product labels or product labeling (written material about the product that accompanies the product) including sources of labeling, such as the Physician's Desk Reference.

The Department believes these modifications effectively balance the privacy interests of individuals with the interests of public health and safety. Since the vast majority of commenters were silent on the question of the potential need for a ''good faith'' exception, the Department believes that these modifications will be sufficient to preserve the current public health activities of persons subject to the jurisdiction of the FDA, without such a safe harbor. However, the Department will continue to evaluate the effect of the Rule to determine whether there is need for further modifications or guidance.

*Response to Other Public Comments*

*Comment:* A few commenters urged the Department to include foreign public health authorities in the Rule's definition of ''public health authority.'' These commenters claimed that medical products are often distributed in multiple countries, and the associated public health issues are experienced globally. They further claimed that requiring covered entities to obtain the permission of a United States-based public health authority before disclosing protected health information to a foreign government public health authority will impede important communications.

*Response:* The Department notes that covered entities are permitted to disclose protected health information for public health purposes, at the direction of a public health authority, to an official of a foreign government agency that is acting in collaboration with a public health authority. The

Department does not have sufficient information at this time as to any potential impacts or workability issues that could arise from this language and, therefore, does not modify the Rule in this regard.

*Comment:* Some commenters, who opposed the proposal as a weakening of the Privacy Rule, suggested that the Department implement a more targeted approach to address only those issues raised in the preamble to the NPRM, such as voluntary adverse event reporting activities, rather than broadening the provision generally.

*Response:* The NPRM was intended to address a number of issues in addition to the concern that the December 2000 Privacy Rule would chill reporting of adverse events to entities from whom the FDA receives much of its adverse event information. For instance, the text of the December 2000 Privacy Rule did not expressly permit disclosure of protected health information to FDA-regulated entities for the purpose of enabling ''lookback,'' which is an activity performed by the blood and plasma industry to identify and quarantine blood and blood products that may be at increased risk of transmitting certain blood-borne diseases, and which includes the notification of individuals who received possibly tainted products, permitting them to seek medical attention and counseling. The NPRM also was intended to simplify the public health reporting provision and to make it more readily understandable. Finally, the approach proposed in the NPRM, and adopted in this final Rule, is intended to add flexibility to the public health reporting provision of the December 2000 Rule, whose exclusive list of permissible disclosures was insufficiently flexible to assure that § 164.512(b)(1)(iii) will allow legitimate public health reporting activities that might arise in the future.

In addition, the Department clarifies that the reporting of adverse events is not restricted to the FDA or persons subject to the jurisdiction of the FDA. A covered entity may, under § 164.512(b), disclose protected health information to a public health authority that is authorized to receive or collect a report on an adverse event. In addition, to the extent an adverse event is required to be reported by law, the disclosure of protected health information for this purpose is also permitted under § 164.512(a). For example, a Federally funded researcher who is a covered health care provider under the Privacy Rule may disclose protected health information related to an adverse event to the National Institutes of Health (NIH) if required to do so by NIH regulations. Even if not required to do so, the researcher may also disclose adverse events directly to NIH as a public health authority. To the extent that NIH has public health matters as part of its official mandate it qualifies as a public health authority under the Privacy Rule, and to the extent it is authorized by law to collect or receive reports about injury and other adverse events such collection would qualify as a public health activity.

2. Institutional Review Board (IRB) or Privacy Board Approval of a Waiver of Authorization

*December 2000 Privacy Rule.* The Privacy Rule builds upon existing Federal regulations governing the conduct of human subjects research. In particular, the Rule at § 164.512(i) establishes conditions under which covered entities can use and disclose protected health information for research purposes without individual authorization if the covered entity first obtains either of the following:

- Documentation of approval of a waiver of authorization from an Institutional Review Board (IRB) or a Privacy Board. The Privacy Rule specifies requirements that must be documented, including the Board's determination that eight defined waiver criteria had been met.
- Where a review of protected health information is conducted preparatory to research or where research is conducted solely on decedents' information, certain representations from the researcher, including that the use or disclosure is sought solely for such a purpose and that the protected health information is necessary for the purpose.

*March 2002 NPRM.* A number of commenters informed the Department that the eight waiver criteria in the December 2000 Privacy Rule were confusing, redundant, and internally inconsistent. These commenters urged the Department to simplify these provisions, noting that they would be especially burdensome and duplicative for research that was currently governed by the Common Rule. In response to these comments, the Department proposed the following modifications to the waiver criteria for all research uses and disclosures of protected health information, regardless of whether or not the research is subject to the Common Rule:

- The Department proposed to delete the criterion that ''the alteration or waiver will not adversely affect the privacy rights and the welfare of the individuals,'' because it may conflict with the criterion regarding the assessment of minimal privacy risk.
- In response to commenters' concerns about the overlap and potential inconsistency among several of the Privacy Rule's criteria, the Department proposed to turn the following three criteria into factors that must be considered as part of the IRB's or Privacy Board's assessment of minimal risk to privacy:
- There is an adequate plan to protect the identifiers from improper use and disclosure;
- There is an adequate plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research, unless there is a health or research justification for retaining the identifiers, or such retention is otherwise required by law; and
- There are adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of protected health information would be permitted by this subpart.
- In response to concerns that the following waiver criterion was unnecessarily duplicative of other provisions to protect patients' confidentiality interests, the Department proposed to eliminate the criterion that: ''the privacy risks to individuals whose protected health information is to be used or disclosed are reasonable in relation to the anticipated benefits, if any, to the individual, and the importance of the knowledge that may reasonably be expected to result from the research.''

In sum, the NPRM proposed that the following waiver criteria replace the waiver criteria in the December 2000 Privacy Rule at § 164.512(i)(2)(ii):

(1) The use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements:

(a) An adequate plan to protect the identifiers from improper use and disclosure;

(b) An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and

(c) Adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the

research project, or for other research for which the use or disclosure of protected health information would be permitted by this subpart;

(2) The research could not practicably be conducted without the waiver or alteration; and

(3) The research could not practicably be conducted without access to and use of the protected health information.

*Overview of Public Comments.* The following discussion provides an overview of the public comment received on this proposal. Additional comments received on this issue are discussed below in the section entitled, ''Response to Other Public Comments.''

The overwhelming majority of commenters were supportive of the Department's proposed modifications to the Privacy Rule's waiver criteria. These commenters found that the proposed revisions adequately addressed earlier concerns that the waiver criteria in the December 2000 Rule were confusing, redundant, and internally inconsistent. However, a few commenters argued that some of the proposed criteria continued to be too subjective and urged that they be eliminated.

*Final Modifications.* The Department agrees with the majority of commenters that supported the proposed waiver criteria, and adopts the modifications as proposed in the NPRM. The criteria safeguard patient privacy, require attention to issues sometimes currently overlooked by IRBs, and are compatible with the Common Rule. Though IRBs and Privacy Boards may initially struggle to interpret the criteria, as a few commenters mentioned, the Department intends to issue guidance documents to address this concern. Furthermore, the Department notes that experience and guidance have enabled IRBs to successfully implement the Common Rule's waiver criteria, which also require subjective determinations.

This final Rule also contains a conforming modification in § 164.512(i)(2)(iii) to replace ''(i)(2)(ii)(D)'' with ''(i)(2)(ii)(C).''

*Response to Other Public Comments*

*Comment:* It was suggested that the Department eliminate the March 2002 NPRM waiver criterion that requires IRBs or Privacy Boards to determine if there is an ''adequate plan to protect identifiers from improper use and disclosure,'' in order to avoid the IRB having to make subjective decisions.

*Response:* The Department disagrees with the commenter that the waiver criterion adopted in this final Rule is too subjective for an IRB or a Privacy Board to use. First, the consideration of whether there is an adequate plan to protect identifiers from improper use and disclosure is one of three factors that an IRB or Privacy Board must weigh in determining that the use or disclosure of protected health information for the research proposal involves no more than a minimal risk to the privacy of the individual. The Department does not believe that the minimal risk determination, which is based upon a similar waiver criterion in the Common Rule, is made unduly subjective by requiring the IRB to take into account the researcher's plans for maintaining the confidentiality of the information.

Second, as noted in the discussion of these provisions in the proposal, the Privacy Rule is intended to supplement and build upon the human subject protections already afforded by the Common Rule and the Food and Drug Administration's human subject protection regulations. One provision already in effect under these authorities is that, to approve a study, an IRB must determine that ''when appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.'' (Common Rule § __.111(a)(7), 21 CFR 56.111(a)(7).) The Department, therefore, believes that IRBs and Privacy Boards are accustomed to making the type of determinations required under the Privacy Rule.

Nonetheless, as stated above, the Department is prepared to respond to actual issues that may arise during the implementation of these provisions and to provide the guidance necessary to address concerns of IRBs, Privacy Boards, and researchers in this area.

*Comment:* A few commenters requested elimination of the waiver element at § 164.512(i)(2)(ii)(A)(2) that would require the IRB or Privacy Board to determine that ''there is an adequate plan to destroy identifiers at the earliest opportunity consistent with the conduct of the research, unless there is a health or research justification for their retention or such retention is required by law.'' These commenters argued that this requirement may lead to premature destruction of the data, which may hinder investigations of defective data analysis or research misconduct.

*Response:* The waiver element at § 164.512(i)(2)(ii)(A)(2) accounts for these concerns by permitting the retention of identifiers if there is a health or research justification, or if such retention is required by law. It is expected that IRBs and Privacy Boards will consider the need for continued analysis of the data, research, and possible investigations of research misconduct when considering whether this waiver element has been met. In addition, destroying identifiers at the earliest opportunity helps to ensure that the use or disclosure of protected health information will indeed pose no more than ''minimal risk to the privacy of individuals.'' Requiring the researcher to justify the need to retain patient identifiers provides needed flexibility for research, while maintaining the goal of protecting individuals' privacy interests. If additional issues arise after implementation, the Department can most appropriately address them through guidance.

*Comment:* Commenters also requested clarification of the proposed waiver element at § 164.512(i)(2)(ii)(A)(3), that will require an IRB or Privacy Board to determine that there are ''adequate written assurances that the protected health information would not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of protected health information would be permitted by this subpart.'' Specifically, the commenter's concern centered on what effect this criterion could have on retrospective studies involving data re-analysis.

*Response:* The Department clarifies that the Privacy Rule permits the use or disclosure of protected health information for retrospective research studies involving data re-analysis only if such use or disclosure is made either with patient authorization or a waiver of patient authorization as permitted by § 164.508 or § 164.512(i), respectively. If issues develop in the course of implementation, the Department intends to provide the guidance necessary to address these questions.

*Comment:* A few commenters suggested clarifying that recruitment for clinical trials by a covered entity using protected health information in the covered entity's possession is a health care operation function, not a marketing function. These commenters argued that a partial IRB or Privacy Board waiver of authorization for recruitment purposes would be too burdensome for the covered entity, and would prevent covered health care providers from communicating with their patients about the availability of clinical trials.

*Response:* Research recruitment is neither a marketing nor a health care operations activity. Under the Rule, a covered entity is permitted to disclose protected health information to the individual who is the subject of the information, regardless of the purpose of the disclosure. *See* § 164.502(a)(1)(i). Therefore, covered health care providers and patients may continue to discuss the option of enrolling in a clinical trial without patient authorization, and

without an IRB or Privacy Board waiver of patient authorization. However, where a covered entity wants to disclose an individual's information to a third party for purposes of recruitment in a research study, the covered entity first must obtain either authorization from that individual as required at § 164.508, or a waiver of authorization as permitted at § 164.512(i).

*Comment:* It was suggested that the Rule should permit covered health care providers to obtain an authorization allowing the use of protected health information for recruitment into clinical trials without specifying the person to whom the information would be disclosed and the exact information to be disclosed, but retaining the authorization requirements of specified duration and purpose, and adding a requirement for the minimum necessary use or disclosure.

*Response:* The Department understands that the Privacy Rule will alter some research recruitment but disagrees with the commenter's proposal to permit broad authorizations for recruitment into clinical trials. The Department decided not to adopt this suggestion because such a blanket authorization would not provide individuals with sufficient information to make an informed choice about whether to sign the authorization. In addition, adopting this change also would be inconsistent with Department's decision to eliminate the distinction in the Rule between research that includes treatment and research that does not.

*Comment:* It was suggested that the Department exempt from the Privacy Rule research that is already covered by the Common Rule and/or FDA's human subject protection regulations. Commenters stated that this would reduce the burden of complying with the Rule for covered entities and researchers already governed by human subject protection regulations, while requiring those not previously subject to compliance with human subject protection regulations to protect individuals' privacy.

*Response:* Many who commented on the December 2000 Privacy Rule argued for this option as well. The Department had previously considered, but chose not to adopt, this approach. Since the Common Rule and the FDA's human subject protection regulations contain only two requirements that specifically address confidentiality protections, the Privacy Rule will strengthen existing human subject privacy protections for research. More importantly, the Privacy Rule creates equal standards of privacy protection for research governed by the existing regulations and research that is not.

*Comment:* It was argued that the waiver provision should be eliminated. The commenter argued that IRBs or Privacy Boards should not have the right to waive a person's privacy rights, and that individuals should have the right to authorize all uses and disclosures of protected health information about themselves.

*Response:* The Department disagrees that safeguarding individuals' privacy interests requires that individuals be permitted to authorize all uses and disclosures of protected health information about themselves. In developing the Privacy Rule, the Department carefully weighed individuals' privacy interests with the need for identifiable health information for certain public policy and national priority purposes. The Department believes that the Privacy Rule reflects an appropriate balance. For example, the Rule appropriately allows for the reporting of information necessary to ensure public health, such as information about a contagious disease that may be indicative of a bioterrorism event, without individual authorization. With respect to research, the Department strongly believes that continued improvements in our nation's health require that researchers be permitted access to protected health information without individual authorization in certain limited circumstances. However, we do believe that researchers' ability to use protected health information without a patient's authorization is a privilege that requires strong confidentiality protections to ensure that the information is not misused. The Department believes that the safeguards required by the final Rule achieve the appropriate balance between protecting individuals' privacy interests, while permitting researchers to access protected health information for important, and potentially life-saving, studies.

*Comment:* A few commenters stated that, if the Rule permits covered entities to release protected health information to sponsor-initiated registries related to quality, safety, or effectiveness of FDA-regulated products, then this permission should apply to academic institutes and non-profit organizations as well. Otherwise, the commenters argued, the Rule establishes a double standard for research registries created by FDA-regulated entities versus registries created by academic or non-profit sponsored entities.

*Response:* The provisions under § 164.512(b)(iii) are intended to allow the disclosure of information to FDA-regulated entities for the limited purpose of conducting public health activities to ensure the qualify, safety, or effectiveness of FDA-regulated products, including drugs, medical devices, biological products, and food. Thus, the Department does not believe a modification to the research provisions is appropriate. The Privacy Rule permits covered entities to disclose protected health information to a registry for research purposes, including those sponsored by academic and non-profit organizations, if such disclosure: is required by law under § 164.512(a), is made pursuant to an IRB or Privacy Board waiver of authorization under § 164.512(i), is made pursuant to the individual's authorization as provided by § 164.508, or consists only of a limited data set as provided by § 164.514(e).

*Comment:* It was suggested that the Department modify the Rule's definition of ''research'' or the provision for preparatory research to explicitly permit the building and maintenance of research databases and repositories. The commenter further asserted that, under the Common Rule, ''research'' signifies an actual research protocol, and would not include a data or tissue compilation that is undertaken to facilitate future protocols. Therefore, since the Privacy Rule and the Common Rule have the same definition of ''research,'' this commenter was concerned that the Privacy Rule would not permit a pre-research practice in which a covered entity compiles protected health information in a systematic way to either assist researchers in their reviews that are preparatory to research, or to conduct future research.

*Response:* The Department does not believe such a modification is necessary. Under the Common Rule, the Office for Human Research Protections (OHRP) has interpreted the definition of ''research'' to include the development of a repository or database for future research purposes. In fact, OHRP has issued guidance on this issue, which can be found at the following URL: *http://ohrp.osophs.dhhs.gov/humansubjects/guidance/reposit.htm.* The Department interprets the definition of ''research'' in the Privacy Rule to be consistent with what is considered research under the Common Rule. Thus, the development of research repositories and databases for future research are considered research for the purposes of the Privacy Rule.

*Comment:* A commenter suggested eliminating the minimum necessary requirement for uses and disclosures made pursuant to a waiver of authorization by an IRB or Privacy

Board. The commenter argued that this proposal would lessen covered entities' concern that they would be held responsible for an IRB or Privacy Board's inappropriate determination and would, thus, increase the likelihood that covered entities would rely on the requesting researcher's IRB or Privacy Board documentation that patient authorization could be waived as permitted at § 164.512(i). This commenter further argued that this proposal would discourage covered entities from imposing duplicate review by the covered entities' own IRB or Privacy Board, thereby decreasing burden for covered entities, researchers, IRBs, and Privacy Boards.

*Response:* Although the Secretary acknowledges the concern of these commenters, the Rule at § 164.514(d)(3)(iii)(D) already permits covered entities to reasonably rely on documentation from an external IRB or Privacy Board as meeting the minimum necessary requirement, provided the documentation complies with the applicable requirements of § 164.512(i). The Department understands that covered entities may elect to require duplicate IRB or Privacy Board reviews before disclosing protected health information to requesting researchers, but has determined that eliminating the minimum necessary requirement would pose inappropriate and unnecessary risk to individuals' privacy. For example, if the covered entity has knowledge that the documentation of IRB or Privacy Board approval was fraudulent with respect to the protected health information needed for a research study, the covered entity should not be permitted to rely on the IRB or Privacy Board's documentation as fulfilling the minimum necessary requirement. Therefore, in the revised Final Rule, the Department has retained the minimum necessary requirement for research uses and disclosures made pursuant to § 164.512(i).

*G. Section 164.514—Other Requirements Relating to Uses and Disclosures of Protected Health Information*

1. De-Identification of Protected Health Information

*December 2000 Privacy Rule.* At § 164.514(a)–(c), the Privacy Rule permits a covered entity to de-identify protected health information so that such information may be used and disclosed freely, without being subject to the Privacy Rule's protections. Health information is de-identified, or not individually identifiable, under the Privacy Rule, if it does not identify an individual and if the covered entity has no reasonable basis to believe that the information can be used to identify an individual. In order to meet this standard, the Privacy Rule provides two alternative methods for covered entities to de-identify protected health information.

First, a covered entity may demonstrate that it has met the standard if a person with appropriate knowledge and experience applying generally acceptable statistical and scientific principles and methods for rendering information not individually identifiable makes and documents a determination that there is a very small risk that the information could be used by others to identify a subject of the information. The preamble to the Privacy Rule refers to two government reports that provide guidance for applying these principles and methods, including describing types of techniques intended to reduce the risk of disclosure that should be considered by a professional when de-identifying health information. These techniques include removing all direct identifiers, reducing the number of variables on which a match might be made, and limiting the distribution of records through a ''data use agreement'' or ''restricted access agreement'' in which the recipient agrees to limits on who can use or receive the data.

Alternatively, covered entities may choose to use the Privacy Rule's safe harbor method for de-identification. Under the safe harbor method, covered entities must remove all of a list of 18 enumerated identifiers and have no actual knowledge that the information remaining could be used, alone or in combination, to identify a subject of the information. The identifiers that must be removed include direct identifiers, such as name, street address, social security number, as well as other identifiers, such as birth date, admission and discharge dates, and five-digit zip code. The safe harbor requires removal of geographic subdivisions smaller than a State, except for the initial three digits of a zip code if the geographic unit formed by combining all zip codes with the same initial three digits contains more than 20,000 people. In addition, age, if less than 90, gender, ethnicity, and other demographic information not listed may remain in the information. The safe harbor is intended to provide covered entities with a simple, definitive method that does not require much judgment by the covered entity to determine if the information is adequately de-identified.

The Privacy Rule also allows for the covered entity to assign a code or other means of record identification to allow de-identified information to be re-identified by the covered entity, if the code is not derived from, or related to, information about the subject of the information. For example, the code cannot be a derivation of the individual's social security number, nor can it be otherwise capable of being translated so as to identify the individual. The covered entity also may not use or disclose the code for any other purpose, and may not disclose the mechanism (*e.g.*, algorithm or other tool) for re-identification.

The Department is cognizant of the increasing capabilities and sophistication of electronic data matching used to link data elements from various sources and from which, therefore, individuals may be identified. Given this increasing risk to individuals' privacy, the Department included in the Privacy Rule the above stringent standards for determining when information may flow unprotected. The Department also wanted the standards to be flexible enough so the Privacy Rule would not be a disincentive for covered entities to use or disclose de-identified information wherever possible. The Privacy Rule, therefore, strives to balance the need to protect individuals' identities with the need to allow de-identified databases to be useful.

*March 2002 NPRM.* The Department heard a number of concerns regarding the de-identification standard in the Privacy Rule. These concerns generally were raised in the context of using and disclosing information for research, public health purposes, or for certain health care operations. In particular, concerns were expressed that the safe harbor method for de-identifying protected health information was so stringent that it required removal of many of the data elements that were essential to analyses for research and these other purposes. The comments, however, demonstrated little consensus as to which data elements were needed for such analyses and were largely silent regarding the feasibility of using the Privacy Rule's alternative statistical method to de-identify information.

Based on the comments received, the Department was not convinced of the need to modify the safe harbor standard for de-identified information. However, the Department was aware that a number of entities were confused by potentially conflicting provisions within the de-identification standard. These entities argued that, on the one hand, the Privacy Rule treats information as de-identified if all listed identifiers on the information are stripped, including

any unique, identifying number, characteristic, or code. Yet, the Privacy Rule permits a covered entity to assign a code or other record identification to the information so that it may be re-identified by the covered entity at some later date.

The Department did not intend such a re-identification code to be considered one of the unique, identifying numbers or codes that prevented the information from being de-identified. Therefore, the Department proposed a technical modification to the safe harbor provisions explicitly to except the re-identification code or other means of record identification permitted by § 164.514(c) from the listed identifiers (§ 164.514(b)(2)(i)(R)).

*Overview of Public Comments.* The following provides an overview of the public comment received on this proposal. Additional comments received on this issue are discussed below in the section entitled, ''Response to Other Public Comments.''

All commenters on our clarification of the safe harbor re-identification code not being an enumerated identifier supported our proposed regulatory clarification.

*Final Modifications.* Based on the Department's intent that the re-identification code not be considered one of the enumerated identifiers that must be excluded under the safe harbor for de-identification, and the public comment supporting this clarification, the Department adopts the provision as proposed. The re-identification code or other means of record identification permitted by § 164.514(c) is expressly excepted from the listed safe harbor identifiers at § 164.514(b)(2)(i)(R).

*Response to Other Public Comments*

*Comment:* One commenter asked if data can be linked inside the covered entity and a dummy identifier substituted for the actual identifier when the data is disclosed to the external researcher, with control of the dummy identifier remaining with the covered entity.

*Response:* The Privacy Rule does not restrict linkage of protected health information inside a covered entity. The model that the commenter describes for the dummy identifier is consistent with the re-identification code allowed under the Rule's safe harbor so long as the covered entity does not generate the dummy identifier using any individually identifiable information. For example, the dummy identifier cannot be derived from the individual's social security number, birth date, or hospital record number.

*Comment:* Several commenters who supported the creation of de-identified data for research based on removal of facial identifiers asked if a keyed-hash message authentication code (HMAC) can be used as a re-identification code even though it is derived from patient information, because it is not intended to re-identify the patient and it is not possible to identify the patient from the code. The commenters stated that use of the keyed-hash message authentication code would be valuable for research, public health and bio-terrorism detection purposes where there is a need to link clinical events on the same person occurring in different health care settings (*e.g.* to avoid double counting of cases or to observe long-term outcomes).

These commenters referenced Federal Information Processing Standard (FIPS) 198: ''The Keyed-Hash Message Authentication Code.'' This standard describes a keyed-hash message authentication code (HMAC) as a mechanism for message authentication using cryptographic hash functions. The HMAC can be used with any iterative approved cryptographic hash function, in combination with a shared secret key. A hash function is an approved mathematical function that maps a string of arbitrary length (up to a pre-determined maximum size) to a fixed length string. It may be used to produce a checksum, called a hash value or message digest, for a potentially long string or message.

According to the commenters, the HMAC can only be breached when the key and the identifier from which the HMAC is derived and the de-identified information attached to this code are known to the public. It is common practice that the key is limited in time and scope (*e.g.* only for the purpose of a single research query) and that data not be accumulated with such codes (with the code needed for joining records being discarded after the de-identified data has been joined).

*Response:* The HMAC does not meet the conditions for use as a re-identification code for de-identified information. It is derived from individually identified information and it appears the key is shared with or provided by the recipient of the data in order for that recipient to be able to link information about the individual from multiple entities or over time. Since the HMAC allows identification of individuals by the recipient, disclosure of the HMAC violates the Rule. It is not solely the public's access to the key that matters for these purposes; the covered entity may not share the key to the re-identification code with anyone, including the recipient of the data, regardless of whether the intent is to facilitate re-identification or not.

The HMAC methodology, however, may be used in the context of the limited data set, discussed below. The limited data set contains individually identifiable health information and is not a de-identified data set. Creation of a limited data set for research with a data use agreement, as specified in § 164.514(e), would not preclude inclusion of the keyed-hash message authentication code in the limited data set. The Department encourages inclusion of the additional safeguards mentioned by the commenters as part of the data use agreement whenever the HMAC is used.

*Comment:* One commenter requested that HHS update the safe harbor de-identification standard with prohibited 3-digit zip codes based on 2000 Census data.

*Response:* The Department stated in the preamble to the December 2000 Privacy Rule that it would monitor such data and the associated re-identification risks and adjust the safe harbor as necessary. Accordingly, the Department provides such updated information in response to the above comment. The Department notes that these three-digit zip codes are based on the five-digit zip Code Tabulation Areas created by the Census Bureau for the 2000 Census. This new methodology also is briefly described below, as it will likely be of interest to all users of data tabulated by zip code.

The Census Bureau will not be producing data files containing U.S. Postal Service zip codes either as part of the Census 2000 product series or as a post Census 2000 product. However, due to the public's interest in having statistics tabulated by zip code, the Census Bureau has created a new statistical area called the Zip Code Tabulation Area (ZCTA) for Census 2000. The ZCTAs were designed to overcome the operational difficulties of creating a well-defined zip code area by using Census blocks (and the addresses found in them) as the basis for the ZCTAs. In the past, there has been no correlation between zip codes and Census Bureau geography. Zip codes can cross State, place, county, census tract, block group and census block boundaries. The geographic entities the Census Bureau uses to tabulate data are relatively stable over time. For instance, census tracts are only defined every ten years. In contrast, zip codes can change more frequently. Because of the ill-defined nature of zip code boundaries, the Census Bureau has no file (crosswalk) showing the relationship

between US Census Bureau geography and US Postal Service zip codes.

ZCTAs are generalized area representations of U.S. Postal Service (USPS) zip code service areas. Simply put, each one is built by aggregating the Census 2000 blocks, whose addresses use a given zip code, into a ZCTA which gets that zip code assigned as its ZCTA code. They represent the majority USPS five-digit zip code found in a given area. For those areas where it is difficult to determine the prevailing five-digit zip code, the higher-level three-digit zip code is used for the ZCTA code. For further information, go to: *http://www.census.gov/geo/www/gazetteer/places2k.html.*

Utilizing 2000 Census data, the following three-digit ZCTAs have a population of 20,000 or fewer persons. To produce a de-identified data set utilizing the safe harbor method, all records with three-digit zip codes corresponding to these three-digit ZCTAs must have the zip code changed to 000. The 17 restricted zip codes are: 036, 059, 063, 102, 203, 556, 692, 790, 821, 823, 830, 831, 878, 879, 884, 890, and 893.

2. Limited Data Sets

*March 2002 NPRM.* As noted above, the Department heard many concerns that the de-identification standard in the Privacy Rule could curtail important research, public health, and health care operations activities. Specific concerns were raised by State hospital associations regarding their current role in using patient information from area hospitals to conduct and disseminate analyses that are useful for hospitals in making decisions about quality and efficiency improvements. Similarly, researchers raised concerns that the impracticality of using de-identified data would significantly increase the workload of IRBs because waivers of individual authorization would need to be sought more frequently for research studies even though no direct identifiers were needed for the studies. Many of these activities and studies were also being pursued for public health purposes. Some commenters urged the Department to permit covered entities to disclose protected health information for research if the protected health information is facially de-identified, that is, stripped of direct identifiers, so long as the research entity provides assurances that it will not use or disclose the information for purposes other than research and will not identify or contact the individuals who are the subjects of the information.

In response to these concerns, the Department, in the NPRM, requested comments on an alternative approach that would permit uses and disclosures of a limited data set which would not include direct identifiers but in which certain potentially identifying information would remain. The Department proposed limiting the use or disclosure of any such limited data set to research, public health, and health care operations purposes only.

From the de-identification safe harbor list of identifiers, we proposed the following as direct identifiers that would have to be removed from any limited data set: name, street address, telephone and fax numbers, e-mail address, social security number, certificate/license number, vehicle identifiers and serial numbers, URLs and IP addresses, and full face photos and any other comparable images. The proposed limited data set could include the following identifiable information: admission, discharge, and service dates; date of death; age (including age 90 or over); and five-digit zip code.

The Department solicited comment on whether one or more other geographic units smaller than State, such as city, county, precinct, neighborhood or other unit, would be needed in addition to, or be preferable to, the five-digit zip code. In addition, to address concerns raised by commenters regarding access to birth date for research or other studies relating to young children or infants, the Department clarified that the Privacy Rule de-identification safe harbor allows disclosure of the age of an individual, including age expressed in months, days, or hours. Given that the limited data set could include all ages, including age in months, days, or hours (if preferable), the Department requested comment on whether date of birth would be needed and, if so, whether the entire date would be needed, or just the month and year.

In addition, to further protect privacy, the Department proposed to condition the disclosure of the limited data set on covered entities obtaining from the recipients a data use or similar agreement, in which the recipient would agree to limit the use of the limited data set to the purposes specified in the Privacy Rule, to limit who can use or receive the data, and agree not to re-identify the data or contact the individuals.

*Overview of Public Comments.* The following discussion provides an overview of the public comment received on this proposal. Additional comments received on this issue are discussed below in the section entitled, ''Response to Other Public Comments.''

Almost all those who commented on this issue supported the basic premise of the limited data set for research, public health, and health care operations. Many of these commenters used the opportunity to reiterate their opposition to the safe harbor and statistical de-identification methods, and some misinterpreted the limited data set proposal as creating another safe-harbor form of de-identified data. In general, commenters agreed with the list of direct identifiers proposed in the preamble of the NPRM; some recommended changes. The requirement of a data use agreement was similarly widely supported, although a few commenters viewed it as unnecessary and others offered additional terms which they argued would make the data use agreement more effective. Others questioned the enforceability of the data use agreements.

A few commenters argued that the limited data set would present a significant risk of identification of individuals because of the increased ability to use the other demographic variables (*e.g.*, race, gender) in such data sets to link to other publicly available data. Some of these commenters also argued that the development of computer-based solutions to support the statistical method of de-identification is advancing rapidly and can support, in some cases better than the limited data set, many of the needs for research, public health and health care operations. These commenters asserted that authorization of the limited data set approach would undermine incentives to further develop statistical techniques for de-identification that may be more protective of privacy.

Most commenters who supported the limited data set concept favored including the five-digit zip code, but also wanted other geographic units smaller than a State to be included in the limited data set. Examples of other geographic units that commenters argued are needed for research, public health or health care operational purposes were county, city, full zip code, census tract, and neighborhood. Various analytical needs were cited to support these positions, such as tracking the occurrence of a particular disease to the neighborhood level or using county level data for a needs assessment of physician specialties. A few commenters opposed inclusion of the 5-digit zip code in the limited data set, recommending that the current Rule, which requires data aggregation at the 3-digit zip code level, remain the standard.

Similarly, the majority of commenters addressing the issue supported inclusion of the full birth date in the

limited data set. These commenters asserted that the full birth date was needed for longitudinal studies, and similar research, to assure accuracy of data. Others stated that while they preferred access to the full birth date, their data needs would be satisfied by inclusion of at least the month and year of birth in the limited data set. A number of commenters also opposed inclusion of the date of birth in the limited data as unduly increasing the risk of identification of individuals.

*Final Modifications.* In view of the support in the public comments for the concept of a limited data set, the Department determines that adoption of standards for the use and disclosure of protected health information for this purpose is warranted. Therefore, the Department adds at § 164.514(e) a new standard and implementation specifications for a limited data set for research, public health, or health care operations purposes if the covered entity (1) uses or discloses only a ''limited data set'' as defined at § 164.514(e)(2), and (2) obtains from the recipient of the limited data set a ''data use agreement'' as defined at § 164.514(e)(4). In addition, the Department adds to the permissible uses and disclosures in § 164.502(a) express reference to the limited data set standards.

The implementation specifications do not delineate the data that can be released through a limited data set. Rather, the Rule specifies the direct identifiers that must be removed for a data set to qualify as a limited data set. As with the de-identification safe harbor provisions, the direct identifiers listed apply to protected health information about the individual or about relatives, employers, or household members of the individual. The direct identifiers include all of the facial identifiers proposed in the preamble to the NPRM: (1) Name; (2) street address (renamed postal address information, other than city, State and zip code); (3) telephone and fax numbers; (4) e-mail address; (5) social security number; (6) certificate/ license numbers; (7) vehicle identifiers and serial numbers; (8) URLs and IP addresses; and (9) full face photos and any other comparable images. The public comment generally supported the removal of this facially identifying information.

In addition to these direct identifiers, the Department designates the following information as direct identifiers that must be removed before protected health information will be considered a limited data set: (1) Medical record numbers, health plan beneficiary numbers, and other account numbers; (2) device identifiers and serial numbers; and (3) biometric identifiers, including finger and voice prints. Only a few commenters specifically stated a need for some or all of these identifiers as part of the limited data set. For example, one commenter wanted an (encrypted) medical record number to be included in the limited data set to support disease management planning and program development to meet community needs and quality management. Another commenter wanted the health plan beneficiary number included in the limited data set to permit researchers to ensure that results indicating sex, gender or ethnic differences were not influenced by the participant's health plan. And a few commenters wanted device identifiers and serial numbers included in the limited data set, to facilitate product recalls and patient safety initiatives. However, the Department has not been persuaded that the need for these identifiers outweighs the potential privacy risks to the individual by their release as part of a limited data set, particularly when the Rule makes other avenues available for the release of information that may directly identify an individual.

The Department does not include in the list of direct identifiers the ''catch-all'' category from the de-identification safe harbor of ''any other unique identifying number, characteristic or code.'' While this requirement is essential to assure that the de-identification safe harbor does in fact produce a de-identified data set, it is difficult to define in advance in the context of a limited data set. Since our goal in establishing a limited data set is not to create de-identified information and since the data use agreement constrains further disclosure of the information, we determined that it would only add complexity to implementation of the limited data set with little added protection.

In response to wide public support, the Department does not designate as a direct identifier any dates related to the individual or any geographic subdivision other than street address. Therefore, as part of a limited data set, researchers and others involved in public health studies will have access to dates of admission and discharge, as well as dates of birth and death for the individual. We agree with commenters who asserted that birth date is critical for certain research, such as longitudinal studies where there is a need to track individuals across time and for certain infant-related research. Rather than adding complexity to the Rule by trying to carve out an exception for these specific situations, and other justifiable uses, we rely on the minimum necessary requirement to keep the Rule simple while avoiding abuse. Birth date should only be disclosed where the researcher and covered entity agree that it is needed for the purpose of the research. Further, even though birth date may be included with a limited data set, the Department clarifies, as it did in the preamble to the proposed rulemaking, that the Privacy Rule allows the age of an individual to be expressed in years or in months, days, or hours as appropriate.

Moreover, the limited data set may include the five-digit zip code or any other geographic subdivision, such as State, county, city, precinct and their equivalent geocodes, except for street address. We substitute for street address the term postal address information, other than city, State and zip code in order to make clear that individual elements of postal address such as street name by itself are also direct identifiers. Commenters identified a variety of needs for various geographical codes (county, city, neighborhood, census tract, precinct) to support a range of essential research, public health and health care operations activities. Some of the examples provided included the need to analyze local geographic variations in disease burdens or in the provision of health services, conducting research looking at pathogens or patterns of health risks which may need to compare areas within a single zip code, or studies to examine data by county or neighborhood when looking for external causes of disease, as would be the case for illnesses and diseases such as bladder cancer that may have environmental links. The Department agrees with these commenters that a variety of geographical designations other than five-digit zip code are needed to permit useful and significant studies and other research to go forward unimpeded. So long as an appropriate data use agreement is in place, the Department does not believe that there is any greater privacy risk in including in the limited data set such geographic codes than in releasing the five-digit zip code.

Finally, the implementation specifications adopted at § 164.514(e) require a data use agreement between the covered entity and the recipient of the limited data set. The need for a data use agreement and the core elements of such an agreement were widely supported in the public comment.

In the NPRM, we asked whether additional conditions should be added to the data use agreement. In response, a few commenters made specific

suggestions. These included prohibiting further disclosure of the limited data set except as required by law, prohibiting further disclosure without the written consent of the covered entity, requiring that the recipient safeguard the information received in the limited data set, prohibiting further disclosure unless the data has been de-identified utilizing the statistical or safe harbor methods of the Privacy Rule, and limiting use of the data to the purpose for which it was received.

In response to these comments, in the final Rule we specify that the covered entity must enter into a data use agreement with the intended recipient which establishes the permitted uses and disclosures of such information by the recipient, consistent with the purposes of research, public health, or health care operations, limits who can use or receive the data, and requires the recipient to agree not to re-identify the data or contact the individuals. In addition, the data use agreement must contain adequate assurances that the recipient use appropriate safeguards to prevent use or disclosure of the limited data set other than as permitted by the Rule and the data use agreement, or as required by law. These adequate assurances are similar to the existing requirements for business associate agreements.

Since the data use agreement already requires the recipient to limit who can use or receive the data, and to prevent uses and disclosures beyond those stated in the agreement, and since we could not anticipate all the possible scenarios under which a limited data set with a data use agreement would be created, the Department concluded that adding any of the other suggested restrictions would bring only marginal additional protection while potentially impeding some of the purposes intended for the limited data set. The Department believes the provisions of the data use agreement provide a firm foundation for protection of the information in the limited data set, but encourages and expects covered entities and data recipients to further strengthen their agreements to conform to current practices.

We do not specify the form of the data use agreement. Thus, private parties might choose to enter into a formal contract, while two government agencies might use a memorandum of understanding to specify the terms of the agreement. In the case of a covered entity that wants to create and use a limited data set for its own research purposes, the requirements of the data use agreement could be met by having affected workforce members sign an agreement with the covered entity, comparable to confidentiality agreements that employees handling sensitive information frequently sign.

A few commenters questioned the enforceability of the data use agreements. The Department clarifies that, if the recipient breaches a data use agreement, HHS cannot take enforcement action directly against that recipient unless the recipient is a covered entity. Where the recipient is a covered entity, the final modifications provide that such covered entity is in noncompliance with the Rule if it violates a data use agreement. See § 164.514(e)(4)(iii)(B). Additionally, the Department clarifies that the disclosing covered entity is not liable for breaches of the data use agreement by the recipient of the limited data set. However, similar to business associate agreements, if a covered entity knows of a pattern of activity or practice of the data recipient that constitutes a material breach or violation of the data recipient's obligation under the data use agreement, then it must take reasonable steps to cure the breach or end the violation, as applicable, and, if unsuccessful, discontinue disclosure of protected health information to the recipient and report the problem to the Secretary. And the recipient is required to report to the covered entity any improper uses or disclosures of limited data set information of which it becomes aware. We also clarify that the data use agreement requirements apply to disclosures of the limited data set to agents and subcontractors of the original limited data set recipient.

In sum, we have created the limited data set option because we believe that this mechanism provides a way to allow important research, public health and health care operations activities to continue in a manner consistent with the privacy protections of the Rule. We agree with those commenters who stated that the limited data set is not de-identified information, as retention of geographical and date identifiers measurably increases the risk of identification of the individual through matching of data with other public (or private) data sets. However, we believe that the limitations on the specific uses of the limited data set, coupled with the requirements of the data use agreement, will provide sufficient protections for privacy and confidentiality of the data. The December 2000 Privacy Rule preamble on the statistical method for de-identification discussed the data use agreement as one of the techniques identified that can be used to reduce the risk of disclosure. A number of Federal agencies that distribute data sets for research or other uses routinely employ data use agreements successfully to protect and otherwise restrict further use of the information.

We note that, while disclosures of protected health information for certain public health purposes is already allowed under § 164.512(b), the limited data set provision may permit disclosures for some public health activities not allowed under that section. These might include disease registries maintained by private organizations or universities or other types of studies undertaken by the private sector or non-profit organizations for public health purposes.

In response to comments, the Department clarifies that, when a covered entity discloses protected health information in a limited data set to a researcher who has entered into an appropriate data use agreement, the covered entity does not also need to have documentation from an IRB or a Privacy Board that individual authorization has been waived for the purposes of the research. However, the covered entity may not disclose any of the direct identifiers listed in § 164.514(e) without either the individual's authorization or documentation of an IRB or Privacy Board waiver of that authorization.

The Department further clarifies that there are other requirements in the Privacy Rule that apply to disclosure of a limited data set, just as they do to other disclosures. For example, any use, disclosure, or request for a limited data set must also adhere to the minimum necessary requirements of the Rule. The covered entity could accomplish this by, for example, requiring the data requestor, in the data use agreement, to specify not only the purposes of the limited data set, but also the particular data elements, or categories of data elements, requested. The covered entity may reasonably rely on a requested disclosure as the minimum necessary, consistent with the provisions of § 164.514(d)(3)(iii). As an example of the use of the minimum necessary standard, a covered entity who believes that another covered entity's request to include date of birth in the limited data set is not warranted is free to negotiate with the recipient about that requirement. If the entity requesting a limited data set including date of birth is not one on whose request a covered entity may reasonably rely under § 164.514(d)(3)(iii), and the covered entity believes inclusion of date of birth is not warranted, the covered entity must either negotiate a reasonably

necessary limited data set or not make a disclosure.

The Department amends § 164.514(e)(3)(ii) to make clear that a covered entity may engage a business associate to create a limited data set, in the same way it can use a business associate to create de-identified data. As with de-identified data, a business associate relationship arises even if the limited data set is not being created for the covered entity's own use. For instance, if a researcher needs county data, but the covered entity's data contains only the postal address of the individual, a business associate may be used to convert the covered entity's geographical information into that needed by the researcher. The covered entity may hire the intended recipient of the limited data set as a business associate for this purpose. That is, the covered entity may provide protected health information, including direct identifiers, to a business associate who is also the intended data recipient, to create a limited data set of the information responsive to the business associate's request.

Finally, the Department amends § 164.528 to make clear that the covered entity does not need to include disclosures of protected health information in limited data sets in any accounting of disclosures provided to the individual. Although the Department does not consider the limited data set to constitute de-identified information, all direct identifiers are removed from the limited data set and the recipient of the data agrees not to identify or contact the individual. The burden of accounting for these disclosures in these circumstances is not warranted, given that the data may not be used in any way to gain knowledge about a specific individual or to take action in relation to that individual.

*Response to Other Public Comments*

*Comment:* A small number of commenters argued that the development of computer-based solutions to support the statistical method of de-identification is advancing rapidly and can support, in some cases better than the limited data set, many of the needs for research, public health and health care operations. They also asserted that authorization of the limited data set approach will undermine incentives to further develop statistical techniques that will be more protective of privacy than the limited data set. They proposed imposing a sunset clause on the limited data set provision in order to promote use of de-identification tools.

*Response:* We agree that progress is being made in the development of electronic tools to de-identify protected health information. However, the information presented by commenters did not convince us that current techniques meet all the needs identified or are easy enough to use that they can have the broad application needed to support key research, public health and health care operations needs. Where de-identification can provide better outcomes than a limited data set, purveyors of such de-identification tools will have to demonstrate to covered entities the applicability and ease of use of their products. We do not believe a sunset provision on the limited data set authority is appropriate. Rather, as part of its ongoing review of the Privacy Rule in general, and the de-identification provisions in particular, the Office for Civil Rights will periodically assess the need for these provisions.

*Comment:* Some commenters said that if HHS clearly defines direct identifiers and facially identifiable information, there is no need for a data use agreement.

*Response:* We disagree. As previously noted, the resulting limited data set is not de-identified; it still contains individually identifiable health information. As a means to assure continued protection of the information once it leaves the control of the covered entity, we believe a data use agreement is essential.

*Comment:* Several commenters wanted to be able to have a single coordinated data use agreement between a State hospital association and its member hospitals where data collection is coordinated through the hospital association. In addition, there was concern that requiring a data use agreement and a business associate agreement in this circumstance would create an excessive and unnecessary burden.

*Response:* Nothing in the requirement for a data use agreement prevents a State hospital association and its member hospitals from being parties to a common data use agreement. Furthermore, that data use agreement can be combined with a business associate agreement into a single agreement that meets the requirements of both Privacy Rule provisions.

*Comment:* A few commenters argued that a data use agreement should not be required for data users getting a limited data set and performing data analysis as part of the Medicaid rebate validation process under which third-party data vendors, working for pharmaceutical companies, collect prescription claims data from State agencies and analyze the results for errors and discrepancies. They argued that State agencies often find entering into such contracts difficult and time consuming. Consequently, if States have to establish data use or similar agreements, then the Medicaid rebate validation process could be adversely impacted.

*Response:* We are not persuaded that there is a compelling reason to exempt this category of limited data set use from the requirements for a data use agreement, as compared to other important uses. The data use agreement is key to ensuring the integrity of the limited data set process and avoiding inappropriate further uses and disclosures.

*Comment:* One commenter stated that allowing disclosure of the limited data set without IRB or Privacy Board review would create a loophole in the Privacy Rule, with Federally funded research continuing to undergo IRB review while private research would not.

*Response:* The Rule continues to make no distinction between disclosure of protected health information to Federally and privately funded researchers. To obtain a limited data set from a covered entity, both Federally-funded and privately-funded researchers must enter into a data use agreement with the covered entity. One of the reasons for establishing the limited data set provisions is that the concept of ''personally identifiable information'' that triggers IRB review of research that is subject to the Common Rule does not coincide with the definition of ''individually identifiable health information'' in the Privacy Rule. The Department believes that the limited data set comes closer to the type of information not requiring IRB approval under the Common Rule than does the de-identified data set of the Privacy Rule. However, there is no uniform definition of ''personally identifiable information'' under the Common Rule; rather, as a matter of practice, it is currently set by each individual IRB.

*Comment:* A few commenters suggested expanding the allowable purposes for the limited data set. One commenter proposed including payment as an allowable purpose, in order to facilitate comparison of premiums charged to insured versus uninsured patients. A few commenters wanted to allow disclosures to journalists if the individual's name and social security number have been removed and if, in the context of the record or file, the identity of the patient has not been revealed. A few commenters suggested that there was no need to restrict the purpose at all as long

as there is a data use agreement. A couple of commenters wanted to extend the purpose to include creation or maintenance of research databases and repositories.

*Response:* If the comparison of premiums charged to different classes of patients is being performed as a health care operation of another entity, then a limited data set could be used for this purpose. It seems unlikely that this activity would occur in relation to a payment activity, so a change to include payment as a permissible purpose is not warranted. A ''payment'' activity must relate to payment for an individual and, thus, will need direct identifiers, and uses and disclosures of protected health information for such purposes is permitted under § 164.506.

With respect to disclosures to journalists, while recognizing the important role performed by newspapers and other media in reporting on public health issues and the health care system, we disagree that the purposes of the limited data set should be expanded to include journalists. A key element of the limited data set is that the recipient enter into a data use agreement that would limit access to the limited data set, prohibit any attempt to identify or contact any individual, and limit further use or disclosure of the limited data set. These limitations are inherently at odds with journalists' asserted need for access to patient information.

The suggestion to allow disclosure of a limited data set for any purpose if there is a data use agreement would undermine the purpose of the Privacy Rule to protect individually identifiable health information from unauthorized disclosures and would conflict with the requirement in the data use agreement to restrict further use to research, public health, health care operations purposes. The Department clarifies that research encompasses the establishment of research databases and repositories. Therefore, no change to the proposal is necessary.

*Comment:* One commenter said that HHS should not create a list of excluded direct identifiers; rather it should enunciate principles and leave it to researchers to apply the principles.

*Response:* The statistical method of de-identification is based on scientific principles and methods and leaves the application to the researcher and the covered entity. Unfortunately, many have viewed this approach as too complex or imprecise for broad use. To allow broad discretion in selection of variables in the creation of a limited data set would trigger the same concerns as the statistical method, because some measure of reasonableness would have to be established. Commenters have consistently asked for precision so that they would not have to worry as to whether they were in compliance with the requirements of the Privacy Rule. The commenter's proposal runs counter to this desire for precision.

*Comment:* One commenter wanted prescription numbers allowed in a limited data set because they do not include any ''facially identifiable information.''

*Response:* Prescription numbers are medical record numbers in that they are used to track an individual's encounter with a health care provider and are uniquely associated with that individual. The fact that an individual receives a new prescription number for each prescription, even if it is randomly generated, is analogous to an individual receiving a separate medical record number for different hospital visits. Thus, a prescription number is an excluded direct identifier under the medical record number exclusion for the limited data set (and also must be excluded in the creation of de-identified data).

*Comment:* One commenter wanted clarification that a sponsor of a multi-employer group health plan could utilize the limited data set approach for the purpose of resolving claim appeals. That commenter also suggested that if the only information that a plan sponsor received was the limited data set, the group health plan should be able to give that information to the plan sponsor without amending plan documents. In lieu of the limited data set, this commenter wanted clarification that redacted information, as delineated in their comment, is a reasonable way to meet the minimum necessary standard if the plan sponsor has certified that the plan documents have been amended pursuant to the requirements of the Privacy Rule.

*Response:* Uses and disclosures of a limited data set is authorized only for public health, research, and health care operations purposes. A claims appeal is more likely to be a payment function, rather than a health care operation. It is also likely to require use of protected health information that includes direct identifiers. The Department disagrees with the commenter's suggestions that the Rule should allow group health plans to disclose a limited data set to a plan sponsor without amending the plan documents to describe such disclosures. Limited data sets are not de-identified information, and thus warrant this degree of protection. Therefore, only summary health information and the enrollment status of the individual can be disclosed by the group health plan to the plan sponsor without amending the plan documents. The Privacy Rule does not specify what particular data elements constitute the minimum necessary for any particular purpose.

*H. Section 164.520—Notice of Privacy Practices for Protected Health Information*

*December 2000 Privacy Rule.* The Privacy Rule at § 164.520 requires most covered entities to provide individuals with adequate notice of the uses and disclosures of protected health information that may be made by the covered entity, and of the individual's rights and the covered entity's responsibilities with respect to protected health information. The Rule delineates specific requirements for the content of the notice, as well as for provision of the notice. The requirements for providing notice to individuals vary based on type of covered entity and method of service delivery. For example, a covered health care provider that has a direct treatment relationship with an individual must provide the notice no later than the date of first service delivery and, if the provider maintains a physical service delivery site, must post the notice in a clear and prominent location and have it available upon request for individuals to take with them. If the first service delivery to an individual is electronic, the covered provider must furnish electronic notice automatically and contemporaneously in response to the individual's first request for service. In addition, if a covered entity maintains a website, the notice must be available electronically through the web site.

*March 2002 NPRM.* The Department proposed to modify the notice requirements at § 164.520(c)(2) to require that a covered health care provider with a direct treatment relationship make a good faith effort to obtain an individual's written acknowledgment of receipt of the provider's notice of privacy practices. Other covered entities, such as health plans, would not be required to obtain this acknowledgment from individuals, but could do so if they chose.

The Department proposed to strengthen the notice requirements in order to preserve a valuable aspect of the consent process. The notice acknowledgment proposal was intended to create the ''initial moment'' between a covered health care provider and an individual, formerly a result of the consent requirement, when individuals may focus on information practices and privacy rights and discuss with the

provider any concerns related to the privacy of their protected health information. This ''initial moment'' also would provide an opportunity for an individual to make a request for additional restrictions on the use or disclosure of his or her protected health information or for additional confidential treatment of communications, as permitted under § 164.522.

With one exception for emergency treatment situations, the proposal would require that the good faith effort to obtain the written acknowledgment be made no later than the date of first service delivery, including service delivered electronically. To address potential operational difficulties with implementing these notice requirements in emergency treatment situations, the Department proposed in § 164.520(c)(2) to delay the requirement for provision of notice until reasonably practicable after the emergency treatment situation, and exempt health care providers with a direct treatment relationship with the individual from having to make a good faith effort to obtain the acknowledgment altogether in such situations.

Other than requiring that the acknowledgment be in writing, the proposal would not prescribe other details of the form of the acknowledgment or limit the manner in which a covered health care provider could obtain the acknowledgment.

The proposal also provided that, if the individual's acknowledgment of receipt of the notice could not be obtained, the covered health care provider would be required to document its good faith efforts to obtain the acknowledgment and the reason why the acknowledgment was not obtained. Failure by a covered entity to obtain an individual's acknowledgment, assuming it otherwise documented its good faith effort, would not be considered a violation of the Privacy Rule.

*Overview of Public Comments.* The following discussion provides an overview of the public comment received on this proposal. Additional comments received on this issue are discussed below in the section entitled, ''Response to Other Public Comments.''

In general, many commenters expressed support for the proposal to require that certain health care providers, as an alternative to obtaining prior consent, make a good faith effort to obtain a written acknowledgment from the individual of receipt of the notice. Commenters stated that even though the requirement would place some burden on certain health care providers, the proposed policy was a reasonable and workable alternative to the Rule's prior consent requirement. A number of these commenters conveyed support for the proposed flexibility of the requirement that would allow covered entities to implement the requirement in accordance with their own practices. Commenters urged that the Department not prescribe (other than that the acknowledgment be in writing) the form or content of the acknowledgment, or other requirements that would further burden the acknowledgment process. In addition, commenters viewed the proposed exception for emergency treatment situations as a practical policy.

A number of other commenters, while supportive of the Department's proposal to make the obtaining of consent optional for all covered entities, expressed concern over the administrative burden the proposed notice acknowledgment requirements would impose on certain health care providers. Some of these commenters viewed the notice acknowledgment as an unnecessary burden on providers that would not afford individuals with any additional privacy rights or protections. Thus, some commenters urged that the good faith acknowledgment not be adopted in the final Rule. As an alternative, it was suggested by some that covered entities instead be required to make a good faith effort to make the notice available to consumers.

Several commenters expressed concerns that the notice acknowledgment process would reestablish some of the same operational problems associated with the prior consent requirement. For example, commenters questioned how the requirement should be implemented when the provider's first contact with the patient is over the phone, electronically, or otherwise not face-to-face, such as with telemedecine. Accordingly, it was suggested that the good faith acknowledgment of the notice be required no later than the date of first face-to-face encounter with the patient rather than first service delivery to eliminate these perceived problems.

A few others urged that the proposed notice acknowledgment requirement be modified to allow for an individual's oral acknowledgment of the notice, so long as the provider maintained a record that the individual's acknowledgment was obtained.

Some commenters did not support the proposal's written notice acknowledgment as a suitable alternative to the consent requirement, stating that such a requirement would not provide individuals with comparable privacy protections or rights. It was stated that there are a number of fundamental differences between a consent and an acknowledgment of the notice. For example, one commenter argued that asking individuals to acknowledge receipt of the notice does not provide a comparable ''initial moment'' between the provider and the individual, especially when the individual is only asked to acknowledge receipt of the notice, and not whether they have read or understood it, or have questions. Further, commenters argued that the notice acknowledgment process would not be the same as seeking the individual's permission through a consent process. Some of these commenters urged that the Department retain the consent requirements and make appropriate modifications to fix the known operational problems associated with the requirement.

A few commenters urged that the Department strengthen the notice acknowledgment process. Some commenters suggested that the Department do so by eliminating the ''good faith'' aspect of the standard and simply requiring certain health care providers to obtain the written acknowledgment, with appropriate exceptions for emergencies and other situations where it may not be practical to do so. It was also suggested that the Department require providers to ensure that the consumer has an understanding of the information provided in the notice. One commenter suggested that this may be achieved by having individuals not only indicate whether they have received the notice, but also be asked on separate lines after each section of the notice whether they have read that section. Another commenter argued that consumers should be asked to sign something more meaningful than a notice acknowledgment, such as a ''Summary of Consumer Rights,'' which clearly and briefly summarizes the ways in which their information may be used by covered entities, as well as the key rights consumers have under the Privacy Rule.

*Final Modifications.* After consideration of the public comment, the Department adopts in this final Rule at § 164.520(c)(2)(ii), the proposed requirement that a covered health care provider with a direct treatment relationship with an individual make a good faith effort to obtain the individual's written acknowledgment of receipt of the notice. Other covered entities, such as health plans, are not required to obtain this acknowledgment from individuals, but may do so if they choose. The Department agrees with

those commenters who stated that the notice acknowledgment process is a workable alternative to the prior consent process, retaining the beneficial aspects of the consent without impeding timely access to quality health care. The Department continues to believe strongly that promoting individuals' understanding of privacy practices is an essential component of providing notice to individuals. Through this requirement, the Department facilitates achieving this goal by retaining the opportunity for individuals to discuss privacy practices and concerns with their health care providers. Additionally, the requirement provides individuals with an opportunity to request any additional restrictions on uses and disclosures of their health information or confidential communications, as permitted by § 164.522.

As proposed in the NPRM, the final Rule requires, with one exception, that a covered direct treatment provider make a good faith effort to obtain the written acknowledgment no later than the date of first service delivery, including service delivered electronically, that is, at the time the notice is required to be provided. During emergency treatment situations, the final Rule at § 164.520(c)(2)(i)(B) delays the requirement for provision of the notice until reasonably practicable after the emergency situation, and at § 164.520(c)(2)(ii) exempts health care providers from having to make a good faith effort to obtain an individual's acknowledgment in such emergency situations. The Department agrees with commenters that such exceptions are practical and necessary to ensure that the notice and acknowledgment requirements do not impede an individual's timely access to quality health care.

The Department also agrees with commenters that the notice acknowledgment process must be flexible and provide covered entities with discretion in order to be workable. Therefore, the final modification adopts the flexibility proposed in the NPRM for the acknowledgment requirement. The Rule requires only that the acknowledgment be in writing, and does not prescribe other details such as the form that the acknowledgment must take or the process for obtaining the acknowledgment. For example, the final Rule does not require an individual's signature to be on the notice. Instead, a covered health provider is permitted, for example, to have the individual sign a separate sheet or list, or to simply initial a cover sheet of the notice to be retained by the provider. Alternatively, a pharmacist is permitted to have the individual sign or initial an acknowledgment within the log book that patients already sign when they pick up prescriptions, so long as the individual is clearly informed on the log book of what they are acknowledging and the acknowledgment is not also used as a waiver or permission for something else (such as a waiver to consult with the pharmacist). For notice that is delivered electronically as part of first service delivery, the Department believes the provider's system should be capable of capturing the individual's acknowledgment of receipt electronically. In addition, those covered health care providers that choose to obtain consent from an individual may design one form that includes both a consent and the acknowledgment of receipt of the notice. Covered health care providers are provided discretion to design the acknowledgment process best suited to their practices.

While the Department believes that the notice acknowledgment process must remain flexible, the Department does not consider oral acknowledgment by the individual to be either a meaningful or appropriate manner by which a covered health care provider may implement these provisions. The notice acknowledgment process is intended to provide a formal opportunity for the individual to engage in a discussion with a health care provider about privacy. At the very least, the process is intended to draw the individual's attention to the importance of the notice. The Department believes these goals are better accomplished by requiring a written acknowledgment and, therefore, adopts such provision in this final modification.

Under the final modification, if an individual refuses to sign or otherwise fails to provide an acknowledgment, a covered health care provider is required to document its good faith efforts to obtain the acknowledgment and the reason why the acknowledgment was not obtained. Failure by a covered entity to obtain an individual's acknowledgment, assuming it otherwise documented its good faith effort, is not a violation of this Rule. Such reason for failure simply may be, for example, that the individual refused to sign the acknowledgment after being requested to do so. This provision also is intended to allow covered health care providers flexibility to deal with a variety of circumstances in which obtaining an acknowledgment is problematic. In response to commenters requests for examples of good faith efforts, the Department intends to provide future guidance on this and other modifications.

A covered entity is required by § 164.530(j) to document compliance with these provisions by retaining copies of any written acknowledgments of receipt of the notice or, if not obtained, documentation of its good faith efforts to obtain such written acknowledgment.

The Department was not persuaded by those commenters who urged that the Department eliminate the proposed notice acknowledgment requirements because of concerns about burden. The Department believes that the final modification is simple and flexible enough so as not to impose a significant burden on covered health care providers. Covered entities are provided much discretion to design the notice acknowledgment process that works best for their business. Further, as described above, the Department believes that the notice acknowledgment requirements are important in that they retain the important aspects of the prior consent process that otherwise would be lost in the final modifications.

In response to commenters' operational concerns about the proposed notice acknowledgment requirements, the Department clarifies that the modification as proposed and now adopted as final is intended to be flexible enough to address the various types of relationships that covered health care providers may have with the individuals to whom they provide treatment, including those treatment situations that are not face-to-face. For example, a health care provider whose first treatment encounter with a patient is over the phone satisfies the notice provision requirements of the Rule by mailing the notice to the individual no later than the day of that service delivery. To satisfy the requirement that the provider also make a good faith effort to obtain the individual's acknowledgment of the notice, the provider may include a tear-off sheet or other document with the notice that requests such acknowledgment be mailed back to the provider. The Department would not consider the health care provider in violation of the Rule if the individual chooses not to mail back an acknowledgment. The Department clarifies, however, that where a health care provider's initial contact with the patient is simply to schedule an appointment, the notice provision and acknowledgment requirements may be satisfied at the time the individual arrives at the provider's facility for his or her

appointment. For service provided electronically, the Department believes that, just as a notice may be delivered electronically, a provider should be capable of capturing the individual's acknowledgment of receipt electronically in response to that transmission.

Finally, the Department does not agree with those commenters who argued that the proposed notice acknowledgment requirements are not an adequate alternative to the prior consent requirements, nor with those who argued that the proposed acknowledgment process should be strengthened if an individual's consent is no longer required. The Department believes that the notice acknowledgment process retains the important aspects of the consent process, such as creating an opportunity for a discussion between the individual and the provider of privacy issues, including the opportunity for the individual to request restrictions on how her information may be used and disclosed as permitted by § 164.522.

Additionally, the Department believes that requiring certain health care providers to obtain the individual's acknowledgment of receipt of the notice, rather than make a good faith effort to do so, would remove the flexibility of the standard and increase the burden substantially on covered entities. Such a modification, therefore, would have the potential to cause workability and operational problems similar to those caused by the prior consent requirements. Prescribing the form or content of the acknowledgment could have the same effect. The Department believes that the notice acknowledgment process must not negatively impact timely access to quality health care.

Also, the Department agrees that it will not be easy for every individual to understand fully the information in the notice, and acknowledges that the onus of ensuring that individuals have an understanding of the notice should not be placed solely on health care providers. The Rule ensures that individuals are provided with a notice in plain language but leaves it to each individual's discretion to review the notice and to initiate a discussion with the covered entity about the use and disclosure of his or her health information or the individual's rights. However, the Department continues to believe strongly that promoting individuals' understanding of privacy practices is an essential component of providing notice to individuals. The Department anticipates that many stakeholders, including the Department, covered entities, consumer organizations, health educators, the mass media and journalists, and a host of other organizations and individuals, will be involved in educating individuals about privacy notices and practices.

*Response to Other Public Comments*

*Comment:* Several commenters requested clarification as to whether a health care provider is required to obtain from individuals a new acknowledgment of receipt of the notice if the facility changes its privacy policy.

*Response:* The Department clarifies that this is not required. To minimize burden on the covered direct treatment provider, the final modification intends the obtaining of the individual's acknowledgment to be consistent with the timing for provision of the notice to the individual, that is, no later than the date of first service delivery. Upon revision of the notice, the Privacy Rule requires only that the direct treatment provider make the notice available upon request on or after the effective date of the revision, and, if he maintains a physical service delivery site, to post the revised notice in a clear and prominent location in his facility. *See* § 164.520(c)(2)(iii). As the Rule does not require a health care provider to provide the revised notice directly to the individual, unless requested by the individual, a new written acknowledgment is not required at the time of revision of the notice.

*Comment:* A few commenters requested clarification as to how the Department intended the notice acknowledgment process to be implemented within an affiliated covered entity or an organized health care arrangement (OHCA).

*Response:* The requirement for an individual's written acknowledgment of the notice corresponds with the requirement that the notice be provided to the individual by certain health care providers at first service delivery, regardless of whether the notice itself is the joint notice of an OHCA, the notice of an affiliated covered entity, or the notice of one entity. With respect to an OHCA, the Privacy Rule permits covered entities that participate in an OHCA to satisfy the notice requirements through the use of a joint notice, provided that the relevant conditions of § 164.520(d) are met. Section 164.520(d)(3) further provides that provision of a joint notice to an individual by any one of the covered entities included in the joint notice satisfies the notice provision requirements at § 164.520(c) with respect to all others covered by the joint notice. Thus, a health care provider with a direct treatment relationship with an individual that is participating in an OHCA only need make a good faith effort to obtain the individual's acknowledgment of the joint notice if that provider is the covered entity within the OHCA that is providing the joint notice to the individual. Where the joint notice is provided to the individual by a participating covered entity other than a provider with a direct treatment relationship with the individual, no acknowledgment need be obtained. However, covered entities that participate in an OHCA are not required to utilize a joint notice and may maintain separate notices. In such case, each covered health care provider with a direct treatment relationship within the OHCA must make a good faith effort to obtain the individual's acknowledgment of the notice he or she provides.

Similarly, an affiliated covered entity may have one single notice that covers all of its affiliates. Thus, if the affiliated covered entity's notice is provided to the individual by a health care provider with which the individual has a direct treatment relationship, the health care provider must make a good faith effort to obtain the individual's acknowledgment of receipt of the notice. Alternatively, where the affiliated entity's notice is provided to the individual by a participating entity other than a provider with a direct treatment relationship with the individual, no acknowledgment need be obtained. However, as with the OHCA, the Department clarifies that covered entities that are part of an affiliated covered entity may maintain separate notices if they choose to do so; if they do so, each provider with a direct treatment relationship with the individual must make a good faith effort to obtain the individual's acknowledgment of the notice he or she provides.

*Comment:* It was suggested that if a provider chooses to obtain consent, the provider should not also be required to obtain the individual's acknowledgment of the notice.

*Response:* For those covered entities that choose to obtain consent, the Rule does not prescribe any details of the form or manner in which the consent must be obtained. Given this discretion, the Department does not believe that all consents will provide the same benefits to the individual as those afforded by the notice acknowledgment process. The Rule, therefore, does not relieve a covered health care provider of his obligations with respect to obtaining an individual's acknowledgment of the

notice if that provider also obtains the individual's consent. However, the Rule provides those covered health care providers that choose to obtain consent from an individual the discretion to design one form that includes both a consent and the acknowledgment of receipt of the notice.

*Comment:* Some commenters asked that the Privacy Rule allow the written acknowledgment of the notice to be obtained electronically without regard to channel of delivery (electronically or on paper) of the notice.

*Response:* Generally, the Privacy Rule allows for electronic documents to qualify as written documents for purposes of meeting the Rule's requirements. This also applies with respect to the notice acknowledgment. For notice delivered electronically, the Department intends a return receipt or other transmission from the individual to suffice as the notice acknowledgment.

For notice delivered on paper in a face-to-face encounter with the provider, although it is unclear to the Department how exactly the provider may do so, the Rule does not preclude providers from obtaining the individual's written acknowledgment electronically. The Department cautions, however, that the notice acknowledgment process is intended to alert individuals to the importance of the notice and provide them the opportunity to discuss privacy issues with their providers. To ensure that individuals are aware of the importance of the notice, the Rule requires that the individual's acknowledgment be in writing. Thus, the Department would not consider a receptionist's notation in a computer system to be an individual's written acknowledgment.

*Comment:* One commenter expressed concern that the Rule did not define ''emergency'' as it applies to ambulance services given the Rule's exceptions to the notice requirements for such situations. This commenter also urged that the Rule's notice provisions at § 164.520(c)(2) with respect to emergency treatment situations be expanded also to apply to non-emergency trips of ambulance providers. The commenter explained that even in non-emergency circumstances, patients, especially the elderly, often suffer from incapacitating or stressful conditions when they need to be transferred by ambulance, at which time it may not be effective or appropriate to provide the notice and obtain the individual's acknowledgment of receipt of the notice.

*Response:* During emergency treatment situations, the final Rule at § 164.520(c)(2)(i)(B) delays the requirement for provision of the notice until reasonably practicable after the emergency situation, and exempts health care providers from having to make a good faith effort to obtain an individual's acknowledgment. As the provisions are not intended to apply only to ambulance providers, the Department does not believe that defining emergency with respect to such providers is appropriate or necessary. Nor does the Department believe that expanding these provisions to cover non-emergency trips of ambulance providers is appropriate. The provisions are intended to provide exceptions for those situations where providing the notice and obtaining an individual's acknowledgment may not be feasible or practicable. Where such extenuating circumstances do not exist, the Department expects that covered health care providers are able to provide individuals with a notice and make a good faith effort to obtain their acknowledgment of receipt. Where an individual does not provide an acknowledgment, the Rule requires only that the provider document his good faith effort to obtain the acknowledgment.

*Comment:* A number of commenters requested clarification on how to implement the ''good faith'' standard and urged the Department to provide more specific guidance and examples. Some commenters expressed concern over the perceived liability that would arise from such a discretionary standard.

*Response:* Covered entities are provided much discretion to implement the notice acknowledgment process as best suited to their specific business practices. The standard is designed as a ''good faith effort'' standard because the Department understands that obtaining an individual's acknowledgment of the notice may not always be feasible or practical, in spite of a covered entity's efforts. Thus, the standard is intended to account for those difficult situations, including where an individual simply refuses to provide the written acknowledgment. Given the discretion covered health care providers have in implementing these standards and the various ways such providers interact with their patients, it is difficult for the Department to provide specific guidance in this area that is generally applicable to many covered health care providers. However, the Department intends to provide future guidance through frequently asked questions or other materials in response to specific scenarios that are raised by industry.

With respect to commenters' concerns regarding potential liability, the Department's position is that a failure by a covered entity to obtain an individual's acknowledgment, assuming it otherwise documented its good faith effort (as required by § 164.520(c)(2)(ii)), will not be considered a violation of this Rule.

*Comment:* Many commenters generally urged that the Department modify the Rule to allow for a simpler, shorter, and, therefore, more readable notice. Some of the commenters explained that a shorter notice would assure that more individuals would take the time to read and be able to understand the information. Others suggested that a shorter notice would help to alleviate burden on the covered entity. A number of these commenters suggested that the Department allow for a shorter summary or 1-page notice to replace the prescriptive notice required by the Privacy Rule. It was recommended that such a notice could refer individuals to a more detailed notice, available on request, or to an HHS web site, for additional information about an individual's rights under the Privacy Rule. Others recommended that the Department allow for a layered notice that contains: (1) A short notice that briefly describes, for example, the entity's principal uses and disclosures of an individual's health information, as well as the individual's rights with respect to that information; and (2) a longer notice, layered beneath the short notice, that contains all the elements required by the Rule.

Certain other commenters urged that one way to make the notice shorter, as well as to alleviate burden on the covered entity, would be to eliminate the requirement that the notice explain the more stringent State privacy laws. Commenters stated that companies that operate in multiple States will have to develop and print up to 50 different notices, and then update and reissue those notices whenever a material change is made to the State law. These commenters recommended instead that the notice simply state that State law may provide additional protections.

A few commenters urged that the Department provide a model notice that covered entities could use in their implementation efforts.

*Response:* The Department does not modify the notice content provisions at § 164.520(b). The Department believes that the elements required by § 164.520(b) are important to fully inform the individual of the covered entity's privacy practices, as well as his or her rights. However, the Department agrees that such information must be provided in a clear, concise, and easy to

understand manner. Therefore, the Department clarifies that covered entities may utilize a ''layered notice'' to implement the Rule's provisions, so long as the elements required by § 164.520(b) are included in the document that is provided to the individual. For example, a covered entity may satisfy the notice provisions by providing the individual with both a short notice that briefly summarizes the individual's rights, as well as other information; and a longer notice, layered beneath the short notice, that contains all the elements required by the Privacy Rule. Covered entities, however, while encouraged to use a layered notice, are not required to do so. Nothing in the final modifications relieve a covered entity of its duty to provide the entire notice in plain language so the average reader can understand it. *See* § 164.520(b)(1).

In response to comments regarding a model notice, it would be difficult for the Department to develop a document that would be generally useful to many different types of covered entities. A covered entity's notice must reflect in sufficient detail the particular uses and disclosures that entity may make. Such uses and disclosures likely will be very different for each type of covered entity. Thus, a uniform, model notice could not capture the wide variation in information practices across covered entities. The Department intends, however, to issue further general guidance to help covered entities implement the notice provisions of the Rule.

*Comment:* A number of commenters also requested that the Department lessen the burden associated with distributing the notice. For example, some commenters asked that covered entities be permitted to satisfy the notice provision requirements by posting the notice at the facility or on a web site and by providing a copy only to those consumers who request one, or by placing copies on display where an interested consumer may take one.

*Response:* The Department's position that making the notice available to individuals, either on request, by posting it at a facility or on a web site, or by placing copies on display, does not substitute for physically providing the notice directly to individuals. Adequate notice of privacy practices is a fundamental right afforded individuals by the Rule. As such, the Department does not believe that the burden of obtaining such information should be placed on the individual. Covered entities are required to distribute the notice in the manner described under § 164.520(c).

*Comment:* A few commenters requested that the Department make clear that no special mailings are required to provide individuals with a covered entity's notice; rather, that the notice may be distributed as part of other mailings or distributions by the covered entity. For example, one commenter argued that the Rule should be flexible enough to allow for notices to be included in a health plan's Summary Plan Descriptions, Booklets, or an Enrollment Application. It was argued that the notice would receive greater attention, be more carefully reviewed and, thus, better understood if it were published in materials known to be widely read by members.

*Response:* The Department clarifies that no special or separate mailings are required to satisfy the notice distribution requirements. The Privacy Rule provides covered entities with discretion in this area. A health plan distributing its notice through the mail, in accordance with § 164.520(c)(1), may do so as part of another mailing to the individual. In addition, a covered entity that provides its notice to an individual by e-mail, in accordance with § 164.520(c)(3), may include additional materials in the e-mail. No separate e-mail is required. However, the Privacy Rule at § 164.508(b)(3) continues to prohibit a covered entity from combining the notice in a single document with an authorization.

*Comment:* Commenters also urged that the Rule permit, for group products, a health plan to send its notice to the administrator of the group product or the plan sponsor, who would then be responsible for distributing the notice to each enrollee/employee. One commenter claimed this distribution method is especially appropriate where there is no regular communication with the covered individuals, as in an employer-pay-all group medical or dental plan. According to the commenter, providing the notice to the employer makes sense because the employer picks the plan and should be aware of the plan's privacy practices when doing so.

*Response:* The Privacy Rule requires a health plan to distribute its notice to each individual covered by the plan. Health plans may arrange to have another entity, or person, for example, a group administrator or a plan sponsor, distribute the notice on their behalf. However, the Department cautions that if such other entity or person fails to distribute the notice to individuals, the health plan would be in violation of the Rule.

*Comment:* Another commenter asked that the Department eliminate the requirement that a covered entity must provide the notice to every dependent, rather than just the head of the household. This commenter argued that while it makes sense to provide the notice to an emancipated minor or to a minor who pursuant to State law has consented to treatment, it does not make sense to send the notice to a 2-year old child.

*Response:* The Privacy Rule provides that a health plan may satisfy the notice provision requirements by distributing the notice to the named insured of a policy under which coverage is provided to the named insured and one or more dependents. A health plan is not required to distribute the notice to each dependent. *See* § 164.520(c)(1)(iii).

Further, a covered health care provider with a direct treatment relationship with the individual is required only to provide the notice to the individual receiving treatment at first service delivery. Where a parent brings a 2-year old child in for treatment, the provider satisfies the notice distribution requirements by providing the notice only to the child's parent.

*I. Section 164.528—Accounting of Disclosures of Protected Health Information*

*December 2000 Privacy Rule.* Under the Privacy Rule at § 164.528, individuals have the right to receive an accounting of disclosures of protected health information made by the covered entity, with certain exceptions. These exceptions, or instances where a covered entity is not required to account for disclosures, include disclosures made by the covered entity to carry out treatment, payment, or health care operations, as well as disclosures to individuals of protected health information about them. The individual must request an accounting of disclosures.

The accounting is required to include the following: (1) Disclosures of protected health information that occurred during the six years prior to the date of the request for an accounting; and (2) for each disclosure: the date of the disclosure; the name of the entity or person who received the protected health information, and, if known, the address of such entity or person; a brief description of the protected health information disclosed; and a brief statement of the purpose of the disclosure that reasonably informs the individual of the basis for the disclosure, or in lieu of such a statement, a copy of the individual's written authorization pursuant to § 164.508 or a copy of a written request

for a disclosure under §§ 164.502(a)(2)(ii) or 164.512. For multiple disclosures of protected health information to the same person, the Privacy Rule allows covered entities to provide individuals with an accounting that contains only the following information: (1) For the first disclosure, a full accounting, with the elements described above; (2) the frequency, periodicity, or number of disclosures made during the accounting period; and (3) the date of the last such disclosure made during the accounting period.

*March 2002 NPRM.* In response to concerns about the high costs and administrative burdens associated with the requirement to account to individuals for the covered entity's disclosure of protected health information, the Department proposed to expand the exceptions to the standard at § 164.528(a)(1) to include disclosures made pursuant to an authorization as provided in § 164.508. Covered entities would no longer be required to account for any disclosures authorized by the individual in accordance with § 164.508. The Department proposed to alleviate burden in this way because, like disclosures of protected health information made directly to the individual—which are already excluded from the accounting provisions in § 164.528(a)(1)—disclosures made pursuant to an authorization are also known by the individual, in as much as the individual was required to sign the forms authorizing the disclosures.

In addition to the exception language at § 164.528(a)(1), the Department proposed two conforming amendments at §§ 164.528(b)(2)(iv) and (b)(3) to delete references in the accounting content requirements to disclosures made pursuant to an authorization.

*Overview of Public Comments.* The following discussion provides an overview of the public comment received on this proposal. Additional comments received on this issue are discussed below in the section entitled, ''Response to Other Public Comments.''

The majority of comments on the accounting proposal supported the elimination of the accounting for authorized disclosures. The commenters agreed that, on balance, since the individual had elected to authorize the disclosure in the first instance, and that election was fully informed and voluntary, subsequently accounting for the disclosure made pursuant to that authorization was not necessary.

Many of the commenters went on to suggest other ways in which the accounting requirement could be made less burdensome. For example, several commenters wanted some or all of the disclosures which are permitted at § 164.512 without individual consent or authorization to also be exempt from the accounting requirements. Others proposed alternative means of accounting for disclosures for research, particularly when such disclosures involve large numbers of records. These commenters argued that accounting for each individual record disclosed for a large research project would be burdensome and may deter covered entities from participating in such research. Rather than an individual accounting, the commenters suggested that the covered entity be required only to disclose a listing of all relevant protocols under which an individual's information may have been released during the accounting period, the timeframes during which disclosures were made under a protocol, and the name of the institution and researcher or investigator responsible for the protocol, together with contact information for the researcher. The National Committee on Vital Health Statistics, while not endorsing a protocol listing directly, recommended the Department consider alternatives to minimize the burden of the accounting requirements on research.

Finally, several commenters objected to the elimination of the accounting requirement for authorized disclosures. Some of these commenters expressed concern that the proposal would eliminate the requirement to account for the authorized disclosure of psychotherapy notes. Others were primarily concerned that the proposal would weaken the accounting rights of individuals. According to these commenters, informing the individual of disclosures was only part of the purpose of an accounting. Even with regard to authorized disclosures, an accounting could be important to verify that disclosures were in accord with the scope and purpose as stated in the authorization and to detect potentially fraudulent, altered, or otherwise improperly accepted authorizations. Since authorizations had to be maintained in any event, accounting for these disclosures represented minimal work for the covered entity.

*Final Modifications.* Based on the general support in the public comment, the Department adopts the modification to eliminate the accounting requirement for authorized disclosures. The authorization process itself adequately protects individual privacy by assuring that the individual's permission is given both knowingly and voluntarily. The Department agrees with the majority of commenters that felt accounting for authorized disclosures did not serve to add to the individual's knowledge about disclosures of protected health information. The Department does recognize the role of accounting requirements in the detection of altered or fraudulent authorizations. However, the Department considers the incidence of these types of abuses, and the likelihood of their detection through a request for an accounting, to be too remote to warrant the burden on all covered entities of including authorized disclosures in an accounting. As noted by some commenters, the covered entity must retain a copy of the authorization to document their disclosure of protected health information and that documentation would be available to help resolve an individual's complaint to either the covered entity or the Secretary.

Specific concern about the elimination of the accounting requirement for authorized disclosures was expressed by mental health professionals, who believed their patients should always have the right to monitor access to their personal information. The Department appreciates theses commenters' concern about the need for heightened protections and accountability with regard to psychotherapy notes. It is because of these concerns that the Rule requires, with limited exceptions, individual authorization for even routine uses and disclosures of psychotherapy notes by anyone other than the originator of the notes. The Department clarifies that nothing in modifications adopted in this rulemaking prevents a mental health professional from including authorized disclosures of psychotherapy notes in an accounting requested by their patients. Indeed, any covered entity may account to the individual for disclosures based on the individual's authorization. The modification adopted by the Department simply no longer requires such an accounting.

In response to comment on this proposal, as well as on the proposals to permit incidental disclosures and disclosures of protected health information, other than direct identifiers, as part of a limited data set, the Department has added two additional exclusions to the accounting requirements. Disclosures that are part of a limited data set and disclosures that are merely incidental to another permissible use or disclosure will not require an accounting. The limited data set does not contain any protected health information that directly identifies the individual and the individual is further protected from identification by the required data use

agreement. The Department believes that accounting for these disclosures would be too burdensome. Similarly, the Department believes that it is impracticable to account for incidental disclosures, which by their very nature, may be uncertain or unknown to the covered entity at the time they occur. Incidental disclosures are permitted as long as reasonable safeguards and minimum necessary standards have been observed for the underlying communication. Moreover, incidental disclosures may most often happen in the context of a communication that relates to treatment or health care operations. In that case, the underlying disclosure is not subject to an accounting and it would be arbitrary to require an accounting for a disclosure that was merely incidental to such a communication.

The Department however disagrees with commenters who requested that other public purpose disclosures not be subject to the accounting requirement. Although the Rule permits disclosure for a variety of public purposes, they are not routine disclosures of the individual's information. The accounting requirement was designed as a means for the individual to find out the non-routine purposes for which his or her protected health information was disclosed by the covered entity, so as to increase the individual's awareness of persons or entities other than the individual's health care provider or health plan in possession of this information. To eliminate some or all of these public purposes would defeat the core purpose of the accounting requirement.

The Department disagrees with commenters' proposal to exempt all research disclosures made pursuant to a waiver of authorization from the accounting requirement. Individuals have a right to know what information about them has been disclosed without their authorization, and for what purpose(s). However, the Department agrees that the Rule's accounting requirements could have the undesired effect of causing covered entities to halt disclosures of protected health information for research. Therefore, the Department adopts commenters' proposal to revise the accounting requirement at § 164.528 to permit covered entities to meet the requirement for research disclosures if they provide individuals with a list of all protocols for which the patient's protected health information may have been disclosed for research pursuant to a waiver of authorization under § 164.512(i), as well as the researcher's name and contact information. The Department agrees with commenters that this option struck the appropriate balance between affirming individuals' right to know how information about them is disclosed, and ensuring that important research is not halted.

The Department considered and rejected a similar proposal by commenters when it adopted the Privacy Rule in December 2000. While recognizing the potential burden for research, the Department determined that the individual was entitled to the same level of specificity in an accounting for research disclosures as any other disclosure. At that time, however, the Department added the summary accounting procedures at § 164.528(b)(3) to address the burden issues of researchers and others in accounting for multiple disclosures to the same entity. In response to the Department's most recent request for comments, researchers and others explained that the summary accounting procedures do not address the burden of having to account for disclosures for research permitted by § 164.512(i). These research projects usually involve many records. It is the volume of records for each disclosure, not the repeated nature of the disclosures, that presents an administrative obstacle for research if each record must be individually tracked for the accounting. Similarly, the summary accounting procedures do not relieve the burden for covered entities that participate in many different studies on a routine basis. The Department, therefore, reconsidered the proposal to account for large research projects by providing a list of protocols in light of these comments.

Specifically, the Department adds a paragraph (4) to § 164.528(b) to provide for simplified accounting for research disclosures as follows:

(1) The research disclosure must be pursuant to § 164.512(i) and involve at least 50 records. Thus, the simplified accounting procedures may be used for research disclosures based on an IRB or Privacy Board waiver of individual authorization, the provision of access to the researcher to protected health information for purposes preparatory to research, or for research using only records of deceased individuals. The large number of records likely to be disclosed for these research purposes justifies the need for the simplified accounting procedures. The Department has determined that a research request for 50 or more records warrants use of these special procedures.

(2) For research protocols for which the individual's protected health information may have been disclosed during the accounting period, the accounting must include the name of the study or protocol, a description of the purpose of the study and the type of protected health information sought, and the timeframe of disclosures in response to the request.

(3) When requested by the individual, the covered entity must provide assistance in contacting those researchers to whom it is likely that the individual's protected health information was actually disclosed.

Support for streamlining accounting for research disclosures came in comments and from NCVHS. The Department wants to encourage research and believes protections afforded information in hands of researcher, particularly research overseen by IRB or Privacy Board, provides assurance of continued confidentiality of information. The Department does not agree that the individual has no need to know that his or her information has been disclosed for a research purpose. Covered entities, of course, may account for research disclosures in the same manner as all other disclosures. Even when the covered entity elects to use the alternative of a protocol listing, the Department encourages covered entities to provide individuals with disclosure of the specific research study or protocol for which their protected health information was disclosed, and other specific information relating to such actual disclosures if they so choose. If the covered entity lists all protocols for which the individual's information may have been disclosed, the Department would further encourage that the covered entity list under separate headings, or on separate lists, all protocols relating to particular health issues or conditions, so that individuals may more readily identify the specific studies for which their protected health information is more likely to have been disclosed.

The Department intends to monitor the simplified accounting procedures for certain research disclosures to determine if they are effective in providing meaningful information to individuals about how their protected health information is disclosed for research purposes, while still reducing the administrative burden on covered entities participating in such research efforts. The Department may make adjustments to the accounting procedures for research in the future as necessary to ensure both goals are fully met.

*Response to Other Public Comments*

*Comment:* A few commenters opposed the proposal to eliminate the accounting requirement for all

authorized disclosures arguing that, absent a full accounting, the individual cannot meaningfully exercise the right to amend or to revoke the authorization. Others also felt that a comprehensive right to an accounting, with no exceptions, was better from an oversight and enforcement standpoint as it encouraged consistent documentation of disclosures. One commenter also pointed to an example of the potential for fraudulent authorizations by citing press accounts of a chain drug store that allegedly took customers signatures from a log that waived their right to consult with the pharmacist and attached those signatures to a form authorizing the receipt of marketing materials. Under the proposal, the commenter asserted, the chain drug store would not have to include such fraudulent authorizations as part of an accounting to the individual.

*Response:* The Department does not agree that the individual's right to amendment is materially affected by the accounting requirements for authorized disclosures. The covered entity that created the protected health information contained in a designated record set has the primary obligation to the individual to amend any erroneous or incomplete information. The individual does not necessarily have a right to amend information that is maintained by other entities that the individual has authorized to have his or her protected health information. Furthermore, the covered entity that has amended its own designated record set at the request of the individual is obligated to make reasonable efforts to notify other persons, including business associates, that are known to have the protected health information that was the subject of the amendment and that may rely on such information to the detriment of the individual. This obligation would arise with regard to persons to whom protected health information was disclosed with the individual's authorization. Therefore, the individual's amendment rights are not adversely affected by the modifications to the accounting requirements. Furthermore, nothing in the modification adversely affects the individual's right to revoke the authorization.

The Department agrees that oversight is facilitated by consistent documentation of disclosures. However, the Department must balance its oversight functions with the burden on entities to track all disclosures regardless of purpose. Based on this balancing, the Department has exempted routine disclosures, such as those for treatment, payment, and health care operations, and others for security reasons. The addition of authorized disclosures to the exemption from the accounting does not materially affect the Department's oversight function. Compliance with the Rule's authorization requirements can still be effectively monitored because covered entities are required to maintain signed authorizations as documentation of disclosures. Therefore, the Department believes that effective oversight, not the happenstance of discovery by an individual through the accounting requirement, is the best means to detect and prevent serious misdeeds such as those alleged in fraudulent authorizations.

*Comment:* A number of commenters recommended other types of disclosures for exemption from the accounting requirement. Many recommended elimination of the accounting requirement for public health disclosures arguing that the burden of the requirement may deter entities from making such disclosures and that because many are made directly to public health authorities by doctors and nurses, rather than from a central records component of the entity, public health disclosures are particularly difficult to track and document. Others suggested exempting from an accounting requirement any disclosure required by another law on the grounds that neither the individual nor the entity has any choice about such required disclosures. Still others wanted all disclosures to a governmental entity exempted as many such disclosures are required and often reports are routine or require lots of data. Some wanted disclosures to law enforcement or to insurers for claims investigations exempted from the accounting requirement to prevent interference with such investigatory efforts. Finally, a few commenters suggested that all of the disclosures permitted or required by the Privacy Rule should be excluded from the accounting requirement.

*Response:* Elimination of an accounting requirement for authorized disclosures is justified in large part by the individual's knowledge of and voluntary agreement to such disclosures. None of the above suggestions for exemption of other permitted disclosures can be similarly justified. The right to an accounting of disclosures serves an important function in informing the individual as to which information was sent to which recipients. While it is possible that informing individuals about the disclosures of their health information may on occasion discourage some worthwhile activity, the Department believes that the individual's right to know who is using their information and for what purposes takes precedence.

*Comment:* One commenter sought an exemption from the accounting requirement for disclosures to adult protective services when referrals are made for abuse, neglect, or domestic violence victims. For the same reasons that the Rule permits waiver of notification to the victim at the time of the referral based on considerations of the victim's safety, the regulation should not make such disclosures known after the fact through the accounting requirement.

*Response:* The Department appreciates the concerns expressed by the commenter for the safety and welfare of the victims of abuse, neglect, or domestic violence. In recognition of these concerns, the Department does give the covered entity discretion in notifying the victim and/or the individual's personal representative at the time of the disclosure. These concerns become more attenuated in the context of an accounting for disclosures, which must be requested by the individual and for which the covered entity has a longer timeframe to respond. Concern for the safety of victims of abuse or domestic violence should not result in stripping these individuals of the rights granted to others. If the individual is requesting the accounting, even after being warned of the potential dangers, the covered entity should honor that request. However, if the request is by the individual's personal representative and the covered entity has a reasonable belief that such person is the abuser or that providing the accounting to such person could endanger the individual, the covered entity continues to have the discretion in § 164.502(g)(5) to decline such a request.

*Comment:* One commenter suggested elimination of the accounting requirement in its entirety. The commenter argued that HIPAA does not require an accounting as the individual's right and the accounting does not provide any additional privacy protections to the individual's information.

*Response:* The Department disagrees with the commenter. HIPAA authorized the Secretary to identify rights of the individual with respect to protected health information and how those rights should be exercised. In absence of regulation, HIPAA also authorized the Secretary to effectuate these rights by regulation. As stated in the preamble to the December 2000 Privacy Rule, the standard adopted by the Secretary that provides individuals with a right to an

accounting of disclosures, is consistent with well-established privacy principles in other law and with industry standards and ethical guidelines, such as the Federal Privacy Act (5 U.S.C. 552a), the July 1977 Report of the Privacy Protection Study Commission, and NAIC Health Information Privacy Model Act. (*See* 65 FR 82739.)

*Comment:* A few commenters requested that the accounting period be shortened from six years to two years or three years.

*Response:* The Department selected six years as the time period for an accounting to be consistent with documentation retention requirements in the Rule. We note that the Rule exempts from the accounting disclosures made prior to the compliance date for Rule, or April 14, 2003. Therefore, it will not be until April 2009 that a full six year accounting period will occur. Also, the Rule permits individuals to request and the covered entity to provide for an accounting for less than full six year period. For example, an individual may be interested only in disclosures that occurred in the prior year or in a particular month. The Department will monitor the use of the accounting requirements after the compliance date and will evaluate the need for changes in the future if the six year period for the accounting proves to be unduly burdensome.

*Comment:* Commenters requested clarification of the need to account for disclosures to business associates, noting that while the regulation states that disclosures to and by a business associate are subject to an accounting, most such disclosures are for health care operations for which no accounting is required.

*Response:* The Department clarifies that the implementation specification in § 164.528(b)(1), that expressly includes in the content of an accounting disclosures to or by a business associate, must be read in conjunction with the basic standard for an accounting for disclosures in § 164.528(a). Indeed, the implementation specification expressly references the standard. Read together, the Rule does not require an accounting of any disclosure to or by a business associate that is for any exempt purpose, including disclosures for treatment, payment, and health care operations.

*Comment:* One commenter wanted health care providers to be able to charge reasonable fees to cover the retrieval and preparation costs of an accounting for disclosures.

*Response:* In granting individuals the right to an accounting, the Department had to balance the individual's right to know how and to whom protected health information is being disclosed and the financial and administrative burden on covered entities in responding to such requests. The balance struck by the Department with regard to cost was to grant the individual a right to an accounting once a year without charge. The covered entity may impose reasonable, cost-based fees for any subsequent requests during the one year period. The Department clarifies that the covered entity may recoup its reasonable retrieval and report preparation costs, as well as any mailing costs, incurred in responding to subsequent requests. The Rule requires that individuals be notified in advance of these fees and provided an opportunity to withdraw or amend its request for a subsequent accounting to avoid incurring excessive fees.

*Comment:* One commenter wanted clarification of the covered entity's responsibility to account for the disclosures of others. For example, the commenter wanted to know if the covered entity was responsible only for its own disclosures or did it also need to account for disclosures by every person that may subsequently handle the information.

*Response:* The Department clarifies in response to this comment that a covered entity is responsible to account to the individual for certain disclosures that it makes and for disclosures by its business associates. The covered entity is not responsible to account to the individual for any subsequent disclosures of the information by others that receive the information from the covered entity or its business associate.

*J. Section 164.532—Transition Provisions*

1. Research Transition

*December 2000 Privacy Rule.* The December 2000 Privacy Rule at § 164.532 contained different transition requirements for research being conducted with an individual's legal permission that included treatment, and for research being conducted with an individual's legal permission that did not include treatment. However, the Rule did not explicitly address transition provisions for research studies ongoing after the compliance date where the legal permission of the individual had not been sought.

*March 2002 NPRM.* Several commenters found the transition provisions for research to be confusing, and further noted that December 2000 Privacy Rule did not address research ongoing after the compliance date where the legal permission of the individual had not been sought. To address these concerns, the Department proposed several revisions to the Privacy Rule's transition provisions. In particular, the Department proposed that there be no distinction in the transition provisions between research that includes treatment and research that does not, and no distinction between the requirements for research conducted with a patient's legal permission and research conducted with an IRB-approved waiver of a patient's informed consent. In sum, the NPRM proposed that covered entities be permitted to use or disclose protected health information created or received for a specific research study before the compliance date (if there was no agreed-to restriction in accordance with § 164.522(a)), if the covered entity has obtained, prior to the compliance date, any one of the following: (1) An authorization or other express legal permission from an individual to use or disclose protected health information for the research study; (2) the informed consent of the individual to participate in the research study; or (3) a waiver, by an IRB of informed consent for the research study in accordance with the Common Rule or FDA's human subject protection regulations. However, even if the researcher obtained, from an IRB, a waiver of informed consent, an authorization would be required if informed consent is later obtained. This may occur if there is a temporary waiver of informed consent for emergency research under the Food and Drug Administration human subject protection regulations.

*Overview of Public Comments.* The following discussion provides an overview of the public comment received on this proposal. Additional comments received on this issue are discussed below in the section entitled, ''Response to Other Public Comments.''

Most commenters supported the proposed revisions to the Privacy Rule's transition provisions for research. However, a few commenters requested that the transition provisions be broadened to permit covered entities to rely on an express legal permission or informed consent approved by an IRB before the compliance date, even if the permission or consent had not been signed by the individual prior to the compliance date. Consequently, a researcher could use the same forms throughout their study, decreasing the chance of introducing error into the research through the use of multiple recruitment procedures, disruption to the research, and the burden for the IRBs and researchers. A few other

commenters suggested that covered entities be permitted to use and disclose protected health information with consent forms approved by an IRB prior to the compliance date until the next review by the IRB, as required by the Common Rule. They argued that this would result in all informed consent forms being in compliance with the Privacy Rule's authorization regulations within a one-year period, and it would avoid disruption to ongoing research, as well as a flood of consent form revision requests to the IRBs.

*Final Modifications.* The Department agrees with the majority of comments that supported the modifications to the transition provisions, and has therefore adopted the research transition modifications as proposed in the NPRM. The Department disagrees with the comments that suggest broadening the transition provisions to permit covered entities to rely on an express legal permission or informed consent that had not been signed by the individual before the compliance date. The Department understands that this provision may disrupt some ongoing research; however, the recruitment periods for some studies may continue long after the compliance date, and it would be unreasonable to grandfather-in existing informed consent documents indefinitely. While the commenter's suggestion to only grandfather-in such informed consent documents until the next review by the IRB would address this concern, the Privacy Rule does not require initial or continuing IRB or Privacy Board review of authorization forms or informed consent documents. Therefore, the Department does not adopt this change to its proposal.

However, the Department understands that some existing express legal permissions, informed consents, or IRB-approved waivers of informed consents are not study specific. Therefore, the final Rule permits covered entities to rely on an express legal permission, informed consent, or IRB-approved waiver of informed consent for future unspecified research, provided the legal permission, informed consent or IRB-approved waiver was obtained prior to the compliance date.

*Response to Other Public Comments*

*Comment:* A commenter requested that the transition provision be narrowed by requiring research that received a waiver of informed consent from an IRB prior to the compliance date but that begins after the compliance date be re-evaluated under the Privacy Rule's waiver criteria.

*Response:* The Department disagrees. Given that the Privacy Rule's waiver criteria for an individual's authorization generally are consistent with the same types of considerations currently applied to a waiver of an individual's informed consent, this suggestion would impose unnecessary burdens on researchers, IRBs, and Privacy Boards, with respect to the few research studies that would fall in this category.

2. Business Associates

*December 2000 Privacy Rule.* The Privacy Rule at § 164.502(e) permits a covered entity to disclose protected health information to a business associate who performs a function or activity on behalf of, or provides a service to, the covered entity that involves the creation, use, or disclosure of, protected health information, provided that the covered entity obtains satisfactory assurances that the business associate will appropriately safeguard the information. The Department recognizes that most covered entities do not perform or carry out all of their health care activities and functions by themselves, but rather use the services of, or receive assistance from, a variety of other persons or entities. Given this framework, the Department intended these provisions to allow such business relationships to continue while ensuring that identifiable health information created or shared in the course of the relationships was protected.

The Privacy Rule requires that the satisfactory assurances obtained from the business associate be in the form of a written contract (or other written arrangement, as between governmental entities) between the covered entity and the business associate that contains the elements specified at § 164.504(e). For example, the agreement must identify the uses and disclosures of protected health information the business associate is permitted or required to make, as well as require the business associate to put in place appropriate safeguards to protect against a use or disclosure not permitted by the contract or agreement.

The Privacy Rule also provides that, where a covered entity knows of a material breach or violation by the business associate of the contract or agreement, the covered entity is required to take reasonable steps to cure the breach or end the violation, and if such steps are unsuccessful, to terminate the contract or arrangement. If termination of the contract or arrangement is not feasible, a covered entity is required to report the problem to the Secretary of HHS. A covered entity that violates the satisfactory assurances it provided as a business associate of another covered entity is in noncompliance with the Privacy Rule.

The Privacy Rule's definition of ''business associate'' at § 160.103 includes the types of functions or activities, and list of services, that make a person or entity who engages in them a business associate, if such activity or service involves protected health information. For example, a third party administrator (TPA) is a business associate of a health plan to the extent the TPA assists the health plan with claims processing or another covered function. Similarly, accounting services performed by an outside consultant give rise to a business associate relationship when provision of the service entails access to the protected health information held by a covered entity.

The Privacy Rule excepts from the business associate standard certain uses or disclosures of protected health information. That is, in certain situations, a covered entity is not required to have a contract or other written agreement in place before disclosing protected health information to a business associate or allowing protected health information to be created by the business associate on its behalf. Specifically, the standard does not apply to: disclosures by a covered entity to a health care provider for treatment purposes; disclosures to the plan sponsor by a group health plan, or a health insurance issuer or HMO with respect to a group health plan, to the extent that the requirements of § 164.504(f) apply and are met; or to the collection and sharing of protected health information by a health plan that is a public benefits program and an agency other than the agency administering the health plan, where the other agency collects protected health information for, or determines eligibility or enrollment with respect to, the government program, and where such activity is authorized by law. See § 164.502(e)(1)(ii).

*March 2002 NPRM.* The Department heard concerns from many covered entities and others about the business associate provisions of the Privacy Rule. The majority expressed some concern over the anticipated administrative burden and cost to implement the business associate provisions. Some stated that many covered entities have existing contracts that are not set to terminate or expire until after the compliance date of the Privacy Rule. Others expressed specific concern that the two-year compliance period does not provide enough time to reopen and renegotiate what could be hundreds or more contracts for large covered entities. These entities went on to urge the

Department to grandfather in existing contracts until such contracts come up for renewal instead of requiring that all contracts be in compliance with the business associate provisions by the compliance date of the Privacy Rule.

In response to these concerns, the Department proposed to relieve some of the burden on covered entities in complying with the business associate provisions by both adding a transition provision to grandfather certain existing contracts for a specified period of time, as well as publishing sample contract language in the proposed Rule. The following discussion addresses the issue of the business associate transition provisions. A discussion of the business associate sample contract language is included in Part X of the preamble.

The Department proposed new transition provisions at § 164.532(d) and (e) to allow covered entities, other than small health plans, to continue to operate under certain existing contracts with business associates for up to one year beyond the April 14, 2003, compliance date of the Privacy Rule. The additional transition period would be available to a covered entity, other than a small health plan, if, prior to the effective date of the transition provision, the covered entity had an existing contract or other written arrangement with a business associate, and such contract or arrangement was not renewed or modified between the effective date of this provision and the Privacy Rule's compliance date of April 14, 2003. The proposed provisions were intended to allow those covered entities with contracts that qualified as described above to continue to disclose protected health information to the business associate, or allow the business associate to create or receive protected health information on its behalf, for up to one year beyond the Privacy Rule's compliance date, regardless of whether the contract meets the applicable contract requirements in the Privacy Rule. The Department proposed to deem such contracts to be compliant with the Privacy Rule until either the covered entity had renewed or modified the contract following the compliance date of the Privacy Rule (April 14, 2003), or April 14, 2004, whichever was sooner. In cases where a contract simply renewed automatically without any change in terms or other action by the parties (also known as ''evergreen contracts''), the Department intended that such evergreen contracts would be eligible for the extension and that deemed compliance would not terminate when these contracts automatically rolled over.

These transition provisions would apply to covered entities only with respect to written contracts or other written arrangements as specified above, and not to oral contracts or other arrangements. In addition, the proposed transition provisions would not apply to small health plans, as defined in the Privacy Rule. Small health plans would be required to have all business associate contracts be in compliance with the Privacy Rule's applicable provisions, by the compliance deadline of April 14, 2004, for such covered entities.

In proposed § 164.532(e)(2), the Department provided that the new transition provisions would not relieve a covered entity of its responsibilities with respect to making protected health information available to the Secretary, including information held by a business associate, as necessary for the Secretary to determine compliance. Similarly, these provisions would not relieve a covered entity of its responsibilities with respect to an individual's rights to access or amend his or her protected health information held by a business associate, or receive an accounting of disclosures by a business associate, as provided for by the Privacy Rule's requirements at §§ 164.524, 164.526, and 164.528. Covered entities still would be required to fulfill individuals' rights with respect to their protected health information, including information held by a business associate of the covered entity. Covered entities would have to ensure, in whatever manner effective, the appropriate cooperation by their business associates in meeting these requirements.

The Department did not propose modifications to the standards and implementation specifications that apply to business associate relationships as set forth at §§ 164.502(e) and 164.504(e), respectively, of the Privacy Rule.

*Overview of Public Comments.* The following discussion provides an overview of the public comment received on this proposal. Additional comments received on this issue are discussed below in the section entitled, ''Response to Other Public Comments.''

Most commenters on this issue expressed general support for a transition period for business associate contracts. Of these commenters, however, many requested that the Department modify the proposal in a number of different ways. For example, a number of commenters urged the Department to modify which contracts qualify for the transition period, such as by making the transition period available to contracts existing as of the compliance date of the Privacy Rule, rather than as of the effective date of the transition modification. Others requested that the Department apply the transition period to all business associate arrangements, even those arrangements for which there was no existing written contract.

Some commenters urged the Department to modify the end date of the transition period. A few of these commenters requested that the transition period apply to existing business associate contracts until they expired or were renewed, with no specified end date in the regulation. It was also suggested that the Department simply provide one extra year, until April 14, 2004, for compliance with the business associate contract provisions, without the provision that a renewal or modification of the contract would trigger an earlier transition period end date. A few commenters requested further guidance as to the types of actions the Department would or would not consider to be a ''renewal or modification'' of the contract.

Additionally, numerous commenters requested that the Department further clarify a covered entity's responsibilities with regard to their business associates during the transition period. Commenters expressed concerns with the proposal's requirement that the transition provisions would not have relieved a covered entity of its responsibilities with respect to an individual's rights to access or amend his or her protected health information held by business associates, or receive an accounting of disclosures by a business associate. Similarly, commenters raised concerns that the transition provisions would not have relieved a covered entity of its responsibilities to make information available to the Secretary, including information held by a business associate, as necessary for the Secretary to determine compliance. Commenters also expressed concerns about the fact that it appeared that covered entities still would have been required to obtain satisfactory assurances from a business associate that protected health information not be used improperly by the business associate, or that the covered entity still would have been required to mitigate any known harmful effects of a business associate's improper use or disclosure of protected health information during the transition period. It was stated that cooperation by a business associate with respect to the covered entity's obligations under the Rule would be difficult, if not

impossible, to secure without a formal agreement.

A few commenters opposed the proposal, one of whom raised concerns that the proposed transition period would encourage covered entities to enter into ''stop gap'' contracts instead of compliant business associate contracts. This commenter urged that the Department maintain the original compliance date for business associate contracts.

*Final Modifications.* In the final Rule, the Department adopts the transition period for certain business associate contracts as proposed in the NPRM. The final Rule's transition provisions at § 164.532(d) and (e) permit covered entities, other than small health plans, to continue to operate under certain existing contracts with business associates for up to one year beyond the April 14, 2003, compliance date of the Privacy Rule. The transition period is available to covered entities who have an existing contract (or other written arrangement) with a business associate prior to the effective date of this modification, provided that the contract is not renewed or modified prior to the April 14, 2003, compliance date of the Privacy Rule. (See the ''Dates'' section above for the effective date of this modification.) Covered entities with contracts that qualify are permitted to continue to operate under those contracts with their business associates until April 14, 2004, or until the contract is renewed or modified, whichever is sooner. During the transition period, such contracts are deemed to be compliant with the Privacy Rule regardless of whether the contract meets the Rule's applicable contract requirements at §§ 164.502(e) and 164.504(e).

The transition provisions are intended to address the concerns of covered entities that the two-year period between the effective date and compliance date of the Privacy Rule is insufficient to reopen and renegotiate all existing contracts for the purposes of bringing them into compliance with the Rule. These provisions also provide covered entities with added flexibility to incorporate the business associate contract requirements at the time they would otherwise modify or renew the existing contract.

Given the intended purpose of these provisions, the Department is not persuaded by the comments that it is necessary to modify the provision to make the transition period available to those contracts existing prior to the Rule's compliance date of April 14, 2003, rather than the effective date of the modification, or, even less so, to any business associate arrangement regardless of whether a written contract currently exists.

A covered entity that does not have a written contract with a business associate prior to the effective date of this modification does not encounter the same burdens described by other commenters associated with having to reopen and renegotiate many existing contracts at once. The Department believes that such a covered entity should be able to enter into a compliant business associate contract by the compliance date of the Rule. Further, those covered entities whose business associate contracts come up for renewal or modification prior to the compliance date have the opportunity to bring such contracts into compliance by April 14, 2003. Thus, a covered entity that enters into a business associate contract after the effective date of this modification, or that has a contract that is renewed or modified prior to the compliance date of the Rule, is not eligible for the transition period and is required to have a business associate contract in place that meets the applicable requirements of §§ 164.502(e) and 164.504(e) by the Privacy Rule's compliance date of April 14, 2003. Further, as in the proposed Rule, the transition provisions apply only to written contracts or other written arrangements. Oral contracts or other arrangements are not eligible for the transition period. The Department clarifies, however, that nothing in these provisions requires a covered entity to come into compliance with the business associate contract provisions prior to April 14, 2003.

Similarly, in response to those commenters who requested that the Department permit existing contracts to be transitioned until April 14, 2004, regardless of whether such contracts are renewed or modified prior to that date, the Department considers a renewal or modification of the contract to be an appropriate, less burdensome opportunity to bring such contracts into compliance with the Privacy Rule. The Department, therefore, does not modify the proposal in such a way. Further, in response to commenters who requested that the Rule grandfather in existing business associate contracts until they expire or are renewed, with no specified end date in the regulation, the Department believes that limiting the transition period to one year beyond the Rule's compliance date is the proper balance between individuals' privacy interests and alleviating burden on the covered entity. All existing business associate contracts must be compliant with the Rule's business associate contract provisions by April 14, 2004.

As in the proposal, evergreen or other contracts that renew automatically without any change in terms or other action by the parties and that exist by the effective date of this modification are eligible for the transition period. The automatic renewal of such contracts itself does not terminate qualification for, or deemed compliance during, the transition period. Renewal or modification for the purposes of these transition provisions requires action by the parties involved. For example, the Department does not consider an automatic inflation adjustment to the price of a contract to be a renewal or modification for purposes of these provisions. Such an adjustment will not trigger the end of the transition period, nor make the contract ineligible for the transition period if the adjustment occurs before the compliance date of the Rule.

The transition provisions do not apply to ''small health plans,'' as defined at § 160.103. Small health plans are required to have business associate contracts that are compliant with §§ 164.502(e) and 164.504(e) by the April 14, 2004, compliance date for such entities. As explained in the proposal, the Department believes that the additional year provided by the statute for these entities to comply with the Privacy Rule provides sufficient time for compliance with the Rule's business associate provisions. In addition, the sample contract provisions provided in the Appendix to the preamble will assist small health plans and other covered entities in their implementation of the Privacy Rule's business associate provisions by April 14, 2004.

Like the proposal, the final Rule at § 164.532(e)(2) provides that, during the transition period, covered entities are not relieved of their responsibilities to make information available to the Secretary, including information held by a business associate, as necessary for the Secretary to determine compliance by the covered entity. Similarly, the transition period does not relieve a covered entity of its responsibilities with respect to an individual's rights to access or amend his or her protected health information held by a business associate, or receive an accounting of disclosures by a business associate, as provided for by the Privacy Rule's requirements at §§ 164.524, 164.526, and 164.528. In addition, unlike the proposed Rule, the final Rule at § 164.532(e)(3) explicitly provides that with respect to those business associate contracts that qualify for the transition period as described above, a covered entity is not relieved of its obligation

under § 164.530(f) to mitigate, to the extent practicable, any harmful effect that is known to the covered entity of a use or disclosure of protected health information by its business associate in violation of the covered entity's policies and procedures or the requirements of this subpart, as required by § 164.530(f).

The Department does not believe that a covered entity should be relieved during the transition period of its responsibilities with respect to cooperating with the Secretary or fulfilling an individual's rights with respect to protected health information held by the business associate, or mitigating any harmful effects of an inappropriate use or disclosure by the business associate. The transition period is intended to alleviate some of the burden on covered entities, but not at the expense of individuals' privacy rights. Eliminating these privacy protections and rights would severely weaken the Rule with respect to those covered entities with contracts that qualify for the transition period.

Further, the Rule provides covered entities some discretion in implementing these requirements with respect to their business associates. For example, a covered entity does not need to provide an individual with access to protected health information held by a business associate if the only information the business associate holds is a duplicate of what the covered entity maintains and to which it has provided the individual access. Covered entities are required to ensure, in whatever manner deemed effective by the covered entity, the appropriate cooperation by their business associates in meeting these requirements.

In response to other concerns from commenters, the Department clarifies that a covered entity is not required to obtain satisfactory assurances (in any form), as required by § 164.502(e)(1), from a business associate to which the transition period applies. The transition period effectively deems such qualified contracts to fulfill the requirement for satisfactory assurances from the business associate.

The Department is aware that the transition provisions may encourage some covered entities to enter into contracts before the effective date of the modification solely to take advantage of the transition period, rather than encourage such entities to execute fully compliant business associate contracts. However, the Department believes that the provision appropriately limits the potential for such misuse by requiring that qualified contracts exist prior to the modification effective date rather than the Privacy Rule's compliance date. Further, the transition provisions do not relieve the covered entity of its obligations with respect to protected health information held by the business associate and, therefore, ensures that an individual's rights, as provided for by the Rule, remain intact during the transition period.

*Response to Other Public Comments*

*Comment:* One commenter requested that the transition period also be applied to the requirement that a group health plan amend plan documents pursuant to § 164.504(f) before protected health information may be disclosed to the plan sponsor.

*Response:* The Department does not make such a modification. The intent of the business associate transition provisions is to alleviate burden on those covered entities with many existing contracts, where as a result, the two-year period between the effective date and compliance date of the Privacy Rule may be insufficient to reopen and renegotiate all such contracts for the purposes of bringing them into compliance with the Rule. The Privacy Rule does not require a business associate contract for disclosure of protected health information from a group health plan to a plan sponsor. Rather, the Rule permits a group health plan to disclose protected health information to a plan sponsor if, among other requirements, the plan documents are amended to appropriately reflect and restrict the plan sponsor's uses and disclosures of such information. As the group health plan should only have one set of plan documents that must be amended, the same burdens described above do not exist with respect to this activity. Thus, the Department expects that group health plans will be able to modify plan documents in accordance with the Rule by the Rule's compliance date.

*Comment:* Many commenters continued to recommend various modifications to the business associate standard, unrelated to the proposed modifications. For example, some commenters urged that the Department eliminate the business associate requirements entirely. Several commenters urged that the Department exempt covered entities from having to enter into contracts with business associates who are also covered entities under the Privacy Rule. Alternatively, one commenter suggested that the Department simplify the requirements by requiring a covered entity that is a business associate to specify in writing the uses and disclosures the covered entity is permitted to make as a business associate.

Other commenters requested that the Department allow business associates to self-certify or be certified by a third party or HHS as compliant with the Privacy Rule, as an alternative to the business associate contract requirement.

Certain commenters urged the Department to modify the Rule to eliminate the need for a contract with accreditation organizations. Some commenters suggested that the Department do so by reclassifying private accreditation organizations acting under authority from a government agency as health oversight organizations, rather than as business associates.

*Response:* The proposed modifications regarding business associates were intended to address the concerns of commenters with respect to having insufficient time to reopen and renegotiate what could be thousands of contracts for some covered entities by the compliance date of the Privacy Rule. The proposed modifications did not address changes to the definition of, or requirements for, business associates generally. The Department has, in previous guidance, as well as in the preamble to the December 2000 Privacy Rule, explained its position with respect to most of the above concerns. However, the Department summarizes its position in response to such comments briefly below.

The Department recognizes that most covered entities acquire the services of a variety of other persons or entities to assist in carrying covered entities' health care activities. The business associate provisions are necessary to ensure that individually identifiable health information created or shared in the course of these relationships is protected. Further, without the business associate provisions, covered entities would be able to circumvent the requirements of the Privacy Rule simply by contracting out certain of its functions.

With respect to a contract between a covered entity and a business associate who is also a covered entity, the Department restates its position that a covered entity that is a business associate should be restricted from using or disclosing the protected health information it creates or receives as a business associate for any purposes other than those explicitly provided for in its contract. Further, to modify the provisions to require or permit a type of written assurance, other than a contract, by a covered entity would add unnecessary complexity to the Rule.

Additionally, the Department at this time does not believe that a business associate certification process would

provide the same kind of protections and guarantees with respect to a business associate's actions that are available to a covered entity through a contract under State law. With respect to certification by a third party, it is unclear whether such a process would allow for any meaningful enforcement (such as termination of a contract) for the actions of a business associate. Further, the Department could not require that a business associate be certified by a third party. Thus, the Privacy Rule still would have to allow for a contract between a covered entity and a business associate.

The Privacy Rule explicitly defines organizations that accredit covered entities as business associates. See the definition of ''business associate'' at § 160.103. The Department defined such organizations as business associates because, like other business associates, they provide a service to the covered entity during which much protected health information is shared. The Privacy Rule treats all organizations that provide accreditation services to covered entities alike. The Department has not been persuaded by the comments that those accreditation organizations acting under grant of authority from a government agency should be treated differently under the Rule and relieved of the conditions placed on other such relationships. However, the Department understands concerns regarding the burdens associated with the business associate contract requirements. The Department clarifies that the business associate provisions may be satisfied by standard or model contract forms which could require little or no modification for each covered entity. As an alternative to the business associate contract, these final modifications permit a covered entity to disclose a limited data set of protected health information, not including direct identifiers, for accreditation and other health care operations purposes subject to a data use agreement. *See* § 164.514(e).

*Comment:* A number of commenters continued to express concern over a covered entity's perceived liability with respect to the actions of its business associate. Some commenters requested further clarification that a covered entity is not responsible for or required to monitor the actions of its business associates. It also was suggested that such language expressly be included in the Rule's regulatory text. One commenter recommended that the Rule provide that business associates are directly liable for their own failure to comply with the Privacy Rule. Another commenter urged that the Department eliminate a covered entity's obligation to mitigate any harmful effects caused by a business associate's improper use or disclosure of protected health information.

*Response:* The Privacy Rule does not require a covered entity to actively monitor the actions of its business associates nor is the covered entity responsible or liable for the actions of its business associates. Rather, the Rule only requires that, where a covered entity knows of a pattern of activity or practice that constitutes a material breach or violation of the business associate's obligations under the contract, the covered entity take steps to cure the breach or end the violation. *See* § 164.504(e)(1). The Department does not believe a regulatory modification is necessary in this area. The Department does not have the statutory authority to hold business associates, that are not also covered entities, liable under the Privacy Rule.

With respect to mitigation, the Department does not accept the commenter's suggestion. When protected health information is used or disclosed inappropriately, the harm to the individual is the same, regardless of whether the violation was caused by the covered entity or a by business associate. Further, this provision is not an absolute standard intended to require active monitoring of the business associate or mitigation of all harm caused by the business associate. Rather, the provision applies only if the covered entity has actual knowledge of the harm, and requires mitigation only ''to the extent practicable'' by the covered entity. *See* § 164.530(f).

*Comment:* Several commenters asked the Department to provide additional clarification as to who is and is not a business associate for purposes of the Rule. For example, commenters questioned whether researchers were business associates. Other commenters requested further clarification as to when a health care provider would be the business associate of another health care provider. One commenter asked the Department to clarify whether covered entities that engage in joint activities under an organized health care arrangement (OHCA) are required to have a business associate contract. Several commenters asked the Department to clarify that a business associate agreement is not required with organizations or persons where contact with protected health information would result inadvertently (if at all), for example, janitorial services.

*Response:* The Department provides the following guidance in response to commenters. Disclosures from a covered entity to a researcher for research purposes as permitted by the Rule do not require a business associate contract. This remains true even in those instances where the covered entity has hired the researcher to perform research on the covered entity's own behalf because research is not a covered function or activity. However, the Rule does not prohibit a covered entity from entering into a business associate contract with a researcher if the covered entity wishes to do so. Notwithstanding the above, a covered entity must enter into a data use agreement, as required by § 164.514(e), prior to disclosing a limited data set for research purposes to a researcher.

With respect to business associate contracts between health care providers, the Privacy Rule explicitly excepts from the business associate requirements disclosures by a covered entity to a health care provider for treatment purposes. *See* § 164.502(e)(1). Therefore, any covered health care provider (or other covered entity) may share protected health information with a health care provider for treatment purposes without a business associate contract. The Department does not intend the Rule to interfere with the sharing of information among health care providers for treatment. However, this exception does not preclude one health care provider from establishing a business associate relationship with another health care provider for some other purpose. For example, a hospital may enlist the services of another health care provider to assist in the hospital's training of medical students. In this case, a business associate contract would be required before the hospital could allow the health care provider access to patient health information.

As to disclosures among covered entities who participate in an organized health care arrangement, the Department clarifies that no business associate contract is needed to the extent the disclosure relates to the joint activities of the OHCA.

The Department also clarifies that a business associate contract is not required with persons or organizations whose functions, activities, or services do not involve the use or disclosure of protected health information, and where any access to protected health information by such persons would be de minimus, if at all. For example, a health care provider is not required to enter into a business associate contract with its janitorial service because the performance of such service does not involve the use or disclosure of protected health information. In this case, where a janitor has contact with

protected health information incidentally, such disclosure is permissible under § 164.502(a)(1)(iii) provided reasonable safeguards are in place.

The Department is aware that similar questions still remain with respect to the business associate provisions of the Privacy Rule and intends to provide technical assistance and further clarifications as necessary to address these questions.

*Comment:* A few commenters urged that the Department modify the Privacy Rule's requirement for a covered entity to take reasonable steps to cure a breach or end a violation of its business associate contract by a business associate. One commenter recommended that the requirement be modified instead to require a covered entity who has knowledge of a breach to ask its business associate to cure the breach or end the violation. Another commenter argued that a covered entity only should be required to take reasonable steps to cure a breach or end a violation if the business associate or a patient reports to the privacy officer or other responsible employee of the covered entity that a misuse of protected health information has occurred.

*Response:* It is expected that a covered entity with evidence of a violation will ask its business associate, where appropriate, to cure the breach or end the violation. Further, the Department intends that whether a covered entity ''knew'' of a pattern or practice of the business associate in breach or violation of the contract will be consistent with common principles of law that dictate when knowledge can be attributed to a corporate entity. Regardless, a covered entity's training of its workforce, as required by § 164.530(b), should address the recognition and reporting of violations to the appropriate responsible persons with the entity.

*Comment:* Several commenters requested clarification as to whether a business associate is required to provide individuals with access to their protected health information as provided by § 164.524 or an accounting of disclosures as provided by § 164.528, or amend protected health information as required by § 164.526. Some commenters wanted clarification that the access and amendment provisions apply to the business associate only if the business associate maintains the original designated record set of the protected health information.

*Response:* Under the Rule, the covered entity is responsible for fulfilling all of an individual's rights, including the rights of access, amendment, and accounting, as provided for by §§ 164.524, 164.526, and 164.528. With limited exceptions, a covered entity is required to provide an individual access to his or her protected health information in a designated record set. This includes information in a designated record set of a business associate, unless the information held by the business associate merely duplicates the information maintained by the covered entity. However, the Privacy Rule does not prevent the parties from agreeing through the business associate contract that the business associate will provide access to individuals, as may be appropriate where the business associate is the only holder of the, or part of the, designated record set.

As governed by § 164.526, a covered entity must amend protected health information about an individual in a designated record set, including any designated record sets (or copies thereof) held by a business associate. Therefore, the Rule requires covered entities to specify in the business associate contract that the business associate will make protected health information available for amendment and will incorporate amendments accordingly. The covered entity itself is responsible for addressing requests from individuals for amendment and coordinating such requests with its business associate. However, the Privacy Rule also does not prevent the parties from agreeing through the contract that the business associate will receive and address requests for amendment on behalf of the covered entity.

With respect to accounting, § 164.528 requires a covered entity to provide an accounting of certain disclosures, including certain disclosures by its business associate, to the individual upon request. The business associate contract must provide that the business associate will make such information available to the covered entity in order for the covered entity to fulfill its obligation to the individual. As with access and amendment, the parties can agree through the business associate contract that the business associate will provide the accounting to individuals, as may be appropriate given the protected health information held by, and the functions of, the business associate.

*Comment:* One commenter asked whether a business associate agreement in electronic form, with an electronic signature, would satisfy the Privacy Rule's business associate requirements.

*Response:* The Privacy Rule generally allows for electronic documents to qualify as written documents for purposes of meeting the Rule's requirements. This also applies with respect to business associate agreements. However, currently, no standards exist under HIPAA for electronic signatures. Thus, in the absence of specific standards, covered entities should ensure any electronic signature used will result in a legally binding contract under applicable State or other law.

*Comment:* Certain commenters raised concerns with the Rule's classification of attorneys as business associates. A few of these commenters urged the Department to clarify that the Rule's requirement at § 164.504(e)(2)(ii)(H), which requires a contract to state the business associate must make information relating to the use or disclosure of protected health information available to the Secretary for purposes of determining the covered entity's compliance with the Rule, not apply to protected health information in possession of a covered entity's lawyer. Commenters argued that such a requirement threatens to impact attorney-client privilege. Others expressed concern over the requirement that the attorney, as a business associate, must return or destroy protected health information at termination of the contract. It was argued that such a requirement is inconsistent with many current obligations of legal counsel and is neither warranted nor useful.

*Response:* The Department does not modify the Rule in this regard. The Privacy Rule is not intended to interfere with attorney-client privilege. Nor does the Department anticipate that it will be necessary for the Secretary to have access to privileged material in order to resolve a complaint or investigate a violation of the Privacy Rule. However, the Department does not believe that it is appropriate to exempt attorneys from the business associate requirements.

With respect to the requirement for the return or destruction of protected health information, the Rule requires the return or destruction of all protected health information at termination of the contract only where feasible or permitted by law. Where such action is not feasible, the contract must state that the information will remain protected after the contract ends for as long as the information is maintained by the business associate, and that further uses and disclosures of the information will be limited to those purposes that make the return or destruction infeasible.

*Comment:* One commenter was concerned that the business associate provisions regarding the return or

destruction of protected health information upon termination of the business associate agreement conflict with various provisions of the Bank Secrecy Act, which require financial institutions to retain certain records for up to five years. The commenter further noted that there are many State banking regulations that require financial institutions to retain certain records for up to ten years. The commenter recommended that the Department clarify, in instances of conflict with the Privacy Rule, that financial institutions comply with Federal and State banking regulations.

*Response:* The Department does not believe there is a conflict between the Privacy Rule and the Bank Secrecy Act retention requirements or that the Privacy Rule would prevent a financial institution that is a business associate of a covered entity from complying with the Bank Secrecy Act. The Privacy Rule generally requires a business associate contract to provide that the business associate will return or destroy protected health information upon the termination of the contract; however, it does not require this if the return or destruction of protected health information is infeasible. Return or destruction would be considered ''infeasible'' if other law, such as the Bank Secrecy Act, requires the business associate to retain protected health information for a period of time beyond the termination of the business associate contract. The Privacy Rule would require that the business associate contract extend the protections of the contract and limit further uses and disclosures to those purposes that make the return or destruction of the information infeasible. In this case, the business associate would have to limit the use or disclosure of the protected health information to purposes of the Bank Secrecy Act or State banking regulations.

*Comment:* A commenter requested clarification concerning the economic impact on business associates of the cost-based copying fees allowed to be charged to individuals who request a copy of their medical record under the right of access provided by the Privacy Rule. See § 164.524. According to the commenter, many hospitals and other covered entities currently outsource their records reproduction function for fees that often include administrative costs over and above the costs of copying. In some cases, the fees may be set in accordance with State law. The Privacy Rule, at § 164.524(c)(4), however, permits only reasonable, cost-based copying fees to be charged to individuals seeking to obtain a copy of their medical record under their right of access. The commenter was concerned that others seeking copies of all or part of the medical record, such as payers, attorneys, or entities that have the individual's authorization, would try to claim the limited copying fees provided in § 164.524(c)(4). The commenter asserted that such a result would drastically alter the economics of the outsourcing industry, driving outsourcing companies out of business, and raising costs for the health industry as a whole. A clarification that the fee structure in § 164.524(c)(4) applies only to individuals exercising their right of access was sought.

*Response:* The Department clarifies that the Rule, at § 164.524(c)(4), limits only the fees that may be charged to individuals, or to their personal representatives in accordance with § 164.502(g), when the request is to obtain a copy of protected health information about the individual in accordance with the right of access. The fee limitations in § 164.524(c)(4) do not apply to any other permissible disclosures by the covered entity, including disclosures that are permitted for treatment, payment or health care operations, disclosures that are based on an individual's authorization that is valid under § 164.508, or other disclosures permitted without the individual's authorization as specified in § 164.512.

The fee limitation in § 164.524(c)(4) is intended to assure that the right of access provided by the Privacy Rule is available to all individuals, and not just to those who can afford to do so. Based on the clarification provided, the Department does not anticipate that this provision will cause any significant disruption in the way that covered entities do business today. To the extent hospitals and other entities outsource this function because it is less expensive than doing it themselves, the fee limitation for individuals seeking access under § 164.524 will affect only a portion of this business; and, in these cases, hospitals should still find it economical to outsource these activities, even if they can only pass on a portion of the costs to the individual.

*K. Technical Corrections and Other Clarifications*

1. Definition of ''Individually Identifiable Health Information''

Part 160 contains the definitions that are relevant to all of the Administrative Simplification provisions at Parts 160 through 164. Although the term ''individually identifiable health information'' is relevant to Parts 160 through 164, it is defined in § 164.501 of the Privacy Rule. To correct this technical error, the Department proposed to move the definition of individually identifiable health information from § 164.501 to § 160.103.

The limited comment on this proposal supported moving the definition into § 160.103, for the same reasons cited by the Department. Therefore, the Department in this final Rule deletes the definition of ''individually identifiable health information'' from § 164.501 of the Privacy Rule, and adds the definition to § 160.103.

2. Technical Corrections

The Privacy Rule contained some technical and typographical errors. Therefore, the Department is making the following corrections:

a. In § 160.102(b), beginning in the second line, ''section 201(a)(5) of the Health Insurance Portability Act of 1996, (Pub. L. 104–191),'' is replaced with ''42 U.S.C. 1320a–7c(a)(5).''

b. In § 160.203(b), in the second line, ''health information'' is replaced with ''individually identifiable health information.''

c. In § 164.102, ''implementation standards'' is corrected to read ''implementation specifications.''

d. In § 164.501, in the definition of ''protected health information'', ''Family Educational Right and Privacy Act'' is corrected to read ''Family Educational Rights and Privacy Act.''

e. In § 164.508(b)(1)(ii), in the fifth line, the word ''be'' is deleted.

f. In § 164.508(b)(3)(iii), a comma is added after the words ''psychotherapy notes.''

g. In § 164.510(b)(3), in the third line, the word ''for'' is deleted.

h. In § 164.512(b)(1)(v)(A), in the fourth line, the word ''a'' is deleted.

i. In § 164.512(b)(1)(v)(C), in the eighth line, the word ''and'' is added after the semicolon.

j. In § 164.512(f)(3), paragraphs (ii) and (iii) are redesignated as (i) and (ii), respectively.

k. In § 164.512(g)(2), in the seventh line, the word ''to'' is added after the word ''directors.''

l. In § 164.512(i)(1)(iii)(A), in the second line, the word ''is'' after the word ''sought'' is deleted.

m. In § 164.514(d)(5), the word ''discloses'' is corrected to read ''disclose.''

n. In § 164.520(c), in the introductory text, ''(c)(4)'' is corrected to read ''(c)(3).''

o. In § 164.522(a)(1)(v), in the sixth line, ''§§ 164.502(a)(2)(i)'' is corrected to read ''§§ 164.502(a)(2)(ii).''

p. In § 164.530(i)(4)(ii)(A), in the second line, ''the requirements'' is

replaced with the word ''specifications.''

## IV. Final Regulatory Impact Analysis

Federal law (5 U.S.C. 804(2), as added by section 251 of Pub. L. No. 104–21), specifies that a ''major rule'' is any rule that the Office of Management and Budget finds is likely to result in:

- An annual effect on the economy of $100 million or more;
- A major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or
- Significant adverse effects in competition, employment, investment productivity, innovation, or on the ability of United States based enterprises to compete with foreign-based enterprises in domestic and export markets.

The impact of the modifications adopted in this rulemaking will have an annual effect on the economy of at least $100 million. Therefore, this Rule is a major rule as defined in 5 U.S.C. 804(2).

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects; distributive impacts; and equity). According to Executive Order 12866, a regulatory action is ''significant'' if it meets any one of a number of specified conditions, including having an annual effect on the economy of $100 million or more, adversely affecting in a material way a sector of the economy, competition, or jobs, or if it raises novel legal or policy issues. The purpose of the regulatory impact analysis is to assist decision-makers in understanding the potential ramifications of a regulation as it is being developed. The analysis is also intended to assist the public in understanding the general economic ramifications of the regulatory changes.

The December 2000 preamble to the Privacy Rule included a regulatory impact analysis (RIA), which estimated the cost of the Privacy Rule at $17.6 billion over ten years. 65 FR 82462, 82758. The modifications to the Privacy Rule adopted by this rulemaking are a result of comment by the industry and the public at large identifying a number of unintended consequences of the Privacy Rule that could adversely affect access to, or the quality of, health care delivery. These modifications should facilitate implementation and compliance with the Privacy Rule, and lower the costs and burdens associated with the Privacy Rule while maintaining the confidentiality of protected health information. The Department estimates the impact of the modifications adopted in this rulemaking will be a net reduction of costs associated with the Privacy Rule of at least $100 million over ten years.

The modifications affect five areas of the Privacy Rule that will have an economic impact: (1) consent; (2) notice; (3) marketing; (4) research; and (5) business associates. In addition, this rulemaking contains a number of changes that, though important, can be categorized as clarifications of intended policy. For example, the modifications permit certain uses and disclosures of protected health information that are incidental to an otherwise permitted use or disclosure. This change recognizes such practices as the need for physicians to talk to patients in semi-private hospital rooms or nurses to communicate with others in public areas, and avoids the costs covered entities might have incurred to reconfigure facilities as necessary to ensure absolute privacy for these common treatment-related communications. This and other modifications adopted in this rulemaking (other than those described below) clarify the intent of the standards in the Privacy Rule and, as such, do not change or alter the associated costs that were estimated for the Privacy Rule. Public comments have indicated that these provisions would be interpreted in a way that could significantly increase costs. However, because that was not the intent of the December 2000 Privacy Rule, the Department is not ascribing cost savings to the clarification of these provisions.

### *A. Summary of Costs and Benefits in the December 2000 Regulatory Impact Statement*

The Privacy Rule was estimated to produce net costs of $17.6 billion, with net present value costs of $11.8 billion (2003 dollars) over ten years (2003–2012). The Department estimates the modifications in this proposal would lower the net cost of the Privacy Rule by approximately $100 million over ten years.

Measuring both the economic costs and benefits of health information privacy was recognized as a difficult task. The paucity of data and incomplete information on current industry privacy and information system practices made cost estimation a challenge. Benefits were difficult to measure because they are, for the most part, inherently intangible. Therefore, the regulatory impact analysis in the Privacy Rule focused on the key policy areas addressed by the privacy standards, some of which are affected by the modifications adopted in this rulemaking.

### *B. Proposed Modifications To Prevent Barriers to Access to or Quality of Health Care*

The modifications adopted in this rulemaking are intended to address the possible adverse effects of the final privacy standards on an individual's access to, or the quality of, health care. The modifications touch on five of the key policy areas addressed by the final regulatory impact analysis, including consent, research, marketing, notice, and business associates.

The Department received few comments on this section of the March 2002 proposal. Most of the comments on the cost implications of the modifications indicated a general belief that the costs would be higher than the Department estimated. None of commenters, however, provided sufficient specific information concerning costs to permit the Department to adjust its estimates. The public comment on each of the key policy areas is summarized in the following sections. However, the estimated cost impact of each area has not changed.

#### 1. Consent

Under the December 2000 Privacy Rule, a covered health care provider with a direct treatment relationship with an individual must have obtained the individual's prior written consent for use or disclosure of protected health information for treatment, payment, or health care operations, subject to a limited number of exceptions. Other covered health care providers and health plans may have obtained such a consent if they so chose. The initial cost of the consent requirement was estimated in December 2000 to be $42 million. Based on assumptions for growth in the number of patients, the total costs for ten years was estimated to be $103 million. *See* 65 FR 82771 (December 28, 2000).[2]

The modifications eliminate the consent requirement. The consent requirement posed many difficulties for an individual's access to health care, and was problematic for operations essential for the quality of the health

[2] The total cost for consent in the regulatory impact analysis showed an initial cost of $166 million and $227 million over ten years. Included in these total numbers is the cost of tracking patient requests to restrict the disclosure of their health information. This right is not changed in these modifications. The numbers here represent the costs associated with the consent functions that are proposed to be repealed.

care delivery system. However, any health care provider or health plan may choose to obtain an individual's consent for treatment, payment, and health care operations. The elimination of the consent requirement reduces the initial cost of the privacy standards by $42 million in the first year and by $103 million over ten years.

As explained in detail in section III.D.1. above, the Department received many comments supporting the proposed elimination of the consent requirement on the ground that it created unintended barriers to timely provision of care, particularly with respect to use and disclosure of health information prior to a health care provider's first face-to-face contact with the individual. These and other barriers discussed above would have entailed costs not anticipated in the economic analyses in the Privacy Rule. These comments also revealed that the consent requirements create administrative burdens, for example, with respect to tracking the status and revocation of consents, that were not foreseen and thus not included in that economic analysis. Therefore, while the estimated costs of the consent provisions over a ten-year period were $103 million, the comments suggest that the costs would likely be much higher. If these comments are accurate, the cost savings associated with retracting the consent provisions would, therefore, also be significantly higher than $103 million over a ten-year period.

*Response to Public Comments*

*Comment:* As discussed in section III.H. above, many commenters expressed support for the proposed requirement that certain health care providers make a good faith effort to obtain a written acknowledgment of receipt of the notice, as a workable alternative to the Rule's prior consent requirement. Many of these commenters conveyed support for the flexibility of the requirement, and most commenters agreed that eliminating the consent requirement would mean considerable savings.

*Response:* The Department received no public comment containing empirical, direct evidence on the estimates of financial impact that either supported or contradicted the Department's calculations. Therefore, our estimates remain unchanged.

*Comment:* Many other commenters confused the net savings associated with the Administrative Simplification provisions with cost savings associated with the Privacy Rule, and relied on this misinformation to argue in favor of retaining the consent provisions for treatment, payment, and health care operations.

*Response:* These commenters were essentially propounding a policy choice and not making a comment on the validity of the estimates for cost savings associated with the elimination of the consent requirement. The comments did not include any reliable estimation that would cause the Department to reevaluate its savings estimate.

2. Notice

In eliminating the consent requirement, the Department preserves the opportunity for a covered health care provider with a direct treatment relationship with an individual to engage in a meaningful communication about the provider's privacy practices and the individual's rights by strengthening the notice requirements. Under the Privacy Rule, these health care providers are required to distribute to individuals their notice of privacy practices no later than the date of the first service delivery after the compliance date. The modifications do not change this distribution requirement, but add a new documentation requirement. A covered health care provider with a direct treatment relationship is required to make a good faith effort to obtain the individual's acknowledgment of receipt of the notice provided at the first service delivery. The form of the acknowledgment is not prescribed and can be as unintrusive as retaining a copy of the notice initialed by the individual. If the provider's good faith effort fails, documentation of the attempt is all that is required. Since the modification does not require any change in the form of the notice or its distribution, the ten-year cost estimate of $391 million for these areas in the Privacy Rule's impact analysis remains the same. *See* 65 FR 82770.

However, the additional effort by direct treatment providers in obtaining and documenting the individual's acknowledgment of receipt of the notice adds costs. This new requirement attaches only to the initial provision of notice by a direct treatment provider to an individual after the compliance date. Under the modification, providers have considerable flexibility on how to achieve this. Some providers could choose to obtain the required written acknowledgment on a separate piece of paper, while others could take different approaches, such as an initialed check-off sheet or a signature line on the notice itself with the provider keeping a copy.

In its December 2000 analysis, the Department estimated that the consent cost would be $0.05 per page based on the fact that the consent had to be a stand alone document requiring a signature. This modification to the notice requirement provides greater flexibility and, therefore, greater opportunity to reduce costs compared to the consent requirement. Without knowing exactly how direct treatment providers will decide to exercise the flexibility provided, the Department cannot, with any precision, estimate the cost to implement this provision. In the NPRM, the Department estimated that the flexibility of the notice acknowledgment requirement would mean that the cost of the notice acknowledgment would be 20 percent less than the cost of the signed consent. The Department did not receive any comments on this estimate and, therefore, does not change it's estimate that the additional cost of the signature requirement, on average, is $0.03 per notice. Based on data obtained from the Medical Expenditure Panel Survey (MEPS), which estimate the number of patient visits in a year, the Department estimates that in the first year there would be 816 million notices distributed to which the new good faith acknowledgment requirement will attach. Over the next nine years, the Department estimates, again based on MEPS data, that there would be 5.3 billion visits to health care providers by new patients (established patients will not need to receive another copy of the notice). At $0.03 per document, the first year cost will be $24 million and the total cost over ten years will be $184 million.

*Response to Public Comments*

*Comment:* As discussed in section III.H. above, a number of other commenters expressed concern over the administrative and financial burden the requirement to obtain a good faith acknowledgment of the notice would impose.

*Response:* The Department received no public comment containing empirical, direct evidence on the estimates of financial impact that either supported or contradicted the Department's calculations. Therefore, our estimates remain unchanged.

*Comment:* One commenter requested that model language for the notice be developed as a means of reducing the costs associated with Privacy Rule compliance.

*Response:* As stated in section III.H. above, in the final Rule, the Department sought to retain the maximum flexibility by requiring only that the acknowledgment be in writing and does not prescribe other details of the form

that the acknowledgment must take or the process for obtaining the acknowledgment. This permits covered health care providers the discretion to design the acknowledgment process as best suited to their practices, including the option of obtaining an electronic acknowledgment regardless of whether the notice is provided electronically or on paper. Furthermore, there is no change to the substance of the notice and the commenter provided no empirical, direct benefit/cost data in support of their proposal.

*Comment:* The Department received comments expressing opposition to obtaining written acknowledgment of the receipt of the notice because it is too costly. Others commented that the acknowledgment increases the administrative burden as it would not replace a signed consent for uses and disclosures of health information when State law requires providers to obtain consent.

*Response:* The Department received no public comment containing empirical, direct evidence on the estimates of financial impact that either supported or contradicted the Department's calculations. Therefore, our estimates remain unchanged.

*Comment:* A number of commenters expressed concern over the perceived increase in liability that would arise from the discretionary standard of ''good faith'' efforts (i.e., risk of tort-based litigation for private right of action under State laws).

*Response:* The Department received no estimate of the impact of this perceived risk of liability. As no empirical, direct evidence on the estimates of financial impact that either supported or contradicted the Department's calculations was supplied, our estimates remain unchanged.

3. Business Associates

The Privacy Rule requires a covered entity to have a written contract, or other arrangement, that documents satisfactory assurances that a business associates will appropriately safeguard protected health information in order to disclose protected health information to the business associate. The regulatory impact analysis for the Privacy Rule provided cost estimates for two aspects of this requirement. In the Privacy Rule, $103 million in first-year costs was estimated for development of a standard business associate contract language. (There were additional costs associated with these requirements related to the technical implementation of new data transfer protocols, but these are not affected by the modification adopted here.) In addition, $197 million in first-year costs and $697 million in total costs over ten years were estimated in the Privacy Rule for the review and oversight of existing business associate contracts.

The modifications do not change the standards for business associate contracts or the implementation specifications with respect to the covered entity's responsibilities for managing the contracts. However, the Department includes sample business associate contract language as part of the preamble to this rulemaking. This sample language is only suggested language and is not a complete contract. The sample language is designed to be adapted to the business arrangement between the covered entity and the business associate and to be incorporated into a contract drafted by the parties. Certain provisions of the sample language have been revised, as described in more detail below, based on the public comment received on the proposal. The December 2000 regulatory impact analysis assumed the development of such standard language by trade and professional associations. While this has occurred to some degree, the Department received strong public comment supporting the for sample contract language. The Department expects that trade and professional associations will continue to provide assistance to their members. However, the sample contract language in this rulemaking will simplify their efforts by providing a base from which they can develop language. The Department had estimated $103 million in initial year costs for this activity based on the assumption it would require one hour per non-hospital provider and two hours for hospitals and health plans to develop contract language and to tailor the language to the particular needs of the covered entity. The additional time for hospitals and health plans reflected the likelihood that these covered entities would have a more extensive number of business associate relationships. Because there will be less effort expended than originally estimated in the Privacy Rule, the Department estimates a reduction in contract development time by one-third because of the availability of the model language. Thus, the Department now estimates that this activity will take 40 minutes for non-hospital providers and 80 minutes for hospitals and health plans. The Department estimates that the savings from the proposed business associate contract language would be approximately $35 million in the first year. The changes being adopted to the sample contract language do not affect these cost estimates.

The Department, in this rulemaking, also gives most covered entities additional time to conform written contracts to the privacy standards. Under the modification, a covered entity's written business associate contracts, existing at the time the modifications become effective, are deemed to comply with the privacy standards until such time as the contracts are renewed or modified, or until April 14, 2004, whichever is earlier. The effect of this proposal is to spread first-year costs over an additional year, with a corresponding postponement of the costs estimated for the out years. However, the Department has no reliable information as to the number of contracts potentially affected by the modification or the average delay that will occur. Therefore, the Department is uncertain about the extent of the cost savings attributable to this modification.

*Response to Public Comments*

*Comment:* While many commenters supported the business associate transition provisions as helpful to reducing the administrative burden and cost of compliance, commenters argued that the business associate provisions would still be very burdensome and costly to implement, especially for small and solo businesses.

*Response:* The Department acknowledges that there are compliance costs associated with the business associate standards. However, no commenters supplied empirical, direct evidence in support of or contradictory to the Department's estimates of the cost savings associated with the business associate transition provisions. Therefore, our estimates remain unchanged.

*Comment:* Some commenters disputed the estimated costs of complying with the business associate requirements based on the quantity of contracts (with suppliers, physicians, local agencies and national concerns), and the number of hours necessary to individually tailor and renegotiate all of these contracts.

*Response:* These comments address the underlying costs of the business associate requirements and do not address the reduction in costs afforded through the sample business associate agreement language. Moreover, no empirical, direct evidence, based on accomplished workload rather than extrapolations of singular events, were provided to contradict the Department's calculations. Therefore, our estimates remain unchanged.

4. Marketing

Under § 164.514(e) of the December 2000 Privacy Rule, certain health-related communications were subject to special conditions on marketing communications, if they also served to promote the use or sale of a product or service. These marketing conditions required that particular disclosures be made as part of the marketing materials sent to individuals. Absent these disclosures, protected health information could only be used or disclosed in connection with such marketing communications with the individual's authorization. The Department is aware that the Privacy Rule's § 164.514(e) conditions for health-related communications created a potential burden on covered entities to make difficult assessments regarding many of their communications. The modifications to the marketing provisions relieve the burden on covered entities by making most marketing subject to an authorization requirement (*see* § 164.508(a)(3)), making clear that necessary treatment and health care operations activities were not marketing, and eliminating the § 164.514(e) conditions on marketing communications.

In developing the December 2000 impact analysis for the Privacy Rule, the Department was unable to estimate the cost of the marketing provisions. There was too little data and too much variation in current practice to estimate how the Privacy Rule might affect marketing. The same remains true today. However, the modifications relieve burden on the covered entities in making communications for treatment and certain health care operations relative to the requirements in the Privacy Rule. Although the Department cannot provide a quantifiable estimate, the effect of these modifications is to lower the costs associated with the Privacy Rule.

*Response to Public Comment*

*Comment:* Many providers, especially mental health providers, opposed the changes to marketing and consent as they fear increased access to individually identifiable health information would cause patients to refrain from seeking treatment. By not seeking timely treatment, the medical conditions could worsen, and result in increased or additional costs to society.

*Response:* The commenters did not attempt to segment out the cost attributed to marketing alone. In fact, no empirical, direct evidence on the estimates of financial impact that either supported or contradicted the Department's calculations was provided. Therefore, our estimates remain unchanged.

5. Research

In the final impact analysis of the December 2000 Privacy Rule, the Department estimated the total cost of the provisions requiring documentation of an Institutional Review Board (IRB) or Privacy Board waiver of individual authorization for the use or disclosure of protected health information for a research purpose as $40 million for the first year and $585 million for the ten-year period. The costs were estimated based on the time that an IRB or Privacy Board would need to consider a request for a waiver under the criteria provided in the Privacy Rule. *See* 65 FR 82770–82771 (December 28, 2000).

The modifications simplify and reduce the number of criteria required for an IRB or Privacy Board to approve a waiver of authorization to better conform to the Common Rule's waiver criteria for informed consent to participate in the research study. The Department estimates that the net effect of these modifications is to reduce the time necessary to assemble the waivers and for an IRB or Privacy Board to consider and act on waiver requests by one quarter. The Department estimates these simplifications would reduce the expected costs first year costs by $10 million and the ten year costs by $146 million, relative to the December 2000 Privacy Rule. Although the Department requested information to better assess this cost savings, the public comment period failed to produce any sound data. Therefore, the Department's estimates have not changed.

The Department adopts three other modifications to simplify the Privacy Rule requirements to relieve the potential administrative burden on research. First, the modifications permit a covered entity to use and disclose protected health information in the form of a limited data set for research, public health, and health care operations. A limited data set does not contain any direct identifiers of individuals, but may contain any other demographic or health information needed for research, public health or health care operations purposes. The covered entity must obtain a data use agreement from the recipient of a limited data set pursuant to which the recipient agrees to restrict use and disclosure of the limited data set and not to identify or contact any individual. With a data use agreement, a researcher may access a limited data set without obtaining individual authorization or having to go through an IRB or a Privacy Board for a waiver of the authorization. (*See* discussion at III.G.2.) Second, the modifications simplify the accounting procedures for research disclosures by the covered entity by eliminating the need to account for disclosures which the individual has authorized or which are part of a limited data set, and by providing a simplified basis to account for a research disclosure involving 50 or more records. (*See* discussion at III.F.2.) Third, the modifications simplify the authorization process for research to facilitate the combining of the informed consent for participation in the research itself with an authorization required under the Privacy Rule. (*See* discussion at III.E.2.) Any cost savings attributed to the later two modifications would accrue primarily to the covered entity disclosing protected health information for research purposes and, therefore, would not affect the costs estimated here for the impact of the Privacy Rule on IRBs.

With regard to limited data sets, the Department anticipates that the modification will avoid IRBs having to review and approve researchers' requests for waiver of authorization for numerous studies that are undertaken today without IRB review and approval. For example, a researcher may not need IRB approval or waiver of informed consent to collect health information that is linked to the individual only by inclusion of the individual's zip code as this may not be personally identifying information under the Common Rule. However, this information would not be considered de-identified information under the Privacy Rule and it could not be disclosed to the researcher without the individual's authorization or an IRB waiver of that authorization. With the limited data set, research that does not require direct identifiers can continue to go on expeditiously without adding burden to IRBs and Privacy Boards. Similarly, limited data sets, similar to the Hospital Discharge Abstract data, will permit much useful information to be available for research, public health, and health care operations purposes.

Although there was broad support for limited data sets in the comments received by the Department, we do not have sufficient information to estimate the amount of research that currently occurs without IRB review or approval and which, but for the provision on limited data sets, would have had to involved the IRB to meet the use and disclosure requirements of the Privacy Rule. Nor did the comments supply information upon which the Department could reasonably rely in making a estimate of the cost savings. Therefore, the Department does not increase its

estimated savings for research to reflect this modification, although we are confident that the overall impact of the Privacy Rule on research will be much lower based on the modifications adopted in this rulemaking.

*Response to Public Comments*

*Comment:* The Department received a number of comments that argued that the Privacy Rule would increase costs and workloads for researchers and research institutions. One commenter delineated these issues as: (1) An increased difficulty in recruiting research participants; (2) the need for increased IRB scrutiny (and the associated resource costs); and (3) the additional paperwork and documentation required.

*Response:* The Department recognized the impact of the final Privacy Rule on researchers and research institutions and provided a cost estimate for this impact as part of the Final Rule. Likewise, the NPRM offered modifications, such as more closely aligning the Privacy and Common Rule criteria, to ease the burden and, correspondingly, estimated cost savings of these proposed modifications. The specific comments appear to dispute the research cost estimates in the final Rule, as their delineated issues are not reflective of the modifications and cost savings specified in the NPRM. In any event, no reliable empirical, direct information on the estimates of financial impact that either supported or contradicted the Department's calculations was provided. Therefore, our estimates remain unchanged.

PRIVACY RULE MODIFICATIONS—TEN-YEAR COST ESTIMATES

| Policy | Original cost | Modification | Change due to modification |
|---|---|---|---|
| Consent | $103 million | Provision removed | −$103 million.[1] |
| Notice | $391 million | Good faith effort to obtain acknowledgment of receipt. | +$184 million. |
| Marketing | Not scored due to lack of data | Fewer activities constitute marketing | Reduction in cost but magnitude cannot be estimated. |
| Business Associates | $103 million for contract modifications. | Model language provided | −$35 million. |
| Research | $585 million | Waiver requirements simplified | −$146 million. |
| Net Change | | | −$100 million. |

[1] As noted above in the discussion on consent, while the estimated costs of the consent provisions were $103 million, comments have suggested that the costs were likely to be much higher. If these comments are accurate, the cost savings associated with retracting the consent provisions would, therefore, also be significantly higher than $103 million.

*C. Costs to the Federal Government*

The modifications adopted in this Rule will result in small savings to the Federal government relative to the costs that would have occurred under the Privacy Rule. Although there will be some increase in costs for the new requirements for obtaining acknowledgment for receipt of the notice, these costs are at least partially offset by the savings in the elimination of the consent. As discussed above, to the extent concerns are accurate that the costs for the consent provisions are much higher than estimated, the cost savings associated with the retraction of these provisions would, therefore, be significantly higher. The Department does not believe the Federal government engages in significant marketing as defined in the Privacy Rule. The Federal government will have business associates under the Privacy Rule, and, therefore, the sample language proposed in this rulemaking will be of benefit to Federal departments and agencies. The Department has not estimated the Federal government's portion of the $35 million savings it estimated for this change. Similarly, the Federal government, which conducts and sponsors a significant amount of research that is subject to IRBs, will realize some savings as a result of the research modifications in this rulemaking. The Department does not have sufficient information, however, to estimate the Federal government's portion of the total $146 million savings with respect to research modifications.

*D. Costs to State and Local Government*

The modifications also may affect the costs to State and local governments. However, these effects likely will be small. As with the Federal government, State and local governments will have any costs of the additional notice requirement offset by the savings realized by the elimination of the consent requirement. As discussed above, to the extent concerns are accurate that the costs for the consent provisions are much higher than estimated, the cost savings associated with the retraction of these provisions would, therefore, be significantly higher. State and local governments could realize savings from the sample language for business associates and the changes in research, but the savings are likely to be small. The Department does not have sufficient information to estimate the State and local government's share of the net savings from the modifications.

*E. Benefits*

The benefits of various provisions of these modifications will be strong privacy protections for individuals coupled with increased access to quality health care, and ease of compliance with privacy protections by covered entities. The changes will have the benefit of eliminating obstacles that could interfere with patient access to timely and high quality health care. The modifications will also improve quality health care by removing obstacles that may have interfered with research activities that form the basis of advancements in medical technology and provide greater understanding of disease. It is extremely difficult to quantify the benefits of enhanced privacy of medical records and elimination of obstacles to research and quality activities. This section provides examples of the qualitative benefits of these Privacy Rule modifications.

1. Strengthened Notice, Flexible Consent

The new requirement that a covered entity make a good faith attempt to obtain written acknowledgment of the notice of privacy practices will increase privacy protections to patients. The strengthened notice requirement will focus individuals on uses and disclosures of their health information, and assure that individuals have the opportunity to discuss privacy concerns with the health care providers with whom they have direct treatment relationships. Awareness of privacy practices should provide patients with a greater degree of comfort in discussing sensitive personal information with

their doctors. The strengthened notice standard was adopted in tandem with changes to make consent more flexible. The changes to the consent requirement have the benefit of removing significant barriers to health care. In many circumstances, the consent requirement would have resulted in delayed treatment and, in other circumstances, would have required patients to be greatly inconvenienced at a time when they needed care, by forcing additional trips simply to sign consent forms. These modifications have the benefit of removing barriers to access to health care that would have resulted from the consent requirement while preserving important privacy protections in the notice standard.

2. Research

Research is key to the continued availability of high quality health care. The modifications remove potential barriers to research. For example, the modifications streamline the criteria to be used by IRBs or Privacy Boards in approving a waiver of individual authorization for research that could not otherwise be done and ensure the criteria are compatible with similar waiver determinations under the Common Rule. Thus, administrative burdens on IRBs and Privacy Boards are eased, without diminishing the health information privacy and confidentiality standards for research. In addition, the research transition provisions have been modified to ensure that the Privacy Rule does not interfere with ongoing or future research for which an individual has granted permission to use his information. By permitting this research to continue, these modifications make sure that vast research resources continue to be usable for important research that result in development of new medical technology and increased quality of health care.

3. Sharing Information for Quality Activities and Public Health

Health plans and health care providers play a valuable role in assessing the quality of health care and improving health care outcomes. The modifications ensure access to health information needed by covered entities and others involved in quality activities. The increased sharing of information will help to limit medical error rates and to determine appropriate, high quality treatment for specific conditions by encouraging these issues to be studied and allowing benchmarking against similar entities. The modifications, in creating a limited data set, also encourages private entities to continue studies and research in support of public health activities. These activities help reduce the spread and occurrence of diseases.

4. Availability of Information About Treatment Alternatives

Understanding treatment alternatives is an important factor in increasing an individual's involvement in his or her own treatment and making informed health care decisions. By streamlining the marketing requirements, the modifications make it easier for a covered entity to understand that they may share valuable information about treatment alternatives with their patients or enrollees, and the conditions for doing so. These modifications make sure that covered entities will be permitted to continue to share important treatment alternative information that gives patients knowledge about newer, less expensive, and/or more appropriate health care options.

*F. Alternatives*

In July 2001, the Department clarified the Privacy Rule in guidance, where feasible, to resolve some of the issues raised by commenters. Issues that could not adequately be addressed through guidance because of the need for a regulatory change are addressed in this rulemaking. The Department examined a number of alternatives to these modifications. One alternative was to not make any changes to the Privacy Rule, but this option was rejected for the reasons explained throughout the preamble. The Department also considered various alternatives to specific provisions in the development of this final Rule. These alternatives are generally discussed above, where appropriate.

## V. Preliminary Regulatory Flexibility Analysis

The Department also examined the impact of this proposed Rule as required by the Small Business Regulatory Enforcement and Fairness Act (SBREFA) (5 U.S.C. 601, *et seq.*). SBREFA requires agencies to determine whether a rule will have a significant economic impact on a substantial number of small entities.

The law does not define the thresholds to use in implementing the law and the Small Business Administration discourages establishing quantitative criteria. However, the Department has long used two criteria—the number of entities affected and the impact on revenue and costs—for assessing whether a regulatory flexibility analysis is necessary. Department guidelines state that an impact of three to five percent should be considered a significant economic impact. Based on these criteria, the Department has determined that a regulatory flexibility analysis is not required.

As described in the December 2000 Regulatory Flexibility Analysis for the Privacy Rule, most covered entities are small businesses—approximately 465,000. *See* Table A, 65 FR 82780 (December 28, 2000). Lessening the burden for small entities, consistent with the intent of protecting privacy, was an important consideration in developing these modifications. However, as discussed in the Final Regulatory Impact Analysis, above, the net affect of the modifications is an overall savings of approximately $100 million over ten years. Even if all of this savings were to accrue to small entities (an over estimation), the impact per small entity would be *de minimis.*

## VI. Collection of Information Requirements

Under the Paperwork Reduction Act (PRA) of 1995, the Department is required to provide 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that the Department solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of the agency;
- The accuracy of the estimate of the information collection burden;
- The quality, utility, and clarity of the information to be collected; and
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Section A below summarizes the proposed information collection requirements on which we explicitly seek, and will consider, public comment for 30 days. Due to the complexity of this regulation, and to avoid redundancy of effort, we are referring readers to Section V (Final Regulatory Impact Analysis published in the **Federal Register** on December 28, 2000), to review the detailed cost assumptions associated with these PRA requirements.

Section B below references the HIPAA Privacy Rule regulation sections published for 60-day public comment on November 3, 1999, and for 30-day public comment on December 28, 2000,

in compliance with the PRA public comment process. These earlier publications contained the information collection requirements for these sections as required by the PRA. The portions of the Privacy Rule, included by reference only in Section B, have not changed subsequent to the two public comment periods. Thus, the Department has fulfilled its statutory obligation to solicit public comment on the information collection requirements for these provisions. The information in Section B is pending OMB PRA approval, but is not reopened for comment. However, for clarity purposes, we will upon this publication submit to OMB for PRA review and approval the entire set of information collection requirements required referenced in §§ 160.204, 160.306, 160.310, 164.502, 164.504, 164.506, 164.508, 164.510, 164.512, 164.514, 164.520, 164.522, 164.524, 164.526, 164.528, and 164.530.

*Section A*

1. Section 164.506—Consent for Treatment, Payment, and Health Care Operations

Under the Privacy Rule, as issued in December 2000, a covered health care provider that has a direct treatment relationship with individuals would have had, except in certain circumstances, to obtain an individual's consent to use or disclose protected health information to carry out treatment, payment, and health care operations. The amended final Rule eliminates this requirement.

2. Section 164.520—Notice of Privacy Practices for Protected Health Information

The amended final Privacy Rule imposes a good faith effort on direct treatment providers to obtain an individual's acknowledgment of receipt of the entity's notice of privacy practices for protected health information, and to document such acknowledgment or, in the absence of such acknowledgment, the entity's good faith efforts to obtain it.

The underlying requirements for notice of privacy practices for protected health information are not changed. These requirements provide that, except in certain circumstances set forth in this section of the Rule, individuals have a right to adequate notice of the uses and disclosures of protected health information that may be made by the covered entity, and of the individual's rights and the covered entity's legal duties with respect to protected health information. To comply with this requirement a covered entity must provide a notice, written in plain language, that includes the elements set forth at § 164.520(b). For health plans, there will be an average of 160.2 million notices each year. We assume that the most efficient means of distribution for health plans will be to send them out annually as part of the materials they send to current and potential enrollees, even though it is not required by the regulation. The number of notices per health plan per year would be about 10,570. We further estimate that it will require each health plan, on average, only 10 seconds to disseminate each notice. The total annual burden associated with this requirement is calculated to be 267,000 hours.

Health care providers with direct treatment relationships would:

- Provide a copy of the notice to an individual at the time of first service delivery to the individual;
- Make the notice available at the service delivery site for individuals to request and take with them;
- Whenever the content of the notice is revised, make it available upon request and post it, if required by this section, in a location where it is reasonable to expect individuals seeking services from the provider to be able to read the notice.

The annual number of notices disseminated by all providers is 613 million. We further estimate that it will require each health care provider, on average, 10 seconds to disseminate each notice. This estimate is based upon the assumption that the required notice will be incorporated into and disseminated with other patient materials. The total annual burden associated with this requirement is calculated to be 1 million hours. However, the amended final Privacy Rule also imposes a good faith effort on direct treatment providers to obtain an individual's acknowledgment of receipt of the provider's notice, and to document such acknowledgment or, in the absence of such acknowledgment, the provider's good faith efforts to obtain it. The estimated burden for the acknowledgment of receipt of the notice is 10 seconds for each notice. This is based on the fact that the provider does not need to take elaborate steps to receive acknowledgment. Initialing a box on an existing form or some other simple means will suffice. With the annual estimate of 613,000,000 acknowledgment forms it is estimated that the acknowledgment burden is 1,000,000 hours.

A covered entity is also required to document compliance with the notice requirements by retaining copies of the versions of the notice issued by the covered entity, and a direct treatment provider is required to retain a copy of each individual's acknowledgment or documentation of the good faith effort as required by § 164.530(j).

3. Appendix to Preamble—Sample Business Associate Contract Provisions

The Department also solicits public comments on the collection of information requirements associated with the model business associate contract language displayed in the Appendix to this preamble Rule. The language displayed has been changed in response to comments on the language that was published with the Notice of Proposed Rulemaking on March 27, 2002. The Department provided the model business associate contract provisions in response to numerous requests for guidance. These provisions were designed to help covered entities more easily comply with the business associate contract requirements of the Privacy Rule. However, use of these model provisions is not required for compliance with the Privacy Rule. Nor is the model language a complete contract. Rather, the model language is designed to be adapted to the business arrangement between the covered entity and the business associate and to be incorporated into a contract drafted by the parties.

*Section B*

As referenced above, the Department has complied with the public comment process as it relates to the information collection requirements contained in the sections of regulation referenced below. The Department is referencing this information solely for the purposes of providing an overview of the regulation sections containing information collection requirements established by the final Privacy Rule.

Section 160.204—Process for Requesting Exception Determinations
Section 160.306—Complaints to the Secretary
Section 160.310—Responsibilities of Covered Entities
Section 164.502—Uses and Disclosures of Protected Health Information: General Rules
Section 164.504—Uses and Disclosures—Organizational Requirements
Section 164.508—Uses and Disclosures for Which Individual Authorization Is Required
Section 164.510—Uses and Disclosures Requiring an Opportunity for the Individual to Agree or to Object
Section 164.512—Uses and Disclosures for Which Consent, an Authorization, or Opportunity to Agree or Object is Not Required
Section 164.514—Other Procedural Requirements Relating to Uses and

Disclosures of Protected Health Information
Section 164.522—Rights to Request Privacy Protection for Protected Health Information
Section 164.524—Access of Individuals to Protected Health Information
Section 164.526—Amendment of Protected Health Information
Section 164.528—Accounting for Disclosures of Protected Health Information
Section 164.530—Administrative Requirements

*C. Comments on Information Collection Requirements in Section A*

The Department has submitted a copy of these modifications to the Privacy Rule to OMB for its review and approval of the information collection requirements summarized in Section A above. If you comment on any of the modifications to the information collection and record keeping requirements in §§ 164.506, 164.520, and/or the model business associate contract language please mail copies directly to the following:

Center for Medicaid and Medicare Services, Information Technology Investment Management Group, Division of CMS Enterprise Standards, Room C2–26–17, 7500 Security Boulevard, Baltimore, MD 21244–1850, ATTN: John Burke, HIPAA Privacy,
and
Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, ATTN: Brenda Aguilar, CMS Desk Officer.

**VII. Unfunded Mandates**

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in an expenditure by State, local, or tribal governments, in the aggregate, or by the private sector, of $110 million in a single year. A final cost-benefit analysis was published in the Privacy Rule of December 28, 2000 (65 FR 82462, 82794). In developing the final Privacy Rule, the Department adopted the least burdensome alternatives, consistent with achieving the Rule's goals. The Department does not believe that the amendments to the Privacy Rule would qualify as an unfunded mandate under the statute.

**VIII. Environmental Impact**

The Department has determined under 21 CFR 25.30(k) 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.

**IX. Executive Order 13132: Federalism**

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. The Federalism implications of the Privacy Rule were assessed as required by Executive Order 13132 and published in the Privacy Rule of December 28, 2000 (65 FR 82462, 82797). The amendments with the most direct effect on Federalism principles concerns the clarifications regarding the rights of parents and minors under State law.

The amendments make clear the intent of the Department to defer to State law with respect to such rights. Therefore, the Department believes that the amended Privacy Rule would not significantly affect the rights, roles and responsibilities of States.

**X. Sample Business Associate Contract Provisions—Appendix**

*March 2002 NPRM.* In response to requests for guidance, the Department provided sample language for business associate contracts. The provisions were provided as an appendix to the preamble and were intended to serve as guidance for covered entities to assist in compliance with the business associate provisions of the Privacy Rule. The proposal was not a model contract, but rather was sample language that could be included in a contract.

*Overview of Public Comment.* The Department received a small number of comments addressing the sample business associate contract provisions. The comments fell into four general categories. Most commenters were pleased with the Department's guidance for business associate contracts and expressed appreciation for such guidance. There were some commenters that thought the language was insufficient and requested the Department create a complete model contract not just sample provisions. The third category of commenters thought the provisions went further than the requirements in the regulation and requested specific changes to the sample language. In addition, a few commenters requested that the Department withdraw the sample provisions asserting that they will eliminate the potential of negotiating or establishing a business associate contract that is tailored to the precise requirements of the particular relationship.

*Final Modifications.* This Rule continues to include sample business associate contract provisions as an appendix to the preamble, because the majority of commenters that addressed this subject found these provisions to be helpful guidance in their compliance efforts with the business associate contract requirements in the Privacy Rule.

The Department has made several changes to the language originally proposed in response to comment. Although these are only sample provisions, the changes, which are described below, should help to clear up some confusion.

First, the Department has changed the name from ''model language'' to ''sample language'' to clarify that the provisions are merely sample clauses, and that none are required to be in a business associate contract so long as the contract meets the requirements of the regulation. The sample language continues to indicate, using square brackets, those instances in which a provision or phrase in a provision applies only in certain circumstances or is optional.

The Department has made three modifications in the Obligations and Activities of the Business Associate provisions. First, there are modifications to clarify that the parties can negotiate appropriate terms regarding the time and manner of providing access to protected health information in a designated record set, providing information to account for disclosures of protected health information, and for making amendments to protected health information in a designated record set. Although the language clarifies that the terms are to be negotiated by the Parties, the agreement must permit the covered entity to comply with its obligations under the Privacy Rule.

Second, the Department has amended the sample language regarding review of business associate practices, books, and records to clarify that the contract must permit the Secretary, not the covered entity, to have access to such records, including protected health information, for purposes of determining the covered entity's compliance with the Privacy Rule. The sample language continues to include the option that parties additionally agree that the business associate shall disclose this information to the covered entity for compliance purposes to indicate that this is still an appropriate approach for this purpose. The modifications also clarify that parties can negotiate the time and manner of providing the covered entity with access to the business associate's internal practices, books, and records.

Finally, the Department has modified the sample language to clarify that business associates are only required to notify the covered entity of uses and disclosures of protected health information not provided for by the agreement of which it becomes aware in order to more closely align the sample contract provisions with the regulation text. The Department did not intend to imply a different standard than that included in the regulation.

The Department has modified the General Use and Disclosure sample language to clarify that there are two possible approaches, and that in each approach the use or disclosure of protected health information by a business associate shall be consistent with the minimum necessary policies and procedures of the covered entity.

The Department has adopted one change to the sample language under Specific Use and Disclosure that clarifies that a permitted specific use of protected health information by the business associate includes reporting violations of law to appropriate Federal and State authorities. This would permit a business associate to use or disclose protected health information in accordance with the standards in § 164.502(j)(1). We indicate that this is optional text, not required by the Privacy Rule. Because we have included this language as sample language, we have deleted discussion of this issue in the statement preceding the sample business associate contract provisions.

Under Obligations of Covered Entity, the Department has clarified that covered entities need only notify business associates of a restriction to the use or disclosure of protected health information in its notice of privacy practices to the extent that such restriction may affect the business associates' use or disclosure of protected health information. The other provisions requiring the covered entity to notify the business associate of restrictions to the use or disclosure of protected health information remain and have been modified to include similar limiting language.

In the Term and Termination provisions, the Department has added clarifying language that indicates that if neither termination nor cure are feasible, the covered entity shall report the violation to the Secretary. We have also clarified that the parties should negotiate how they will determine whether the return or destruction of protected health information is infeasible.

Finally, the Department has clarified the miscellaneous provision regarding interpretation to clarify that ambiguities shall be resolved to permit the covered entity's compliance with the Privacy Rule.

Each entity should carefully analyze each of the sample provisions to ensure that it is appropriate given the specific business associate relationship. Some of the modifications are intended to address some commenters concerns that the sample language is weighted too heavily in favor of the covered entity. Individual parties are reminded that all contract provisions are subject to negotiation, provided that they are consistent with the requirements in the Privacy Rule. The sample language is not intended to, and cannot, substitute for responsible legal advice.

*Response to Other Public Comments*

*Comment:* Several commenters noted that the sample language was missing certain required contractual elements, such as an effective date, insurance and indemnification clauses, procedures for amending the contract, as well as other provisions that may be implicated by the Privacy Rule, such as the Electronic Transactions Standards. Some of these commenters requested that the guidance be a complete model contract rather than sample contract provisions so that the covered entity would not need legal assistance.

*Response:* The Department intentionally did not make this guidance a complete model contract, but rather provided only those provisions specifically tied to requirements of the Privacy Rule. As stated above, this guidance does not substitute for legal advice. Other contract provisions may be dictated by State or other law or by the relationship between the parties. It is not feasible to provide sample contracts that would accommodate each situation. Parties are free to negotiate additional terms, including those that may be required by other laws or regulations.

*Comment:* Some commenters requested that use of the sample business associate contract language create a safe harbor for an entity that adopts them.

*Response:* The sample business associate contract provisions are not a safe harbor. Rather, the sample language is intended to provide guidance and assist covered entities in the effort required to enter into a business associate agreement. Use of the sample provisions or similar provisions, where appropriate, would be considered strong evidence of compliance with the business associate contract provisions of the Privacy Rule. However, contracts will necessarily vary based on State law and the relationship between the covered entity and the business associate.

*Comment:* Some commenters were concerned that the sample provision permitting a covered entity to have access to the practices, books, and records of the business associate would impose an audit requirement on the covered entity.

*Response:* The sample business associate contract provisions do not impose any additional requirements on covered entities. Only the regulation imposes requirements. Therefore, the inclusion of the provision that the business associate shall allow the covered entity access to the business associate practices, books, and records does not indicate that the Privacy Rule imposes an audit requirement on the covered entity. We have stated numerous times that the Privacy Rule does not require covered entities to monitor the activities of their business associates.

*Comment:* One commenter noted that the business associate should not be required, under the contract, to mitigate damages resulting from a violation.

*Response:* We disagree. In order for a covered entity to be able to act as it is required to under the Privacy Rule when a business associate is holding protected health information, the covered entity must require the same activities of the business associate through the contract.

*Comment:* One commenter noted that the Privacy Rule does not explicitly direct that a covered entity provide its notice of privacy practices to its business associates.

*Response:* We agree and have modified the language in the sample provision accordingly. However, in order for the business associate to act consistently with the privacy practices of the covered entity, which is required by the Privacy Rule, the parties may find it necessary to require disclosure of these policies. To the extent that parties can craft an alternate approach, they are free to do so.

*Comment:* One commenter indicated that traditional contract terms such as ''term'' and ''termination'' should not be included in the sample language if the Department's intention is to address only those terms required by the Rule.

*Response:* Because termination of the business associate agreement is specifically addressed in the Privacy Rule, we have retained these provisions in the sample language. As with all other provisions, parties are free to negotiate alternative Term and Termination provisions that meet their unique situations and concerns,

provided that they meet the requirements of the Privacy Rule.

*Comment:* Another commenter indicated that the sample language should not require the return or destruction of protected health information in the possession of subcontractors or agents of the business associate.

*Response:* We have retained this language as this is consistent with the Privacy Rule. Section 164.504(e)(2)(ii)(D) requires that the business associate contract include a provision that the business associate ensures that any agents, including subcontractors, agree to the same restrictions and conditions as the business associate. Generally, the contract must require the business associate to return or destroy protected health information; therefore, the contract also must require the business associate to have agents and subcontractors to do the same. This is reflected in the sample contract language.

*Comment:* One commenter requested that the sample language include a provision that the covered entity may impose monetary damages on a business associate for violation of its privacy policies.

*Response:* We have not included such a provision because the Privacy Rule does not address this issue. The Privacy Rule would not prohibit a monetary damages provision from being included in the contract. This, again, is a matter to be negotiated between covered entities and their business associates.

*Comment:* One commenter suggested that specific references to sections in the Rule be deleted and either replaced by a general statement that the contract shall be interpreted in a manner consistent with the Rule or supplemented with clarifying language with examples.

*Response:* We believe that using section reference is a valid and expeditious approach as it incorporates changes as modifications are made to the Privacy Rule. A business associate contract may take a different approach than using section references to the Privacy Rule.

*Comment:* One commenter asked that the sample business associate contract provisions be included in the Rule rather than published as an appendix to the preamble so that it will be in the Code of Federal Regulations.

*Response:* We have published the sample business associate contract provisions as an appendix to the preamble because they are meant as guidance. The sample language shall be available on the Office for Civil Rights web site at *www.hhs.gov/ocr/hipaa;* and may be updated or revised as necessary.

**Appendix to the Preamble—Sample Business Associate Contract Provisions**

*Statement of Intent*

The Department provides these sample business associate contract provisions in response to numerous requests for guidance. This is only sample language. These provisions are designed to help covered entities more easily comply with the business associate contract requirements of the Privacy Rule. However, use of these sample provisions is not required for compliance with the Privacy Rule. The language may be amended to more accurately reflect business arrangements between the covered entity and the business associate.

These or similar provisions may be incorporated into an agreement for the provision of services between the entities or they may be incorporated into a separate business associate agreement. These provisions only address concepts and requirements set forth in the Privacy Rule and alone are not sufficient to result in a binding contract under State law. They do not include many formalities and substantive provisions that are required or typically included in a valid contract. Reliance on this sample is not sufficient for compliance with State law and does not replace consultation with a lawyer or negotiations between the parties to the contract.

Furthermore, a covered entity may want to include other provisions that are related to the Privacy Rule but that are not required by the Privacy Rule. For example, a covered entity may want to add provisions in a business associate contract in order for the covered entity to be able to rely on the business associate to help the covered entity meet its obligations under the Privacy Rule. In addition, there may be permissible uses or disclosures by a business associate that are not specifically addressed in these sample provisions, for example having a business associate create a limited data set. These and other types of issues will need to be worked out between the parties.

*Sample Business Associate Contract Provisions* [3]

Definitions (Alternative Approaches)

*Catch-all definition:*

Terms used, but not otherwise defined, in this Agreement shall have the same meaning as those terms in the Privacy Rule.

*Examples of specific definitions:*

(a) *Business Associate.* ''Business Associate'' shall mean [Insert Name of Business Associate].

(b) *Covered Entity.* ''Covered Entity'' shall mean [Insert Name of Covered Entity].

(c) *Individual.* ''Individual'' shall have the same meaning as the term ''individual'' in 45 CFR 164.501 and shall include a person who qualifies as a personal representative in accordance with 45 CFR 164.502(g).

(d) *Privacy Rule.* ''Privacy Rule'' shall mean the Standards for Privacy of Individually Identifiable Health Information at 45 CFR part 160 and part 164, subparts A and E.

(e) *Protected Health Information.* ''Protected Health Information'' shall have the same meaning as the term ''protected health information'' in 45 CFR 164.501, limited to the information created or received by Business Associate from or on behalf of Covered Entity.

(f) *Required By Law.* ''Required By Law'' shall have the same meaning as the term ''required by law'' in 45 CFR 164.501.

(g) *Secretary.* ''Secretary'' shall mean the Secretary of the Department of Health and Human Services or his designee.

Obligations and Activities of Business Associate

(a) Business Associate agrees to not use or disclose Protected Health Information other than as permitted or required by the Agreement or as Required By Law.

(b) Business Associate agrees to use appropriate safeguards to prevent use or disclosure of the Protected Health Information other than as provided for by this Agreement.

(c) Business Associate agrees to mitigate, to the extent practicable, any harmful effect that is known to Business Associate of a use or disclosure of Protected Health Information by Business Associate in violation of the requirements of this Agreement. [This provision may be included if it is appropriate for the Covered Entity to pass on its duty to mitigate damages to a Business Associate.]

(d) Business Associate agrees to report to Covered Entity any use or disclosure of the Protected Health Information not provided for by this Agreement of which it becomes aware.

(e) Business Associate agrees to ensure that any agent, including a

[3] Words or phrases contained in brackets are intended as either optional language or as instructions to the users of these sample provisions and are not intended to be included in the contractual provisions.

subcontractor, to whom it provides Protected Health Information received from, or created or received by Business Associate on behalf of Covered Entity agrees to the same restrictions and conditions that apply through this Agreement to Business Associate with respect to such information.

(f) Business Associate agrees to provide access, at the request of Covered Entity, and in the time and manner [Insert negotiated terms], to Protected Health Information in a Designated Record Set, to Covered Entity or, as directed by Covered Entity, to an Individual in order to meet the requirements under 45 CFR 164.524. [Not necessary if business associate does not have protected health information in a designated record set.]

(g) Business Associate agrees to make any amendment(s) to Protected Health Information in a Designated Record Set that the Covered Entity directs or agrees to pursuant to 45 CFR 164.526 at the request of Covered Entity or an Individual, and in the time and manner [Insert negotiated terms]. [Not necessary if business associate does not have protected health information in a designated record set.]

(h) Business Associate agrees to make internal practices, books, and records, including policies and procedures and Protected Health Information, relating to the use and disclosure of Protected Health Information received from, or created or received by Business Associate on behalf of, Covered Entity available [to the Covered Entity, or] to the Secretary, in a time and manner [Insert negotiated terms] or designated by the Secretary, for purposes of the Secretary determining Covered Entity's compliance with the Privacy Rule.

(i) Business Associate agrees to document such disclosures of Protected Health Information and information related to such disclosures as would be required for Covered Entity to respond to a request by an Individual for an accounting of disclosures of Protected Health Information in accordance with 45 CFR 164.528.

(j) Business Associate agrees to provide to Covered Entity or an Individual, in time and manner [Insert negotiated terms], information collected in accordance with Section [Insert Section Number in Contract Where Provision (i) Appears] of this Agreement, to permit Covered Entity to respond to a request by an Individual for an accounting of disclosures of Protected Health Information in accordance with 45 CFR 164.528.

*Permitted Uses and Disclosures by Business Associate*

General Use and Disclosure Provisions [(a) and (b) are alternative approaches]

(a) *Specify purposes:*

Except as otherwise limited in this Agreement, Business Associate may use or disclose Protected Health Information on behalf of, or to provide services to, Covered Entity for the following purposes, if such use or disclosure of Protected Health Information would not violate the Privacy Rule if done by Covered Entity or the minimum necessary policies and procedures of the Covered Entity: [List Purposes].

(b) *Refer to underlying services agreement:*

Except as otherwise limited in this Agreement, Business Associate may use or disclose Protected Health Information to perform functions, activities, or services for, or on behalf of, Covered Entity as specified in [Insert Name of Services Agreement], provided that such use or disclosure would not violate the Privacy Rule if done by Covered Entity or the minimum necessary policies and procedures of the Covered Entity.

*Specific Use and Disclosure Provisions [only necessary if parties wish to allow Business Associate to engage in such activities]*

(a) Except as otherwise limited in this Agreement, Business Associate may use Protected Health Information for the proper management and administration of the Business Associate or to carry out the legal responsibilities of the Business Associate.

(b) Except as otherwise limited in this Agreement, Business Associate may disclose Protected Health Information for the proper management and administration of the Business Associate, provided that disclosures are Required By Law, or Business Associate obtains reasonable assurances from the person to whom the information is disclosed that it will remain confidential and used or further disclosed only as Required By Law or for the purpose for which it was disclosed to the person, and the person notifies the Business Associate of any instances of which it is aware in which the confidentiality of the information has been breached.

(c) Except as otherwise limited in this Agreement, Business Associate may use Protected Health Information to provide Data Aggregation services to Covered Entity as permitted by 42 CFR 164.504(e)(2)(i)(B).

(d) Business Associate may use Protected Health Information to report violations of law to appropriate Federal and State authorities, consistent with § 164.502(j)(1).

*Obligations of Covered Entity*

Provisions for Covered Entity To Inform Business Associate of Privacy Practices and Restrictions [provisions dependent on business arrangement]

(a) Covered Entity shall notify Business Associate of any limitation(s) in its notice of privacy practices of Covered Entity in accordance with 45 CFR 164.520, to the extent that such limitation may affect Business Associate's use or disclosure of Protected Health Information.

(b) Covered Entity shall notify Business Associate of any changes in, or revocation of, permission by Individual to use or disclose Protected Health Information, to the extent that such changes may affect Business Associate's use or disclosure of Protected Health Information.

(c) Covered Entity shall notify Business Associate of any restriction to the use or disclosure of Protected Health Information that Covered Entity has agreed to in accordance with 45 CFR 164.522, to the extent that such restriction may affect Business Associate's use or disclosure of Protected Health Information.

Permissible Requests by Covered Entity

Covered Entity shall not request Business Associate to use or disclose Protected Health Information in any manner that would not be permissible under the Privacy Rule if done by Covered Entity. [Include an exception if the Business Associate will use or disclose protected health information for, and the contract includes provisions for, data aggregation or management and administrative activities of Business Associate].

Term and Termination

(a) *Term.* The Term of this Agreement shall be effective as of [Insert Effective Date], and shall terminate when all of the Protected Health Information provided by Covered Entity to Business Associate, or created or received by Business Associate on behalf of Covered Entity, is destroyed or returned to Covered Entity, or, if it is infeasible to return or destroy Protected Health Information, protections are extended to such information, in accordance with the termination provisions in this Section. [Term may differ.]

(b) *Termination for Cause.* Upon Covered Entity's knowledge of a material breach by Business Associate, Covered Entity shall either:

(1) Provide an opportunity for Business Associate to cure the breach or

end the violation and terminate this Agreement [and the ___ Agreement/ sections __ of the ___ Agreement] if Business Associate does not cure the breach or end the violation within the time specified by Covered Entity;

(2) Immediately terminate this Agreement [and the ___ Agreement/ sections __ of the ___ Agreement] if Business Associate has breached a material term of this Agreement and cure is not possible; or

(3) If neither termination nor cure are feasible, Covered Entity shall report the violation to the Secretary. [Bracketed language in this provision may be necessary if there is an underlying services agreement. Also, opportunity to cure is permitted, but not required by the Privacy Rule.]

(c) *Effect of Termination.*

(1) Except as provided in paragraph (2) of this section, upon termination of this Agreement, for any reason, Business Associate shall return or destroy all Protected Health Information received from Covered Entity, or created or received by Business Associate on behalf of Covered Entity. This provision shall apply to Protected Health Information that is in the possession of subcontractors or agents of Business Associate. Business Associate shall retain no copies of the Protected Health Information.

(2) In the event that Business Associate determines that returning or destroying the Protected Health Information is infeasible, Business Associate shall provide to Covered Entity notification of the conditions that make return or destruction infeasible. Upon [Insert negotiated terms] that return or destruction of Protected Health Information is infeasible, Business Associate shall extend the protections of this Agreement to such Protected Health Information and limit further uses and disclosures of such Protected Health Information to those purposes that make the return or destruction infeasible, for so long as Business Associate maintains such Protected Health Information.

*Miscellaneous*

(a) *Regulatory References.* A reference in this Agreement to a section in the Privacy Rule means the section as in effect or as amended.

(b) *Amendment.* The Parties agree to take such action as is necessary to amend this Agreement from time to time as is necessary for Covered Entity to comply with the requirements of the Privacy Rule and the Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104–191.

(c) *Survival.* The respective rights and obligations of Business Associate under Section [Insert Section Number Related to ''Effect of Termination''] of this Agreement shall survive the termination of this Agreement.

(d) *Interpretation.* Any ambiguity in this Agreement shall be resolved to permit Covered Entity to comply with the Privacy Rule.

**List of Subjects**

*45 CFR Part 160*

Electronic transactions, Employer benefit plan, Health, Health care, Health facilities, Health insurance, Health records, Medicaid, Medical research, Medicare, Privacy, Reporting and record keeping requirements.

*45 CFR Part 164*

Electronic transactions, Employer benefit plan, Health, Health care, Health facilities, Health insurance, Health records, Medicaid, Medical research, Medicare, Privacy, Reporting and record keeping requirements.

Dated: August 6, 2002.

**Tommy G. Thompson,**

*Secretary.*

For the reasons set forth in the preamble, the Department amends 45 CFR subtitle A, subchapter C, as follows:

## PART 160—GENERAL ADMINISTRATIVE REQUIREMENTS

1. The authority citation for part 160 continues to read as follows:

**Authority:** Sec. 1171 through 1179 of the Social Security Act (42 U.S.C. 1320d–1329d–8), as added by sec. 262 of Pub. L. No. 104–191, 110 Stat. 2021–2031 and sec. 264 of Pub. L. No. 104–191 (42 U.S.C. 1320d–2(note)).

2. Amend § 160.102(b), by removing the phrase ''section 201(a)(5) of the Health Insurance Portability Act of 1996, (Pub. L. No. 104–191)'' and adding in its place the phrase ''the Social Security Act, 42 U.S.C. 1320a–7c(a)(5)''.

3. In § 160.103 add the definition of ''individually identifiable health information'' in alphabetical order to read as follows:

**§ 160.103 Definitions.**

* * * * *

*Individually identifiable health information* is information that is a subset of health information, including demographic information collected from an individual, and:

(1) Is created or received by a health care provider, health plan, employer, or health care clearinghouse; and

(2) Relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and

(i) That identifies the individual; or

(ii) With respect to which there is a reasonable basis to believe the information can be used to identify the individual.

* * * * *

4. In § 160.202 revise paragraphs (2) and (4) of the definition of ''more stringent'' to read as follows:

**§ 160.202 Definitions.**

* * * * *

*More stringent* means * * *

(2) With respect to the rights of an individual, who is the subject of the individually identifiable health information, regarding access to or amendment of individually identifiable health information, permits greater rights of access or amendment, as applicable.

* * * * *

(4) With respect to the form, substance, or the need for express legal permission from an individual, who is the subject of the individually identifiable health information, for use or disclosure of individually identifiable health information, provides requirements that narrow the scope or duration, increase the privacy protections afforded (such as by expanding the criteria for), or reduce the coercive effect of the circumstances surrounding the express legal permission, as applicable.

* * * * *

5. Amend § 160.203(b) by adding the words ''individually identifiable'' before the word ''health''.

## PART 164—SECURITY AND PRIVACY

### Subpart E—Privacy of Individually Identifiable Health Information

1. The authority citation for part 164 continues to read as follows:

**Authority:** 42 U.S.C. 1320d–2 and 1320d–4, sec. 264 of Pub. L. No. 104–191, 110 Stat. 2033–2034 (42 U.S.C. 1320d–2(note)).

2. Amend § 164.102 by removing the words ''implementation standards'' and adding in its place the words ''implementation specifications.''

3. In § 164.500, remove ''consent,'' from paragraph (b)(1)(v).

4. Amend § 164.501 as follows:

a. In the definition of ''health care operations'' remove from the introductory text of the definition '', and any of the following activities of an

organized health care arrangement in which the covered entity participates'' and revise paragraphs (6)(iv) and (v).

b. Remove the definition of ''individually identifiable health information''.

c. Revise the definition of ''marketing''.

d. In paragraph (1)(ii) of the definition of ''payment,'' remove the word ''covered''.

e. Revise paragraph (2) of the definition of ''protected health information''.

f. Remove the words ''a covered'' and replace them with ''an'' in the definition of ''required by law''.

The revisions read as follows:

**§ 164.501 Definitions.**

* * * * *

*Health care operations* means * * *

(6) * * *

(iv) The sale, transfer, merger, or consolidation of all or part of the covered entity with another covered entity, or an entity that following such activity will become a covered entity and due diligence related to such activity; and

(v) Consistent with the applicable requirements of § 164.514, creating de-identified health information or a limited data set, and fundraising for the benefit of the covered entity.

* * * * *

*Marketing* means:

(1) To make a communication about a product or service that encourages recipients of the communication to purchase or use the product or service, unless the communication is made:

(i) To describe a health-related product or service (or payment for such product or service) that is provided by, or included in a plan of benefits of, the covered entity making the communication, including communications about: the entities participating in a health care provider network or health plan network; replacement of, or enhancements to, a health plan; and health-related products or services available only to a health plan enrollee that add value to, but are not part of, a plan of benefits.

(ii) For treatment of the individual; or

(iii) For case management or care coordination for the individual, or to direct or recommend alternative treatments, therapies, health care providers, or settings of care to the individual.

(2) An arrangement between a covered entity and any other entity whereby the covered entity discloses protected health information to the other entity, in exchange for direct or indirect remuneration, for the other entity or its affiliate to make a communication about its own product or service that encourages recipients of the communication to purchase or use that product or service.

* * * * *

*Protected health information* means * * *

(2) *Protected health information* excludes individually identifiable health information in:

(i) Education records covered by the Family Educational Rights and Privacy Act, as amended, 20 U.S.C. 1232g;

(ii) Records described at 20 U.S.C. 1232g(a)(4)(B)(iv); and

(iii) Employment records held by a covered entity in its role as employer.

* * * * *

5. Amend § 164.502 as follows:

a. Revise paragraphs (a)(1)(ii), (iii), and (vi).

b. Revise paragraph (b)(2)(ii).

c. Redesignate paragraphs (b)(2)(iii) through (v) as paragraphs (b)(2)(iv) through (vi).

d. Add a new paragraph (b)(2)(iii).

e. Redesignate paragraphs (g)(3)(i) through (iii) as (g)(3)(i)(A) through (C) and redesignate paragraph (g)(3) as (g)(3)(i).

f. Add a new paragraph (g)(3)(ii).

The revisions and additions read as follows:

**§ 164.502 Uses and disclosures of protected health information: general rules.**

(a) Standard. * * *

(1) *Permitted uses and disclosures.* * * *

(ii) For treatment, payment, or health care operations, as permitted by and in compliance with § 164.506;

(iii) Incident to a use or disclosure otherwise permitted or required by this subpart, provided that the covered entity has complied with the applicable requirements of § 164.502(b), § 164.514(d), and § 164.530(c) with respect to such otherwise permitted or required use or disclosure;

* * * * *

(vi) As permitted by and in compliance with this section, § 164.512, or § 164.514(e), (f), or (g).

* * * * *

(b) *Standard: Minimum necessary.* * * *

(2) *Minimum necessary does not apply.* * * *

(ii) Uses or disclosures made to the individual, as permitted under paragraph (a)(1)(i) of this section or as required by paragraph (a)(2)(i) of this section;

(iii) Uses or disclosures made pursuant to an authorization under § 164.508;

* * * * *

(g)(1) *Standard: Personal representatives.* * * *

(3) *Implementation specification: unemancipated minors.* * * *

(i) * * *

(ii) Notwithstanding the provisions of paragraph (g)(3)(i) of this section:

(A) If, and to the extent, permitted or required by an applicable provision of State or other law, including applicable case law, a covered entity may disclose, or provide access in accordance with § 164.524 to, protected health information about an unemancipated minor to a parent, guardian, or other person acting *in loco parentis*;

(B) If, and to the extent, prohibited by an applicable provision of State or other law, including applicable case law, a covered entity may not disclose, or provide access in accordance with § 164.524 to, protected health information about an unemancipated minor to a parent, guardian, or other person acting *in loco parentis*; and

(C) Where the parent, guardian, or other person acting *in loco parentis*, is not the personal representative under paragraphs (g)(3)(i)(A), (B), or (C) of this section and where there is no applicable access provision under State or other law, including case law, a covered entity may provide or deny access under § 164.524 to a parent, guardian, or other person acting *in loco parentis,* if such action is consistent with State or other applicable law, provided that such decision must be made by a licensed health care professional, in the exercise of professional judgment.

* * * * *

6. Amend § 164.504 as follows:

a. In paragraph (a), revise the definitions of ''health care component'' and ''hybrid entity''.

b. Revise paragraph (c)(1)(ii).

c. Revise paragraph (c)(2)(ii).

d. Revise paragraph (c)(3)(iii).

e. Revise paragraph (f)(1)(i).

f. Add paragraph (f)(1)(iii).

The revisions and addition read as follows:

**§ 164.504 Uses and disclosures: Organizational requirements.**

(a) *Definitions.* * * *

*Health care component* means a component or combination of components of a hybrid entity designated by the hybrid entity in accordance with paragraph (c)(3)(iii) of this section.

*Hybrid entity* means a single legal entity:

(1) That is a covered entity;

(2) Whose business activities include both covered and non-covered functions; and

(3) That designates health care components in accordance with paragraph (c)(3)(iii) of this section.

* * * * *

(c)(1) *Implementation specification: Application of other provisions.* * * *

(ii) A reference in such provision to a ''health plan,'' ''covered health care provider,'' or ''health care clearinghouse'' refers to a health care component of the covered entity if such health care component performs the functions of a health plan, health care provider, or health care clearinghouse, as applicable; and

* * * * *

(2) *Implementation specifications: Safeguard requirements.* * * *

(ii) A component that is described by paragraph (c)(3)(iii)(B) of this section does not use or disclose protected health information that it creates or receives from or on behalf of the health care component in a way prohibited by this subpart; and

* * * * *

(3) *Implementation specifications: Responsibilities of the covered entity.* * * *

(iii) The covered entity is responsible for designating the components that are part of one or more health care components of the covered entity and documenting the designation as required by § 164.530(j), provided that, if the covered entity designates a health care component or components, it must include any component that would meet the definition of covered entity if it were a separate legal entity. Health care component(s) also may include a component only to the extent that it performs:

(A) Covered functions; or

(B) Activities that would make such component a business associate of a component that performs covered functions if the two components were separate legal entities.

* * * * *

(f)(1) *Standard: Requirements for group health plans.* (i) Except as provided under paragraph (f)(1)(ii) or (iii) of this section or as otherwise authorized under § 164.508, a group health plan, in order to disclose protected health information to the plan sponsor or to provide for or permit the disclosure of protected health information to the plan sponsor by a health insurance issuer or HMO with respect to the group health plan, must ensure that the plan documents restrict uses and disclosures of such information by the plan sponsor consistent with the requirements of this subpart.

* * * * *

(iii) The group health plan, or a health insurance issuer or HMO with respect to the group health plan, may disclose to the plan sponsor information on whether the individual is participating in the group health plan, or is enrolled in or has disenrolled from a health insurance issuer or HMO offered by the plan.

* * * * *

7. Revise § 164.506 to read as follows:

**§ 164.506 Uses and disclosures to carry out treatment, payment, or health care operations.**

(a) *Standard: Permitted uses and disclosures.* Except with respect to uses or disclosures that require an authorization under § 164.508(a)(2) and (3), a covered entity may use or disclose protected health information for treatment, payment, or health care operations as set forth in paragraph (c) of this section, provided that such use or disclosure is consistent with other applicable requirements of this subpart.

(b) *Standard: Consent for uses and disclosures permitted.* (1) A covered entity may obtain consent of the individual to use or disclose protected health information to carry out treatment, payment, or health care operations.

(2) Consent, under paragraph (b) of this section, shall not be effective to permit a use or disclosure of protected health information when an authorization, under § 164.508, is required or when another condition must be met for such use or disclosure to be permissible under this subpart.

(c) *Implementation specifications: Treatment, payment, or health care operations.*

(1) A covered entity may use or disclose protected health information for its own treatment, payment, or health care operations.

(2) A covered entity may disclose protected health information for treatment activities of a health care provider.

(3) A covered entity may disclose protected health information to another covered entity or a health care provider for the payment activities of the entity that receives the information.

(4) A covered entity may disclose protected health information to another covered entity for health care operations activities of the entity that receives the information, if each entity either has or had a relationship with the individual who is the subject of the protected health information being requested, the protected health information pertains to such relationship, and the disclosure is:

(i) For a purpose listed in paragraph (1) or (2) of the definition of health care operations; or

(ii) For the purpose of health care fraud and abuse detection or compliance.

(5) A covered entity that participates in an organized health care arrangement may disclose protected health information about an individual to another covered entity that participates in the organized health care arrangement for any health care operations activities of the organized health care arrangement.

8. Revise § 164.508 to read as follows:

**§ 164.508 Uses and disclosures for which an authorization is required.**

(a) *Standard: authorizations for uses and disclosures.*—(1) *Authorization required: general rule.* Except as otherwise permitted or required by this subchapter, a covered entity may not use or disclose protected health information without an authorization that is valid under this section. When a covered entity obtains or receives a valid authorization for its use or disclosure of protected health information, such use or disclosure must be consistent with such authorization.

(2) *Authorization required: psychotherapy notes.* Notwithstanding any provision of this subpart, other than the transition provisions in § 164.532, a covered entity must obtain an authorization for any use or disclosure of psychotherapy notes, except:

(i) To carry out the following treatment, payment, or health care operations:

(A) Use by the originator of the psychotherapy notes for treatment;

(B) Use or disclosure by the covered entity for its own training programs in which students, trainees, or practitioners in mental health learn under supervision to practice or improve their skills in group, joint, family, or individual counseling; or

(C) Use or disclosure by the covered entity to defend itself in a legal action or other proceeding brought by the individual; and

(ii) A use or disclosure that is required by § 164.502(a)(2)(ii) or permitted by § 164.512(a); § 164.512(d) with respect to the oversight of the originator of the psychotherapy notes; § 164.512(g)(1); or § 164.512(j)(1)(i).

(3) *Authorization required: Marketing.* (i) Notwithstanding any provision of this subpart, other than the transition provisions in § 164.532, a covered entity must obtain an authorization for any use or disclosure of protected health

information for marketing, except if the communication is in the form of:

(A) A face-to-face communication made by a covered entity to an individual; or

(B) A promotional gift of nominal value provided by the covered entity.

(ii) If the marketing involves direct or indirect remuneration to the covered entity from a third party, the authorization must state that such remuneration is involved.

(b) *Implementation specifications: general requirements.*—(1) *Valid authorizations.* (i) A valid authorization is a document that meets the requirements in paragraphs (a)(3)(ii), (c)(1), and (c)(2) of this section, as applicable.

(ii) A valid authorization may contain elements or information in addition to the elements required by this section, provided that such additional elements or information are not inconsistent with the elements required by this section.

(2) *Defective authorizations.* An authorization is not valid, if the document submitted has any of the following defects:

(i) The expiration date has passed or the expiration event is known by the covered entity to have occurred;

(ii) The authorization has not been filled out completely, with respect to an element described by paragraph (c) of this section, if applicable;

(iii) The authorization is known by the covered entity to have been revoked;

(iv) The authorization violates paragraph (b)(3) or (4) of this section, if applicable;

(v) Any material information in the authorization is known by the covered entity to be false.

(3) *Compound authorizations.* An authorization for use or disclosure of protected health information may not be combined with any other document to create a compound authorization, except as follows:

(i) An authorization for the use or disclosure of protected health information for a research study may be combined with any other type of written permission for the same research study, including another authorization for the use or disclosure of protected health information for such research or a consent to participate in such research;

(ii) An authorization for a use or disclosure of psychotherapy notes may only be combined with another authorization for a use or disclosure of psychotherapy notes;

(iii) An authorization under this section, other than an authorization for a use or disclosure of psychotherapy notes, may be combined with any other such authorization under this section, except when a covered entity has conditioned the provision of treatment, payment, enrollment in the health plan, or eligibility for benefits under paragraph (b)(4) of this section on the provision of one of the authorizations.

(4) *Prohibition on conditioning of authorizations.* A covered entity may not condition the provision to an individual of treatment, payment, enrollment in the health plan, or eligibility for benefits on the provision of an authorization, except:

(i) A covered health care provider may condition the provision of research-related treatment on provision of an authorization for the use or disclosure of protected health information for such research under this section;

(ii) A health plan may condition enrollment in the health plan or eligibility for benefits on provision of an authorization requested by the health plan prior to an individual's enrollment in the health plan, if:

(A) The authorization sought is for the health plan's eligibility or enrollment determinations relating to the individual or for its underwriting or risk rating determinations; and

(B) The authorization is not for a use or disclosure of psychotherapy notes under paragraph (a)(2) of this section; and

(iii) A covered entity may condition the provision of health care that is solely for the purpose of creating protected health information for disclosure to a third party on provision of an authorization for the disclosure of the protected health information to such third party.

(5) *Revocation of authorizations.* An individual may revoke an authorization provided under this section at any time, provided that the revocation is in writing, except to the extent that:

(i) The covered entity has taken action in reliance thereon; or

(ii) If the authorization was obtained as a condition of obtaining insurance coverage, other law provides the insurer with the right to contest a claim under the policy or the policy itself.

(6) *Documentation.* A covered entity must document and retain any signed authorization under this section as required by § 164.530(j).

(c) *Implementation specifications: Core elements and requirements.—(1) Core elements.* A valid authorization under this section must contain at least the following elements:

(i) A description of the information to be used or disclosed that identifies the information in a specific and meaningful fashion.

(ii) The name or other specific identification of the person(s), or class of persons, authorized to make the requested use or disclosure.

(iii) The name or other specific identification of the person(s), or class of persons, to whom the covered entity may make the requested use or disclosure.

(iv) A description of each purpose of the requested use or disclosure. The statement ''at the request of the individual'' is a sufficient description of the purpose when an individual initiates the authorization and does not, or elects not to, provide a statement of the purpose.

(v) An expiration date or an expiration event that relates to the individual or the purpose of the use or disclosure. The statement ''end of the research study,'' ''none,'' or similar language is sufficient if the authorization is for a use or disclosure of protected health information for research, including for the creation and maintenance of a research database or research repository.

(vi) Signature of the individual and date. If the authorization is signed by a personal representative of the individual, a description of such representative's authority to act for the individual must also be provided.

(2) *Required statements.* In addition to the core elements, the authorization must contain statements adequate to place the individual on notice of all of the following:

(i) The individual's right to revoke the authorization in writing, and either:

(A) The exceptions to the right to revoke and a description of how the individual may revoke the authorization; or

(B) To the extent that the information in paragraph (c)(2)(i)(A) of this section is included in the notice required by § 164.520, a reference to the covered entity's notice.

(ii) The ability or inability to condition treatment, payment, enrollment or eligibility for benefits on the authorization, by stating either:

(A) The covered entity may not condition treatment, payment, enrollment or eligibility for benefits on whether the individual signs the authorization when the prohibition on conditioning of authorizations in paragraph (b)(4) of this section applies; or

(B) The consequences to the individual of a refusal to sign the authorization when, in accordance with paragraph (b)(4) of this section, the covered entity can condition treatment, enrollment in the health plan, or eligibility for benefits on failure to obtain such authorization.

(iii) The potential for information disclosed pursuant to the authorization to be subject to redisclosure by the recipient and no longer be protected by this subpart.

(3) *Plain language requirement.* The authorization must be written in plain language.

(4) *Copy to the individual.* If a covered entity seeks an authorization from an individual for a use or disclosure of protected health information, the covered entity must provide the individual with a copy of the signed authorization.

9. Amend § 164.510 as follows:

a. Revise the first sentence of the introductory text.

b. Remove the word ''for'' from paragraph (b)(3).

The revision reads as follows:

**§ 164.510 Uses and disclosures requiring an opportunity for the individual to agree or to object.**

A covered entity may use or disclose protected health information, provided that the individual is informed in advance of the use or disclosure and has the opportunity to agree to or prohibit or restrict the use or disclosure, in accordance with the applicable requirements of this section. * * *

* * * * *

10. Amend § 164.512 as follows:

a. Revise the section heading and the first sentence of the introductory text.

b. Revise paragraph (b)(1)(iii).

c. In paragraph (b)(1)(v)(A) remove the word ''a'' before the word ''health.''

d. Add the word ''and'' after the semicolon at the end of paragraph (b)(1)(v)(C).

e. Redesignate paragraphs (f)(3)(ii) and (iii) as (f)(3)(i) and (ii).

f. In the second sentence of paragraph (g)(2) add the word ''to'' after the word ''directors.''

g. In paragraph (i)(1)(iii)(A) remove the word ''is'' after the word ''disclosure.''

h. Revise paragraph (i)(2)(ii).

i. In paragraph (i)(2)(iii) remove ''(i)(2)(ii)(D)'' and add in its place ''(i)(2)(ii)(C)''.

The revisions read as follows:

**§ 164.512 Uses and disclosures for which an authorization or opportunity to agree or object is not required.**

A covered entity may use or disclose protected health information without the written authorization of the individual, as described in § 164.508, or the opportunity for the individual to agree or object as described in § 164.510, in the situations covered by this section, subject to the applicable requirements of this section. * * *

* * * * *

(b) *Standard: uses and disclosures for public health activities.*

(1) *Permitted disclosures.* * * *

(iii) A person subject to the jurisdiction of the Food and Drug Administration (FDA) with respect to an FDA-regulated product or activity for which that person has responsibility, for the purpose of activities related to the quality, safety or effectiveness of such FDA-regulated product or activity. Such purposes include:

(A) To collect or report adverse events (or similar activities with respect to food or dietary supplements), product defects or problems (including problems with the use or labeling of a product), or biological product deviations;

(B) To track FDA-regulated products;

(C) To enable product recalls, repairs, or replacement, or lookback (including locating and notifying individuals who have received products that have been recalled, withdrawn, or are the subject of lookback); or

(D) To conduct post marketing surveillance;

* * * * *

(i) *Standard: Uses and disclosures for research purposes.* * * *

(2) *Documentation of waiver approval.* * * *

(ii) *Waiver criteria.* A statement that the IRB or privacy board has determined that the alteration or waiver, in whole or in part, of authorization satisfies the following criteria:

(A) The use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements;

(*1*) An adequate plan to protect the identifiers from improper use and disclosure;

(*2*) An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and

(*3*) Adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of protected health information would be permitted by this subpart;

(B) The research could not practicably be conducted without the waiver or alteration; and

(C) The research could not practicably be conducted without access to and use of the protected health information.

* * * * *

11. Amend § 164.514 as follows:

a. Revise paragraph (b)(2)(i)(R).

b. Revise paragraph (d)(1).

c. Revise paragraph (d)(4)(iii).

d. In paragraph (d)(5), remove the word ''discloses'' and add in its place the word ''disclose''.

e. Revise paragraph (e).

The revisions read as follows:

**§ 164.514 Other requirements relating to uses and disclosures of protected health information.**

* * * * *

(b) *Implementation specifications: Requirements for de-identification of protected health information.* * * *

(2)(i) * * *

(R) Any other unique identifying number, characteristic, or code, except as permitted by paragraph (c) of this section; and

* * * * *

(d)(1) *Standard: minimum necessary requirements.* In order to comply with § 164.502(b) and this section, a covered entity must meet the requirements of paragraphs (d)(2) through (d)(5) of this section with respect to a request for, or the use and disclosure of, protected health information.

* * * * *

(4) *Implementation specifications: Minimum necessary requests for protected health information.* * * *

(iii) For all other requests, a covered entity must:

(A) Develop criteria designed to limit the request for protected health information to the information reasonably necessary to accomplish the purpose for which the request is made; and

(B) Review requests for disclosure on an individual basis in accordance with such criteria.

* * * * *

(e) (1) *Standard: Limited data set.* A covered entity may use or disclose a limited data set that meets the requirements of paragraphs (e)(2) and (e)(3) of this section, if the covered entity enters into a data use agreement with the limited data set recipient, in accordance with paragraph (e)(4) of this section.

(2) *Implementation specification: Limited data set:* A limited data set is protected health information that excludes the following direct identifiers of the individual or of relatives, employers, or household members of the individual:

(i) Names;

(ii) Postal address information, other than town or city, State, and zip code;

(iii) Telephone numbers;

(iv) Fax numbers;

(v) Electronic mail addresses;
(vi) Social security numbers;
(vii) Medical record numbers;
(viii) Health plan beneficiary numbers;
(ix) Account numbers;
(x) Certificate/license numbers;
(xi) Vehicle identifiers and serial numbers, including license plate numbers;
(xii) Device identifiers and serial numbers;
(xiii) Web Universal Resource Locators (URLs);
(xiv) Internet Protocol (IP) address numbers;
(xv) Biometric identifiers, including finger and voice prints; and
(xvi) Full face photographic images and any comparable images.

(3) *Implementation specification: Permitted purposes for uses and disclosures.* (i) A covered entity may use or disclose a limited data set under paragraph (e)(1) of this section only for the purposes of research, public health, or health care operations.

(ii) A covered entity may use protected health information to create a limited data set that meets the requirements of paragraph (e)(2) of this section, or disclose protected health information only to a business associate for such purpose, whether or not the limited data set is to be used by the covered entity.

(4) *Implementation specifications: Data use agreement.*—(i) *Agreement required.* A covered entity may use or disclose a limited data set under paragraph (e)(1) of this section only if the covered entity obtains satisfactory assurance, in the form of a data use agreement that meets the requirements of this section, that the limited data set recipient will only use or disclose the protected health information for limited purposes.

(ii) *Contents.* A data use agreement between the covered entity and the limited data set recipient must:

(A) Establish the permitted uses and disclosures of such information by the limited data set recipient, consistent with paragraph (e)(3) of this section. The data use agreement may not authorize the limited data set recipient to use or further disclose the information in a manner that would violate the requirements of this subpart, if done by the covered entity;

(B) Establish who is permitted to use or receive the limited data set; and

(C) Provide that the limited data set recipient will:

(*1*) Not use or further disclose the information other than as permitted by the data use agreement or as otherwise required by law;

(*2*) Use appropriate safeguards to prevent use or disclosure of the information other than as provided for by the data use agreement;

(*3*) Report to the covered entity any use or disclosure of the information not provided for by its data use agreement of which it becomes aware;

(*4*) Ensure that any agents, including a subcontractor, to whom it provides the limited data set agrees to the same restrictions and conditions that apply to the limited data set recipient with respect to such information; and

(*5*) Not identify the information or contact the individuals.

(iii) *Compliance.* (A) A covered entity is not in compliance with the standards in paragraph (e) of this section if the covered entity knew of a pattern of activity or practice of the limited data set recipient that constituted a material breach or violation of the data use agreement, unless the covered entity took reasonable steps to cure the breach or end the violation, as applicable, and, if such steps were unsuccessful:

(1) Discontinued disclosure of protected health information to the recipient; and

(2) Reported the problem to the Secretary.

(B) A covered entity that is a limited data set recipient and violates a data use agreement will be in noncompliance with the standards, implementation specifications, and requirements of paragraph (e) of this section.

* * * * *

12. Amend § 164.520 as follows:

a. Remove the words ''consent or'' from paragraph (b)(1)(ii)(B).

b. In paragraph (c), introductory text, remove ''(c)(4)'' and add in its place ''(c)(3)''.

c. Revise paragraph (c)(2)(i).

d. Redesignate paragraphs (c)(2)(ii) and (iii) as (c)(2)(iii) and (iv).

e. Add new paragraph (c)(2)(ii).

f. Amend redesignated paragraph (c)(2)(iv) by removing ''(c)(2)(ii)'' and adding in its place ''(c)(2)(iii)''.

g. Amend paragraph (c)(3)(iii) by adding a sentence at the end.

h. Revise paragraph (e).

The revisions and addition read as follows:

**§ 164.520 Notice of privacy practices for protected health information.**

* * * * *

(c) *Implementation specifications: provision of notice.* * * *

(2) *Specific requirements for certain covered health care providers.* * * *

(i) Provide the notice:

(A) No later than the date of the first service delivery, including service delivered electronically, to such individual after the compliance date for the covered health care provider; or

(B) In an emergency treatment situation, as soon as reasonably practicable after the emergency treatment situation.

(ii) Except in an emergency treatment situation, make a good faith effort to obtain a written acknowledgment of receipt of the notice provided in accordance with paragraph (c)(2)(i) of this section, and if not obtained, document its good faith efforts to obtain such acknowledgment and the reason why the acknowledgment was not obtained;

* * * * *

(3) *Specific requirements for electronic notice.* * * *

(iii) * * * The requirements in paragraph (c)(2)(ii) of this section apply to electronic notice.

* * * * *

(e) *Implementation specifications: Documentation.* A covered entity must document compliance with the notice requirements, as required by § 164.530(j), by retaining copies of the notices issued by the covered entity and, if applicable, any written acknowledgments of receipt of the notice or documentation of good faith efforts to obtain such written acknowledgment, in accordance with paragraph (c)(2)(ii) of this section.

13. Amend § 164.522 by removing the reference to ''164.502(a)(2)(i)'' in paragraph (a)(1)(v), and adding in its place ''164.502(a)(2)(ii)''.

14. Amend § 164.528 as follows:

a. In paragraph (a)(1)(i), remove ''§ 164.502'' and add in its place ''§ 164.506''.

b. Remove the word ''or'' from paragraph (a)(1)(v).

c. Redesignate paragraph (a)(1)(vi) as (a)(1)(ix) and redesignate paragraphs (a)(1)(iii) through (v) as (a)(1)(v) through (vii).

d. Add paragraphs (a)(1)(iii), (iv), and (a)(1)(viii).

e. Revise paragraph (b)(2), introductory text.

f. Revise paragraph (b)(2)(iv).

g. Remove ''or pursuant to a single authorization under § 164.508,'' from paragraph (b)(3), introductory text.

h. Add paragraph (b)(4).

The additions and revisions read as follows:

**§ 164.528 Accounting of disclosures of protected health information.**

(a) *Standard: Right to an accounting of disclosures of protected health information.*

(1) * * *

(iii) Incident to a use or disclosure otherwise permitted or required by this subpart, as provided in § 164.502;

(iv) Pursuant to an authorization as provided in § 164.508;

* * * * *

(viii) As part of a limited data set in accordance with § 164.514(e); or

* * * * *

(b) *Implementation specifications: Content of the accounting.* * * *

(2) Except as otherwise provided by paragraphs (b)(3) or (b)(4) of this section, the accounting must include for each disclosure:

* * * * *

(iv) A brief statement of the purpose of the disclosure that reasonably informs the individual of the basis for the disclosure or, in lieu of such statement, a copy of a written request for a disclosure under §§ 164.502(a)(2)(ii) or 164.512, if any.

* * * * *

(4)(i) If, during the period covered by the accounting, the covered entity has made disclosures of protected health information for a particular research purpose in accordance with § 164.512(i) for 50 or more individuals, the accounting may, with respect to such disclosures for which the protected health information about the individual may have been included, provide:

(A) The name of the protocol or other research activity;

(B) A description, in plain language, of the research protocol or other research activity, including the purpose of the research and the criteria for selecting particular records;

(C) A brief description of the type of protected health information that was disclosed;

(D) The date or period of time during which such disclosures occurred, or may have occurred, including the date of the last such disclosure during the accounting period;

(E) The name, address, and telephone number of the entity that sponsored the research and of the researcher to whom the information was disclosed; and

(F) A statement that the protected health information of the individual may or may not have been disclosed for a particular protocol or other research activity.

(ii) If the covered entity provides an accounting for research disclosures, in accordance with paragraph (b)(4) of this section, and if it is reasonably likely that the protected health information of the individual was disclosed for such research protocol or activity, the covered entity shall, at the request of the individual, assist in contacting the entity that sponsored the research and the researcher.

* * * * *

15. Amend § 164.530 as follows:

a. Redesignate paragraph (c)(2) as (c)(2)(i).

b. Add paragraph (c)(2)(ii).

c. Remove the words ''the requirements'' from paragraph (i)(4)(ii)(A) and add in their place the word ''specifications.''

The addition reads as follows:

**§ 164.530 Administrative requirements.**

* * * * *

(c) *Standard: Safeguards.* * * *

(2) *Implementation specifications: Safeguards.* (i) * * *

(ii) A covered entity must reasonably safeguard protected health information to limit incidental uses or disclosures made pursuant to an otherwise permitted or required use or disclosure.

* * * * *

16. Revise § 164.532 to read as follows:

**§ 164.532 Transition provisions.**

(a) *Standard: Effect of prior authorizations.* Notwithstanding §§ 164.508 and 164.512(i), a covered entity may use or disclose protected health information, consistent with paragraphs (b) and (c) of this section, pursuant to an authorization or other express legal permission obtained from an individual permitting the use or disclosure of protected health information, informed consent of the individual to participate in research, or a waiver of informed consent by an IRB.

(b) *Implementation specification: Effect of prior authorization for purposes other than research.* Notwithstanding any provisions in § 164.508, a covered entity may use or disclose protected health information that it created or received prior to the applicable compliance date of this subpart pursuant to an authorization or other express legal permission obtained from an individual prior to the applicable compliance date of this subpart, provided that the authorization or other express legal permission specifically permits such use or disclosure and there is no agreed-to restriction in accordance with § 164.522(a).

(c) *Implementation specification: Effect of prior permission for research.* Notwithstanding any provisions in §§ 164.508 and 164.512(i), a covered entity may, to the extent allowed by one of the following permissions, use or disclose, for research, protected health information that it created or received either before or after the applicable compliance date of this subpart, provided that there is no agreed-to restriction in accordance with § 164.522(a), and the covered entity has obtained, prior to the applicable compliance date, either:

(1) An authorization or other express legal permission from an individual to use or disclose protected health information for the research;

(2) The informed consent of the individual to participate in the research; or

(3) A waiver, by an IRB, of informed consent for the research, in accordance with 7 CFR 1c.116(d), 10 CFR 745.116(d), 14 CFR 1230.116(d), 15 CFR 27.116(d), 16 CFR 1028.116(d), 21 CFR 50.24, 22 CFR 225.116(d), 24 CFR 60.116(d), 28 CFR 46.116(d), 32 CFR 219.116(d), 34 CFR 97.116(d), 38 CFR 16.116(d), 40 CFR 26.116(d), 45 CFR 46.116(d), 45 CFR 690.116(d), or 49 CFR 11.116(d), provided that a covered entity must obtain authorization in accordance with § 164.508 if, after the compliance date, informed consent is sought from an individual participating in the research.

(d) *Standard: Effect of prior contracts or other arrangements with business associates.* Notwithstanding any other provisions of this subpart, a covered entity, other than a small health plan, may disclose protected health information to a business associate and may allow a business associate to create, receive, or use protected health information on its behalf pursuant to a written contract or other written arrangement with such business associate that does not comply with §§ 164.502(e) and 164.504(e) consistent with the requirements, and only for such time, set forth in paragraph (e) of this section.

(e) *Implementation specification: Deemed compliance.*— (1) *Qualification.* Notwithstanding other sections of this subpart, a covered entity, other than a small health plan, is deemed to be in compliance with the documentation and contract requirements of §§ 164.502(e) and 164.504(e), with respect to a particular business associate relationship, for the time period set forth in paragraph (e)(2) of this section, if:

(i) Prior to October 15, 2002, such covered entity has entered into and is operating pursuant to a written contract or other written arrangement with a business associate for such business associate to perform functions or activities or provide services that make the entity a business associate; and

(ii) The contract or other arrangement is not renewed or modified from

October 15, 2002, until the compliance date set forth in § 164.534.

(2) *Limited deemed compliance period.* A prior contract or other arrangement that meets the qualification requirements in paragraph (e) of this section, shall be deemed compliant until the earlier of:

(i) The date such contract or other arrangement is renewed or modified on or after the compliance date set forth in § 164.534; or

(ii) April 14, 2004.

(3) *Covered entity responsibilities.* Nothing in this section shall alter the requirements of a covered entity to comply with part 160, subpart C of this subchapter and §§ 164.524, 164.526, 164.528, and 164.530(f) with respect to protected health information held by a business associate.

[FR Doc. 02–20554 Filed 8–9–02; 2:00 pm]

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**Wednesday,**
**August 14, 2002**

**Part VI**

# Department of Housing and Urban Development

**24 CFR Parts 902 et al.**
**Deregulation for Small Public Housing Agencies; Proposed Rule**

**DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT**

**24 CFR Parts 902, 903 and 985**

**[Docket No. FR–4753–P–01]**

**RIN 2577–AC34**

## Deregulation for Small Public Housing Agencies

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

**ACTION:** Proposed rule.

**SUMMARY:** This proposed rule would simplify and streamline HUD's regulatory requirements for small public housing agencies (PHAs) that administer the public housing and voucher assistance programs under the United States Housing Act of 1937. Specifically, the proposed rule would further streamline the PHA Annual Plan requirements for certain small PHAs. HUD also proposes to deregulate the assessment and scoring of small PHAs under the Public Housing Assessment System (PHAS) and the Section 8 Management Assessment Program (SEMAP), consistent with its basic regulatory responsibilities. HUD believes that these changes will alleviate administrative burden, and better enable small PHAs to focus on their core mission of providing decent, safe, and affordable housing for the neediest American families. In addition to the changes that solely concern small PHAs, this proposed rule would also streamline HUD's review of the Annual Plans submitted by all PHAs (large and small).

**DATES:** *Comments Due Date:* September 13, 2002.

**ADDRESSES:** Interested persons are invited to submit comments regarding this proposed rule to the Rules Docket Clerk, Office of General Counsel, Room 10276, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410–0500. Communications should refer to the above docket number and title. Facsimile (FAX) comments are not acceptable. A copy of each communication will be available for public inspection and copying between 7:30 a.m. and 5:30 p.m. weekdays at the above address.

**FOR FURTHER INFORMATION CONTACT:** Rod Solomon, Deputy Assistant Secretary for Policy, Program and Legislative Initiatives, Department of Housing and Urban Development, 451 Seventh Street, SW., Room 4116, Washington, DC 20410; telephone (202) 708–0713 (this is not a toll-free number). Persons with hearing- or speech-impairments may access this number via TTY by calling the toll-free Federal Information Relay Service at 1–800–877–8339.

**SUPPLEMENTARY INFORMATION:**

### I. Background

This proposed rule would simplify and streamline HUD's regulatory requirements for small public housing agencies (PHAs) that administer the public housing and voucher assistance programs under the United States Housing Act of 1937 (42 U.S.C. 1437 *et seq.*) (the ''1937 Act''). HUD has an obligation to monitor and regulate the use of Federal housing funds in order to ensure that taxpayer dollars are well spent. HUD is also mindful that compliance with its regulatory requirements may impose administrative burdens on PHAs and divert scarce resources. The cost of excessive regulation is especially problematic for small PHAs, because they often possess the fewest staff and technical resources.

This proposed rule would make several deregulatory changes to alleviate the administrative burden imposed on small PHAs, while still requiring basic accountability. The proposed rule would further streamline the PHA Annual Plan requirements for small PHAs. HUD also proposes to deregulate the assessment and scoring of small PHAs under the Public Housing Assessment System (PHAS) and the Section 8 Management Assessment Program (SEMAP) consistent with its basic regulatory responsibilities. HUD believes that deregulating small PHAs will better enable them to focus on their core mission of providing safe, decent, and affordable housing to the neediest American families.

The specific deregulatory changes that would be made by this proposed rule are as follows:

*A. Further Streamlining PHA Annual Plan Requirements (24 CFR Part 903)*

The PHA Plan process provides an easily identifiable source by which public housing residents, participants in the tenant-based assistance programs, and other members of the public may locate basic PHA policies rules and requirements concerning the PHA's operations, programs, and services. Through these plans—a 5-Year Plan and an annual plan—a PHA advises HUD, its residents, and members of the public of the PHA's mission for serving low-income and very low-income families, and the PHA's strategy for addressing those needs. HUD's regulations for the PHA Plans are located at 24 CFR part 903. This proposed rule would simplify PHA Annual Plan requirements.

1. Further Streamlining Annual Plan Submission Requirements for Small PHAs

In accordance with section 5A of the 1937 Act (which established the PHA Plan process), HUD's PHA Plan regulations at § 903.11(a)(2) and (c)(2) currently provide for the submission of streamlined Annual Plans by small PHAs (those with less than 250 public housing units) that are not designated as troubled or that are not at risk of being designated as troubled under section 6(j)(2) of the 1937 Act (see the PHAS regulations at § 902.67 for how a PHA is designated as troubled or determined to be ''at risk'' of being designated as troubled). On September 18, 2000, HUD issued Public and Indian Housing (PIH) Notice 2000–43, which implemented a new streamlining initiative for small PHAs: the ''Small PHA Plan Update.'' The Small PHA Plan Update reduces the amount of information contained in a streamlined plan by requiring that—for certain plan elements—PHAs need only describe the changes made since submission of their last Annual Plan. A copy of PIH Notice 2000–43 may be obtained via the HUD Internet homepage at *http://www.hud.gov.*

HUD proposes to further streamline the PHA Annual Plan submission requirements for small PHAs. Specifically, the proposed rule would require that the Annual Plan submitted by a small PHA only address policies concerning capital improvements (see § 903.7(g)) and the civil rights certification (see § 903.7(o)). For the other policies and programs that § 903.11(c)(2) currently requires must be addressed in a PHA's streamlined plan (such as deconcentration, demolition and disposition, housing needs, and financial resources), the PHA would only be required to submit a certification listing those policies it has revised since submission of its last Annual Plan. In addition, the small PHA would also be required to certify that: (i) The Resident Advisory Board had an opportunity to review and comment on the changes prior to implementation; (ii) the changes were duly approved by the PHA board of directors (or similar governing body); and (iii) the revised policies and programs are available for review and inspection at the principal office of the PHA during normal business hours.

Every fifth fiscal year, in the same year the PHA submits its 5-Year Plan, the small PHA would be required to submit a more detailed Annual Plan that more fully addresses the elements

required under § 903.11(c)(2). However, PHAs would not be required to provide information concerning pet ownership policies (see § 903.7(n)) and fiscal year audit findings (see § 903.7(p)), since the PHA is already required to maintain these supporting documents and make them available to the public. Further, the information concerning housing needs (see § 903.7(a)) need only be provided to the extent that it pertains to the housing needs of families on the PHA's public housing and tenant-based assistance waiting lists. The PHA already provides the other housing needs information required under § 903.7(a) through the Consolidated Plan process under 24 CFR part 91.

In order to facilitate HUD review of small PHA 5-Year and streamlined Annual Plans, the proposed rule also provides that HUD may require that half of all PHAs with less than 250 public housing units submit their 5-Year Plan one fiscal year in advance (in the fourth PHA fiscal year, rather than the fifth PHA fiscal year). This change will split the workload for HUD offices reviewing small PHA plans among two years, thus expediting HUD review and approval of the PHA plans.

In addition to the substantive changes discussed above, this proposed rule would also consolidate Annual Plan submission requirements for small PHAs in a separate regulatory section (§ 903.12). This non-substantive, organizational revision is designed to improve the clarity of the plan submission requirements and the deregulatory changes being proposed by HUD.

2. Streamlining the Scope of HUD Review for All PHAs

The proposed rule would also streamline HUD's review of Annual Plans submitted by all PHAs (large and small), by implementing the statutory authority provided by section 5A(i)(2) of the 1937 Act to exempt certain plan elements from HUD review and approval. Specifically, the proposed rule provides that HUD's review of Annual Plans will generally be limited to the PHA policies concerning deconcentration (see § 903.7(b)), capital improvements (see § 903.7(g)), demolition and disposition (see § 903.7(h)), and the civil rights certification (see § 903.7(o)). As required by section 5A(i)(2), HUD will also review any other plan element that has been challenged.

*B. Biannual PHAS Assessments for Small PHAs With Less Than 250 Public Housing Units (24 CFR part 902).*

HUD's regulations at 24 CFR part 902 describe the policies and procedures governing the PHAS. The PHAS provides a management tool for effectively and fairly measuring the performance of a PHA. The goals of the PHAS are to improve the delivery of services in public housing and enhance trust in the public housing system among PHAs, public housing residents, HUD, and the general public. This proposed rule would streamline and simplify the assessment and scoring of small PHAs under the PHAS.

The proposed rule would provide for the assessment and scoring of a small PHA with less than 250 public housing units once every other PHA fiscal year (as opposed to the current annual PHAS rating) unless the PHA elects to have its performance assessed on an annual basis or is designated as troubled. Given the limited number of public housing units managed by small PHAs, it is unlikely that there will be significant variations in performance from year to year and the risk of going to biannual scoring is minimal. Accordingly, HUD has determined that, unless the PHA has a history of poor performance and is designated as troubled, a biannual PHAS assessment is sufficient to monitor its performance.

*C. Deregulating SEMAP for Small PHAs (24 CFR part 985).*

HUD's regulations at 24 CFR part 985 describe the policies and procedures governing the SEMAP. SEMAP provides for objective measurement of the performance of a PHA in key areas of the tenant-based assistance program. SEMAP enables HUD to ensure program integrity and accountability by identifying PHA management capabilities and deficiencies and by improving risk assessment to effectively target monitoring and program assistance. PHAs can use the SEMAP performance analysis to assess their own program operations. The proposed rule would make three deregulatory changes to SEMAP concerning small PHAs.

1. Exemption for Small PHAs Not Subject to Single Audit Act Requirements

The proposed rule would exempt PHAs that expend less than $300,000 in Federal awards in any PHA fiscal year from SEMAP assessment and scoring. The current SEMAP regulations exempt these small PHAs from assessment under 7 (out of the 16) SEMAP indicators (see § 985.3). The exemption is due to the fact that PHAs with such limited Federal funding are not subject to the requirements of the Single Audit Act. Since HUD uses the annual independent audit to verify the information provided by PHAs for these indicators, there is no effective method for HUD to assess performance under these factors for PHAs not subject to the Single Audit Act. Given the relatively small amount of Federal funds expended by these PHAs, and the already limited scope of their SEMAP assessments, conducting SEMAP reviews for these small PHAs is not beneficial enough to justify the administrative burden. Accordingly, HUD proposes to exempt these small PHAs from the requirements of 24 CFR part 985.

2. Biannual SEMAP Assessments for Small PHAs

The proposed rule would also provide for the biannual SEMAP assessment of small PHAs with less than 250 assisted units (as opposed to the current annual SEMAP rating), unless the PHA elects to have its performance assessed on an annual basis or is designated as troubled. As was noted above in the discussion of the proposed changes to the PHAS, the limited number of units serviced by small PHAs makes it unlikely that there will be significant variations in performance from year to year and the risk of conducting SEMAP assessments once every other fiscal year is minimal. Accordingly, HUD has determined that, unless the PHA has a history of poor performance and is designated as troubled, a biannual assessment is sufficient to monitor its performance under SEMAP.

3. Streamlined On-Site Review Requirements for Small PHAs

The proposed rule would also streamline the on-site review requirements for small PHAs designated as troubled. Under the current SEMAP regulations HUD must conduct an on-site review of any PHA that receives an overall performance rating of troubled (see § 985.107(a)). Since SEMAP ratings are generally calculated based on the percentage of the PHA's leased housing units that meet the specified criteria, a difference of one or two units can have a disproportionate impact on a small PHA's SEMAP score. Accordingly, there may be small PHAs designated as troubled for which an on-site review is unnecessary to diagnose problems and potential remedies. The proposed rule would address this concern by providing that HUD may elect not to conduct an on-site review if the PHA has less than 250 assisted units and

HUD determines that an on-site review is unnecessary to determine the needs of the PHA and the actions required to address the program deficiencies. HUD will monitor the performance of a small PHA that is designated as troubled, but for which no on-site review is conducted, by using available data, such as independent public accountant (IPA) audit reports, information derived from the HUD form 50058, and PHA year-end statements.

**II. Justification for Reduced Comment Period**

It is the general practice of the Department to provide a 60-day public comment period on all proposed rules. The Department, however, is reducing its usual 60-day public comment period to 30 days for this proposed rule. In an effort to have an effective rule in place as close as possible to the beginning of Fiscal Year 2003, and given that the proposed changes are deregulatory in nature and remove administrative burdens thus better enabling small PHAs to focus on their core mission of providing decent, safe, and affordable housing, the Department believes that a 30-day public comment period is justified under these circumstances. All public comments will be considered in the development of the final rule.

**III. Findings and Certifications**

*Public Reporting Burden*

The information collection requirements contained in the PHA Plan process (24 CFR part 903) and the PHAS (24 CFR part 902) have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) and assigned OMB Control Numbers 2535–0106, 2535–0107, 2507–0001, and 2577–0226, respectively. The regulatory amendments contained in §§ 902.9, 903.5, 903.11, and 903.12 of this proposed rule merely modify the scope and frequency of these currently approved information collection requirements to streamline and reduce the paperwork burden imposed on small PHAs. HUD invites public comment on the information collection requirements contained in this proposed rule. All public comments will be considered in the development of the final rule and may result in revisions to the information collection requirements at the final rule stage. In accordance with the Paperwork Reduction Act, HUD may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection displays a currently valid OMB control number.

*Regulatory Planning and Review*

The Office of Management and Budget (OMB) reviewed this rule under Executive Order 12866, *Regulatory Planning and Review.* OMB determined that this rule is a ''significant regulatory action'' as defined in section 3(f) of the Order (although not an economically significant regulatory action under the Order). Any changes made to the rule as a result of that review are identified in the docket file, which is available for public inspection in the Office of the Rules Docket Clerk, Office of General Counsel, Room 10276, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410–0500.

*Unfunded Mandates Reform Act*

Title II of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. This proposed rule does not impose any Federal mandates on any State, local, or tribal governments or the private sector within the meaning of the Unfunded Mandates Reform Act of 1995.

*Executive Order 13132, Federalism*

Executive Order 13132 (entitled ''Federalism'') prohibits an agency from publishing any rule that has federalism implications if the rule either imposes substantial direct compliance costs on State and local governments and is not required by statute, or the rule preempts State law, unless the agency meets the consultation and funding requirements of section 6 of the Executive Order. This proposed rule does not have federalism implications and does not impose substantial direct compliance costs on State and local governments or preempt State law within the meaning of the Executive Order.

*Environmental Impact*

A Finding of No Significant Impact with respect to the environment has been made in accordance with HUD regulations at 24 CFR part 50, which implement section 102(2)(C) of the National Environmental Policy Act of 1969 (42 U.S.C. 4223). The Finding of No Significant Impact is available for public inspection between the hours of 7:30 a.m. and 5:30 p.m. weekdays in the Office of the Rules Docket Clerk, Office of General Counsel, Room 10276, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410–0500.

*Impact on Small Entities*

The Secretary, in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)) has reviewed and approved this proposed rule and in so doing certifies that this rule will not have a significant economic impact on a substantial number of small entities. Although the proposed rule is exclusively concerned with small PHAs with less than 250 public housing or leased housing units, the proposed amendments are deregulatory in nature. Specifically, the proposed rule would eliminate, simplify and streamline regulatory requirements for these small PHAs regarding the PHA Annual Plan process and assessments conducted under the PHAS and SEMAP. Further, the proposed deregulatory amendments would not change the amount of funding available to these PHAs. Accordingly, the economic impact of this rule will not be significant, and it will not affect a substantial number of small entities.

Notwithstanding HUD's determination that this rule will not have a significant economic effect on a substantial number of small entities, HUD specifically invites comments regarding any less burdensome alternatives to this rule that will meet HUD's objectives as described in this preamble.

**List of Subjects**

*24 CFR Part 902*

Administrative practice and procedure, Public housing, Reporting and recordkeeping requirements.

*24 CFR Part 903*

Administrative practice and procedure, Public housing, Reporting and recordkeeping requirements.

*24 CFR Part 985*

Grant programs—housing and community development, Housing, Rent subsidies, Reporting and recordkeeping requirements.

Accordingly, for the reasons described in the preamble, HUD proposes to amend 24 CFR parts 902, 903 and 985 as follows:

## PART 902—PUBLIC HOUSING ASSESSMENT SYSTEM

1. The authority citation for 24 CFR part 902 continues to read as follows:

**Authority:** 42 U.S.C. 1437d(j), 42 U.S.C. 3525(d).

2. Add § 902.9 to read as follows:

**§ 902.9 Frequency of PHAS scoring for small PHAs.**

REAC will assess and score the performance of a PHA with less than

250 public housing units every other PHA fiscal year, unless the small PHA:

(a) Elects to have its performance assessed on an annual basis; or

(b) Is designated as troubled, in accordance with § 902.67.

3. Revise the introductory text of paragraph § 902.33(a) to read as follows:

**§ 902.33 Financial reporting requirements.**

(a) *Annual financial report.* All PHAs must submit their unaudited and audited financial data to HUD on an annual basis. The financial information must be:

* * * * *

4. Revise the first sentence of § 902.60(d) to read as follows:

**§ 902.60 Data collection.**

* * * * *

(d) *Management operations and resident service and satisfaction information.* A PHA shall provide certification to HUD as to data required under subpart D, Management Operations, of this part and subpart E, Resident Service and Satisfaction, of this part not later than two months after the end of the PHA's fiscal year that is being assessed and scored, with no penalty applying, however, until the 16th day of the third month after the PHA fiscal year end. ***

* * * * *

## PART 903—PUBLIC HOUSING AGENCY PLANS

5. The authority citation for 24 CFR part 903 continues to read as follows:

**Authority:** 42 U.S.C. 1437c; 42 U.S.C. 3535(d).

6. Amend § 903.5(a)(3) by adding a sentence at the end to read as follows:

**§ 903.5 When must a PHA submit the plans to HUD?**

(a) * * *

(3) * * * However, HUD may require that half of all PHAs with less than 250 public housing units submit their 5-Year Plan one fiscal year in advance (in the fourth PHA fiscal year rather than the fifth PHA fiscal year).

* * * * *

7. Revise § 903.11(c)(2) to read as follows:

**§ 903.11 Are certain PHAs eligible to submit a streamlined Annual Plan?**

* * * * *

(c) * * *

(2) For small PHAs that are not designated as troubled (see § 902.67(c)) or that are not at risk of being designated as troubled (see § 902.67(b)(4)) under section 6(j)(2) of the 1937 Act, the requirements for streamlined Annual Plans are described in § 903.12.

* * * * *

8. Add § 903.12 to read as follows:

**§ 903.12 What are the streamlined Annual Plan requirements for small PHAs?**

(a) *General.* PHAs with less than 250 public housing units (small PHAs) and that have not been designated as troubled (see § 902.67(c)) or that are not at risk of being designated as troubled (see § 902.67(b)(4)) under section 6(j) of the 1937 Act may submit streamlined Annual Plans in accordance with this section.

(b) *Streamlined Annual Plan requirements for fiscal years in which 5-Year Plan is also due.* For the fiscal year in which its 5-Year Plan is also due, the streamlined Annual Plan of the small PHA shall consist of the information required by § 903.7 (a), (b), (c), (d), (g), (h), (k), (o) and (r). The information required by § 903.7(a) must be included only to the extent it pertains to the housing needs of families that are on the PHA's public housing and Section 8 tenant-based assistance waiting lists. The information required by § 903.7(k) must be included only to the extent that the PHA participates in homeownership programs under section 8(y) of the 1937 Act.

(c) *Streamlined Annual Plan requirements for all other fiscal years.* For all other fiscal years, the streamlined Annual Plan must include the information required by § 903.7(g) and (o) and a certification from the PHA that:

(1) Lists the policies and programs covered by § 903.7(a), (b), (c), (d), (h), (k) and (r) that the PHA has revised since submission of its last Annual Plan; and

(2) Provides assurance by the PHA that:

(i) The Resident Advisory Board had an opportunity to review and comment on the changes to the policies and programs before implementation by the PHA;

(ii) The changes were duly approved by the PHA board of directors (or similar governing body); and

(iii) The revised policies and programs are available for review and inspection, at the principal office of the PHA during normal business hours.

9. Amend § 903.23 by redesignating paragraphs (b) through (d) as paragraphs (c) through (e), respectively and adding new paragraph (b) to read as follows:

**§ 903.23 What is the process by which HUD reviews, approve, or disapproves an Annual Plan?**

* * * * *

(b) *Scope of HUD review.* HUD's review of the Annual Plan (and any significant amendments or modifications to the plan) will be limited to the information required by § 903.7(b), (g), (h), and (o), and any other element of the PHA's Annual Plan that is challenged.

* * * * *

## PART 985—SECTION 8 MANAGEMENT ASSESSMENT PROGRAM (SEMAP)

10. The authority citation for 24 CFR part 985 continues to read as follows:

**Authority:** 42 U.S.C. 1437a, 1437c, 1437f, and 3535(d).

11. Add § 985.1(c) to read as follows:

**§ 985.1 Purpose and applicability.**

* * * * *

(c) *Small PHAs exempt from Single Audit Act requirements.* A PHA that expends less than $300,000 in Federal awards in any PHA fiscal year is not subject to this part.

12. In § 985.3, remove the second undesignated introductory paragraph.

13. Revise § 985.105(a) to read as follows:

**§ 985.105 HUD SEMAP responsibilities.**

(a) *Frequency of SEMAP assessments.* (1) *Annual review.* Except as provided in paragraph (a)(2) of this section, HUD shall assess each PHA's performance under SEMAP annually and shall assign each PHA a SEMAP score and overall performance rating.

(2) *Biannual review for small PHAs.* HUD shall assess and score the performance of a PHA with less than 250 assisted units once every other PHA fiscal year, unless the PHA:

(i) Elects to have its performance assessed on an annual basis; or

(ii) Is designated as troubled, in accordance with § 985.103.

* * * * *

14. Revise § 985.107(a) to read as follows:

**§ 985.107 Required actions for PHA with troubled performance rating.**

(a) *On-site reviews.* (1) *Required reviews for troubled PHAs.* Except as provided in paragraph (a)(2) of this section, HUD will conduct an on-site review of PHA program management for any PHA assigned an overall performance rating of troubled to assess the magnitude and seriousness of the PHA's noncompliance with performance requirements.

(2) *On-site reviews for small PHAs.* Notwithstanding paragraph (a)(1) of this section, HUD may elect not to conduct an on-site review of a troubled PHA, if:

(i) The PHA has less than 250 assisted units; and

(ii) HUD determines that an on-site review is unnecessary to determine the

needs of the PHA and the actions required to address the program deficiencies.

* * * * *

Dated: July 18, 2002.

**Michael M. Liu,**

*Assistant Secretary for Public and Indian Housing.*

[FR Doc. 02–20547 Filed 8–13–02; 8:45 am]

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## REMINDERS

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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