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A cumulative list of the parts affected this month can be found in the Reader Aids section at the end of this issue.

Rules and Regulations

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This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

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MERIT SYSTEMS PROTECTION BOARD

5 CFR Part 1200

Board Organization

AGENCY: Merit Systems Protection Board.

ACTION: Final rule.

SUMMARY: The Merit Systems Protection Board is amending its organization and functions statement to reflect changes in the Board's headquarters organization and assignment of functions. These changes have been made to further streamline the Board's headquarters operations, enabling the agency to continue performing its functions effectively at the reduced budget and staffing levels expected through fiscal year 2000.

EFFECTIVE DATE: September 23, 1997.

FOR FURTHER INFORMATION CONTACT: Robert E. Taylor, Clerk of the Board, (202) 653–7200.

SUPPLEMENTARY INFORMATION: In response to the second phase of the Administration's Reinventing Government initiative (REGO II), the Chairman of the Merit Systems Protection Board appointed a REGO II Task Force to review all Board operations and to make recommendations for changes in organization, functions, and procedures that would enable the agency to continue performing its functions effectively at the reduced budget and staffing levels expected through fiscal year 2000. In response to the recommendations of the Task Force, certain organizational and functional changes have been effected. This amendment to 5 CFR part 1200 reflects the following changes:

The Office of the Administrative Law Judge and Regional Operations has been separated into two offices, the Office of the Administrative Law Judge and the Office of Regional Operations.

The Administrative Law Judge will continue to hear all Special Counsel complaints for disciplinary action, including Hatch Act cases, and proposed actions against administrative law judges. The Administrative Law Judge will also hear other assigned cases.

The Office of Regional Operations will manage the adjudicatory and administrative functions of the MSPB regional and field offices. References to the number of such offices have been removed.

The responsibility for preparing proposed decisions for the Board in original jurisdiction cases has been reassigned from the Office of the General Counsel to the Office of Appeals Counsel. As a result, most processing of cases that are decided by the 3-member Board is now centralized in the Office of Appeals Counsel. The Office of the General Counsel remains responsible for preparing proposed decisions for the Board in cases that the Board assigns.

Most of the Board's information services have been consolidated in the Office of the Clerk of the Board. Requests for non-case related information from the White House, Congress, and the media will continue to be handled by the Office of the General Counsel, and requests for information concerning the Board's studies will continue to be handled by the Office of Policy and Evaluation.

The Office of Planning and Resource Management Services has been abolished, and its three divisions now report to the Chairman through the Chief of Staff.

The Board is publishing this rule as a final rule pursuant to 5 U.S.C. 1204(h).

List of Subjects in 5 CFR Part 1200

Organization and functions (Government agencies).

Accordingly, the Board amends 5 CFR part 1200 as follows:

PART 1200—[AMENDED]

Subpart B—Offices of the Board, consisting of § 1200.10, is revised to read as follows:

Subpart B—Offices of the Board

Authority: 5 U.S.C. 1204 (h) and (j).

§ 1200.10 Staff organization and functions.

(a) The Board's headquarters staff is organized into the following offices and divisions:

(1) Office of Regional Operations.
(2) Office of the Administrative Law Judge.
(3) Office of Appeals Counsel.
(4) Office of the Clerk of the Board.
(5) Office of the General Counsel.
(6) Office of Policy and Evaluation.
(7) Office of Equal Employment Opportunity.
(8) Financial and Administrative Management Division.
(9) Human Resources Management Division.
(10) Information Resources Management Division.

(b) The principal functions of the Board's headquarters offices are as follows:

(1) *Office of Regional Operations.* The Director, Office of Regional Operations, manages the adjudicatory and administrative functions of the MSPB regional and field offices.

(2) *Office of the Administrative Law Judge.* The Administrative Law Judge hears Hatch Act cases, disciplinary action complaints brought by the Special Counsel, actions against administrative law judges, appeals of actions taken against MSPB employees, and other cases that the Board assigns.

(3) *Office of Appeals Counsel.* The Director, Office of Appeals Counsel, prepares proposed decisions that recommend appropriate action by the Board in petition for review cases, original jurisdiction cases, and other cases assigned by the Board.

(4) *Office of the Clerk of the Board.* The Clerk of the Board enters petitions for review and other headquarters cases onto the Board's docket and monitors their processing. The Clerk of the Board also does the following:

(i) Serves as the Board's public information center, including providing information on the status of cases, distributing copies of Board decisions and publications, and operating the Board's Library and on-line information services;

(ii) Manages the Board's records, reports, legal research, and correspondence control programs; and

(iii) Answers requests under the Freedom of Information and Privacy Acts at the Board's headquarters, and answers other requests for information

except those for which the Office of the General Counsel or the Office of Policy and Evaluation is responsible.

(5) *Office of the General Counsel.* The General Counsel provides legal advice to the Board and its headquarters and regional offices; represents the Board in court proceedings; prepares proposed decisions for the Board in cases that the Board assigns; coordinates legislative policy and performs legislative liaison; responds to requests for non-case related information from the White House, Congress, and the media; and plans and directs audits and investigations.

(6) *Office of Policy and Evaluation.* The Director, Policy and Evaluation, carries out the Board's statutory responsibility to conduct special reviews and studies of the civil service and other merit systems in the Executive Branch, as well as oversight reviews of the significant actions of the Office of Personnel Management. The office prepares the Board's reports of these reviews and studies, submits them to the President and the Congress, and makes them available to other interested individuals and organizations. The office is responsible for distributing the Board's reports and for responding to requests for information or briefings concerning them.

(7) *Office of Equal Employment Opportunity.* The Director, Office of Equal Employment Opportunity, manages the Board's equal employment programs.

(8) *Financial and Administrative Management Division.* The Financial and Administrative Management Division administers the budget, accounting, procurement, property management, physical security, and general services functions of the Board. It also develops and coordinates internal management programs and projects, including review of internal controls agencywide.

(9) *Human Resources Management Division.* The Human Resources Management Division develops policies and manages the Board's human resources programs, including staffing, classification, employee relations, performance management, payroll, personnel security, and training and development functions.

(10) *Information Resources Management Division.* The Information Resources Management Division develops, implements, and maintains the Board's automated information systems.

(c) *Regional and Field Offices.* The Board has regional and field offices located throughout the country (See Appendix II to 5 CFR part 1201 for a list of the regional and field offices). Judges in the regional and field offices hear and decide initial appeals and other assigned cases as provided for in the Board's regulations.

Dated: September 18, 1997.

Robert E. Taylor,

Clerk of the Board.

[FR Doc. 97–25301 Filed 9–22–97; 8:45 am]

BILLING CODE 7400–01–U

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 50

[Docket No. 97–061–1]

Expenses Associated With Transporting and Disposing of Tuberculosis-Exposed Animals

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Interim rule and request for comments.

SUMMARY: We are amending the regulations concerning animals destroyed because of tuberculosis to allow the U.S. Department of Agriculture to pay herd owners some of their expenses for transporting tuberculosis-exposed cattle, bison, and cervids to slaughter or to the point of disposal, and for disposing of the animals. Prior to this interim rule, herd owners could only receive help with these costs for affected animals. Consequently, herd owners in some cases elected to keep exposed animals in a herd until testing revealed them to be either free of tuberculosis or affected with tuberculosis, or elected not to depopulate an affected herd, providing opportunity for further spread of the disease. This interim rule also makes minor changes to the provisions for paying some of the expenses for transporting tuberculosis-affected animals to the point of disposal and disposing of them. This interim rule is necessary to ensure continued progress toward eradicating tuberculosis in the U.S. livestock population.

DATES: Interim rule effective September 17, 1997. Consideration will be given only to comments received on or before November 24, 1997.

ADDRESSES: Please send an original and three copies of your comments to Docket No. 97–061–1, Regulatory Analysis and Development, PPD, APHIS, suite 3C03, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Please state that your comments refer to Docket No. 97–061–1. Comments received may be inspected at USDA, room 1141, South Building, 14th Street and Independence Avenue SW., Washington, DC, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays. Persons wishing to inspect comments are requested to call ahead on (202) 690–2817 to facilitate entry into the comment reading room.

FOR FURTHER INFORMATION CONTACT: Dr. Mitchell A. Essey, Senior Staff Veterinarian, National Animal Health Programs, VS, APHIS, 4700 River Road Unit 36, Riverdale, MD 20737–1231, (301) 734–7727.

SUPPLEMENTARY INFORMATION:

Background

Bovine tuberculosis (referred to below as tuberculosis) is a serious communicable disease of cattle, bison, and other species, including humans, caused by *Mycobacterium bovis.* Tuberculosis causes weight loss, general debilitation, and sometimes death. The regulations at 9 CFR part 50, ''Animals Destroyed Because of Tuberculosis'' (the regulations), administered by the Animal and Plant Health Inspection Service (APHIS) of the U.S. Department of Agriculture (the Department), provide for payment of Federal indemnity to owners of certain cattle, bison, cervids, and swine destroyed because of tuberculosis.

As part of the program to control and eradicate tuberculosis in livestock, the payment of indemnity is intended to provide owners with an incentive for promptly destroying cattle, bison, and cervids that are affected with or exposed to tuberculosis and, in limited cases, swine that are exposed to tuberculosis. Because the continued presence of tuberculosis in a herd seriously threatens the health of other animals in that herd and possibly other herds, the prompt destruction of tuberculosis-affected and -exposed animals is critical if tuberculosis eradication efforts in the United States are to succeed.

As set forth in § 50.4 of the regulations, cattle, bison, and cervids are classified as affected with tuberculosis on the basis of an intradermal tuberculin test applied by a Federal, State, or an accredited veterinarian, or by other diagnostic procedure approved in advance by the Administrator of APHIS. Cattle, bison, and cervids are classified as exposed to tuberculosis when such cattle, bison, and cervids (1) are part of a known affected herd, or (2) are found to have moved from an affected herd before the time infection was disclosed in the herd and after the time the herd had

apparently become affected, or (3) are found to have been exposed by virtue of nursing an affected dam.

For affected cattle, bison, and cervids eligible for indemnity, the regulations provide for Federal help in paying a portion of the expenses incurred by owners in transporting the animals to the point of disposal, and disposing of the animals (see § 50.8). However, there are no similar provisions for paying a portion of the expenses of transporting tuberculosis-exposed cattle, bison, and cervids to slaughter or to the point where disposal will take place, or disposing of these animals.

When the provisions concerning payment of expenses for transporting and disposing of affected animals were added to the regulations in 1980, it was done because many slaughtering establishments were refusing to accept affected animals, and the animals often had to be shipped long distances to slaughtering plants that would accept them, or had to be disposed of by other means, such as by burial, incineration, or rendering. The refusal to take affected animals was due, at least in part, to the requirement that meat taken from affected animals and intended for consumption be cooked, for public health reasons, thereby increasing slaughtering costs and reducing the value of the meat. Most slaughtering establishments continued to accept tuberculosis-exposed animals, however, because meat from a tuberculosis-exposed animal may be used without restriction if the animal is found free of tuberculosis upon inspection at slaughter.

Today, however, the incidence of tuberculosis in the United States has declined markedly. As we approach eradication, far fewer animals, either affected with or exposed to tuberculosis, are moving to slaughter. Many slaughtering establishments are not willing to take even tuberculosis-exposed animals. Consequently, tuberculosis-exposed animals must sometimes be shipped long distances to slaughtering plants that will accept them. In such cases, rather than pay for such long-distance shipping, some owners opt to keep the exposed animals in their herd until testing reveals them to be either free of tuberculosis or affected with tuberculosis, or elect not to depopulate an affected herd. This ''wait and see'' approach provides opportunity for the disease to progress and spread, particularly in herds that have received an animal subsequently identified as tuberculosis-exposed.

It is possible that, if the number of slaughtering establishments willing to take exposed animals declines further, some owners of exposed animals may need to find other means of disposal. And whereas slaughtering establishments generally pay some salvage value for the meat from exposed animals, owners having to dispose of their animals by other means would have to pay all costs for that disposal and could expect no salvage value from their animals. Under these circumstances, owners might choose to keep exposed animals in the herd, thereby impeding tuberculosis eradication efforts in the United States.

Therefore, we are amending § 50.8 to allow the Department to pay herd owners some of their expenses associated with transporting tuberculosis-exposed cattle, bison, and cervids to slaughter or to the point where disposal will take place, and disposing of the animals. We believe this action is necessary to ensure continued progress toward eradicating tuberculosis in the United States. Specifically, the regulations, as amended, will allow the Department to pay herd owners one-half the expenses of transporting tuberculosis-exposed cattle, bison, and cervids to slaughter or to the point where disposal will take place, and disposing of the animals, provided that the Department may pay more than one-half of the expenses when the Administrator of APHIS determines that doing so will contribute to the tuberculosis eradication program. The APHIS Veterinarian in Charge for the State in which the animals reside must approve the payment in advance in writing. For reimbursement to be made, the owner of the animals must present the APHIS Veterinarian in Charge with a copy of either a receipt for expenses paid or a bill for services rendered. Any bill for services rendered by the owner may not be greater than the normal fee charged by commercial haulers or renderers for similar services.

Section 50.8 has contained provisions, applicable to owners of tuberculosis-affected animals, requiring (1) that claims for payment of transportation or disposal expenses be made on forms furnished by APHIS, (2) that the forms be signed by an APHIS or State representative, or jointly by them, and (3) that the owner of the animals also sign the forms certifying acceptance of the amount claimed. APHIS will no longer require use of special claims forms for payment of expenses for disposal or transportation of tuberculosis-affected animals. Rather, the owner will be asked simply to document those expenses by submitting to the Veterinarian in Charge a copy of either a receipt for expenses paid or a bill for services rendered. Therefore, we are amending § 50.8 to remove the provisions concerning forms for payment of expenses for disposal or transportation of tuberculosis-affected animals. Instead, § 50.8 will require owners of affected animals to present the APHIS Veterinarian in Charge with a copy of either a receipt for expenses paid or a bill for services rendered.

We are also amending § 50.8 to allow the Department to pay herd owners more than one-half of the expenses for transporting tuberculosis-affected cattle, bison, and cervids to slaughter or to the point where disposal will take place, and disposing of the animals, when the Administrator of APHIS determines that doing so will contribute to the tuberculosis eradication program.

Finally, we are amending § 50.8 to remove the provision that the Department will not pay any portion of expenses of transporting or disposing of affected animals when the transportation or disposal is provided by the owner of the affected animals. This no longer appears to be a necessary prohibition because owners can often provide transportation and carry out disposal for less money than they would have to pay someone else to do it.

Immediate Action

The Administrator of the Animal and Plant Health Inspection Service has determined that there is good cause for publishing this interim rule without prior opportunity for public comment. Immediate action is necessary to facilitate the prompt removal and destruction of tuberculosis-exposed animals from U.S. livestock herds. Of particular concern at this time is the prompt removal and destruction of tuberculosis-exposed cattle on the Island of Molokai, in Hawaii, where tuberculosis was recently confirmed in one herd of cattle. Because wildlife on this small island intermingles with the cattle, the cattle must be removed as quickly as possible to minimize the risk that tuberculosis will be spread both to wildlife and to cattle in neighboring herds. Outlets for tuberculosis-exposed animals in Hawaii are very limited and, for animals that have not yet reached market weight, nonexistent. About 160 animals in the affected herd on Molokai have not reached market weight and must be transported to the U.S. mainland for slaughter at considerable expense to the owner. This interim rule is necessary to assist the owner with transportation costs so that the cattle can be promptly removed from the island to minimize the potential spread of tuberculosis.

Because prior notice and other public procedures with respect to this action

are impracticable and contrary to the public interest under these conditions, we find good cause under 5 U.S.C. 553 to make it effective upon publication in the **Federal Register**. We will consider comments that are received within 60 days of publication of this rule in the **Federal Register**. After the comment period closes, we will publish another document in the **Federal Register**. It will include a discussion of any comments we receive and any amendments we are making to the rule as a result of the comments.

Executive Order 12866 and Regulatory Flexibility Act

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

This interim rule amends the regulations concerning animals destroyed because of tuberculosis to allow the Department to pay herd owners one half of their expenses for transporting tuberculosis-exposed animals to slaughter or to the point of disposal, and for disposing of the animals. It also allows the Department to pay more than one half of the expenses for transporting and disposing of tuberculosis-affected or tuberculosis-exposed animals, when the Administrator of APHIS determines that doing so will contribute to the tuberculosis eradication program in the United States, and allows herd owners to be reimbursed for one half of their expenses for transporting or disposing of exposed or affected animals when the transportation or disposal is provided by the owner of the animals.

The U.S. livestock industry relies on healthy animals for its economic well being. The well being of the overall U.S. economy depends, in turn, on a healthy livestock industry. The industry's role in the economy is significant. For example, the total value of U.S. livestock output in l991 was $66.6 billion, about half of the value of all agricultural production in the United States that year. The value of live animal exports and exports of meat products totalled $4.3 billion in l991, equivalent to 10 percent of the value of all U.S. agricultural exports that year. In l996, there were 1,194,390 U.S. operations with cattle and calves, and the inventory of cattle and calves at the end of that year stood at 101.2 million head. The value of cattle and calves in the United States in l996 was more than $52 billion.

Recent studies on the economic impact of a tuberculosis epidemic in U.S. livestock are not available. However, an earlier study indicates that the impact would be significant. A comprehensive computer model developed by Canada in 1979 indicates that, if the tuberculosis eradication program were discontinued, annual losses in the United States would amount to over $1 billion. Another study, conducted in l972, concluded that the benefits of the tuberculosis eradication program exceeded costs by a 3.64 to 1 margin.

APHIS's costs for administering this interim rule are not expected to exceed $67,500 annually, based on the following: We estimate that the average cost of transporting a tuberculosis-exposed animal to slaughter would be $50. In most cases, APHIS would pay one half of that cost, or $25. We estimate that approximately 2,000 tuberculosis-exposed cattle, bison, and cervids may be moved to slaughter or other point of disposal during the first year after this rule is effective, and that we would pay approximately $25 each toward transportation for three quarters of them, and an average of $50 each for one quarter of them. Costs would be lower in succeeding years as the prevalence of tuberculosis declines in the United States.

Although the benefits of this interim rule (i.e., enhanced values for U.S. livestock, particularly in export markets) are difficult to quantify, those benefits should certainly exceed the cost of the program.

The 2,000 tuberculosis-exposed animals that we estimate might be moved to slaughter or other disposal during the first year of this program represent about 20 different herds. About 4 of these herds, with 200–400 animals each, may be depopulated. The remainder of the herds are expected to send only a few animals each to slaughter. We estimate that no more than 15 of the herds are owned by entities that would be considered ''small'' under criteria (fewer than 200 cattle each) established by the Small Business Administration.

Under these circumstances, the Administrator of APHIS has determined that this action will not have a significant economic impact on a substantial number of small entities.

Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 7 CFR part 3015, subpart V.)

Executive Order 12988

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

Paperwork Reduction Act

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

List of Subjects in 9 CFR Part 50

Animal diseases, Bison, Cattle, Hogs, Indemnity payments, Reporting and recordkeeping requirements, Tuberculosis.

Accordingly, 9 CFR part 50 is amended as follows:

PART 50—ANIMALS DESTROYED BECAUSE OF TUBERCULOSIS

1. The authority citation for part 50 continues to read as follows:

Authority: 21 U.S.C. 111–113, 114, 114a, 114a–1, 120, 121, 125, and 134b; 7 CFR 2.22, 2.80, and 371.2(d).

2. Section 50.8 is revised to read as follows:

§ 50.8 Payment of expenses for transporting and disposing of affected and exposed animals.

The Department may pay, when approved in advance in writing by the Veterinarian in Charge, one half the expenses of transporting affected or exposed cattle, bison, and cervids to slaughter or to the point where disposal will take place, and one half the expenses of destroying, burying, incinerating, rendering, or otherwise disposing of affected or exposed cattle, bison, and cervids; *Provided that,* the Department may pay more than one-half of the expenses when the Administrator determines that doing so will contribute to the tuberculosis eradication program. For reimbursement to be made, the owner of the animals must present the Veterinarian in Charge with a copy of either a receipt for expenses paid or a bill for services rendered. Any bill for services rendered by the owner must not be greater than the normal fee for similar services provided by a commercial hauler or renderer.

Done in Washington, DC, this 17th day of September 1997.

Craig A. Reed,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 97–25214 Filed 9–22–97; 8:45 am]

BILLING CODE 3410–34–P

FARM CREDIT SYSTEM INSURANCE CORPORATION

12 CFR Part 1402

RIN 3055–AA06

Releasing Information

AGENCY: Farm Credit System Insurance Corporation.

ACTION: Final rule.

SUMMARY: The Farm Credit System Insurance Corporation (Corporation), through the Corporation Board (Board), issues a final rule amending its regulations governing the release of information. The objective of this action is to conform applicable Corporation regulations to the requirements of the Freedom of Information Act (FOIA), 5 U.S.C. 552, as amended by the Electronic Freedom of Information Act Amendments of 1996 (1996 Amendments), Pub. L. 104–231, and to clarify the address of the official who receives FOIA requests for records.

EFFECTIVE DATE: October 2, 1997.

FOR FURTHER INFORMATION CONTACT: Dorothy L. Nichols, General Counsel, Farm Credit System Insurance Corporation, McLean, VA 22102, (703) 883–4211, TDD (703) 883–4444.

SUPPLEMENTARY INFORMATION: Through the Electronic Freedom of Information Act Amendments of 1996, Congress amended the FOIA to address, among other things, the timing of agency responses to FOIA requests. The FOIA was amended to increase the time limit for agency responses from 10 to 20 working days. Another time-related amendment requires agencies to promulgate regulations under which requests for expedited processing will be considered and to grant such requests upon a showing of a compelling need. These amendments are effective October 2, 1997.

In response to the amendment of the FOIA, the Corporation is amending its regulations at part 1402, subpart B, as a final rule. The amendments to part 1402, subpart B, reflect the requirements of the FOIA, as amended, and are not interpretative. The 1996 Amendments provide Federal agencies with no discretion and require the time-related amendments to be effective on October 2, 1997. Moreover, the regulations that the Corporation adopts to implement the 1996 Amendments and to clarify the address of the Freedom of Information Officer are ministerial, minor, technical, and noncontroversial. For these reasons, the Corporation finds good cause to determine that public notice and comment for this regulation are unnecessary, impractical, and contrary to the public interest, pursuant to the Administrative Procedure Act, 5 U.S.C. 553(a)(3)(B).

Sections 1402.13 and 1402.14 (a) and (d) are amended to reflect that, effective October 2, 1997, the Corporation will have 20 days within which to respond to FOIA requests for records.

Section 1402.13 is also amended to provide that FOIA requests for records should be addressed to the Freedom of Information Officer, Farm Credit System Insurance Corporation, 1501 Farm Credit Drive, McLean, VA 22102.

Finally, the Corporation has added new § 1402.14(e) to address the new requirement that the Corporation promulgate regulations concerning the granting of a request for expedited processing of a FOIA request upon a requester's showing of a compelling need for the information. The new regulation requires the Freedom of Information Officer to notify a requester within 10 calendar days after receipt of such a request whether the Corporation granted expedited processing and, if so, to process the request as soon as practicable. The regulation defines ''compelling need'' to mean that a failure to obtain the requested records on an expedited basis could reasonably be expected to pose an imminent threat to the life or physical safety of an individual, or, with respect to a request made by a person primarily engaged in disseminating information, that there is an urgency to inform the public concerning actual or alleged Federal Government activity. The regulation further provides that a requester demonstrate a compelling need by a statement certified by the requester to be true and correct to the best of such person's knowledge and belief. The procedures for expedited processing apply to both requests for information and to administrative appeals.

The remaining provisions of the 1996 Amendments to the FOIA do not require amendment of the Corporation's regulations governing the release of information at part 1402.

List of Subjects in 12 CFR Part 1402

Courts, Freedom of information, Government employees.

For the reasons stated in the preamble, part 1402 of chapter XIV, title 12 of the Code of Federal Regulations is amended to read as follows:

PART 1402—RELEASING INFORMATION

1. The authority citation for part 1402 is revised to read as follows:

Authority: Secs. 5.58, 5.59 of the Farm Credit Act (12 U.S.C. 2277a–7, 2277a–8); 5 U.S.C. 552; 52 FR 10012; E.O. 12600, 52 FR 23781, 3 CFR, 1987 Comp., p. 235.

Subpart B—Availability of Records of the Farm Credit System Insurance Corporation

2. Section 1402.13 is revised to read as follows:

§ 1402.13 Request for records.

Requests for records shall be in writing and addressed to the attention of the Freedom of Information Officer, Farm Credit System Insurance Corporation, McLean, Virginia 22102. A request improperly addressed will be deemed not to have been received for purposes of the 20-day time period set forth in § 1402.14(a) of this part until it is received, or would have been received, by the Freedom of Information Officer with the exercise of due diligence by Corporation personnel. Records requested in conformance with this subpart and which are not exempt records may be received in person or by mail as specified in the request. Records to be received in person will be available for inspection or copying during business hours on a regular business day in the offices of the Farm Credit System Insurance Corporation, 1501 Farm Credit Drive, McLean, Virginia 22102.

3. Section 1402.14 is amended by revising paragraphs (a) and (d) and adding paragraph (e) to read as follows:

§ 1402.14 Response to requests for records.

(a) Within 20 days (excluding Saturdays, Sundays, and legal public holidays), or any extensions thereof as provided in paragraph (d) of this section, of the receipt of a request by the Freedom of Information Officer, the Freedom of Information Officer shall determine whether to comply with or deny such a request and transmit a written notice thereof to the requester.

* * * * *

(d) In ''unusual circumstances,'' the 20-day time limit prescribed in paragraphs (a) and (c) of this section, or both, may be extended by the Freedom of Information Officer or, in the case of an appeal, by the General Counsel, provided that the total of all extensions does not exceed 10 days (excluding

Saturdays, Sundays, and legal public holidays). Extensions shall be made by written notice to the requester setting forth the reasons for the extension and the date on which a determination is expected to be dispatched. As used in this paragraph, ''*unusual circumstances*'' means, but only to the extent reasonably necessary to the proper processing of the request:

(1) The need to search for and collect the requested records from facilities or other establishments that are separate from the office processing the request;

(2) The need to search for, collect, and appropriately examine a voluminous amount of separate and distinct records which are demanded in a single request; or

(3) The need for consultation, which shall be conducted with all practicable speed, with another agency having a substantial interest in the determination of the request or among two or more components of the agency having a substantial subject matter interest therein.

(e) A requester may obtain, upon request, expedited processing of a request for records when the requester demonstrates a ''compelling need'' for the information. The Freedom of Information Officer will notify the requester within 10 calendar days after receipt of such a request whether the Corporation granted expedited processing. If expedited processing was granted, the request will be processed as soon as practicable.

(1) For the purposes of this paragraph, ''*compelling need*'' means:

(i) That a failure to obtain requested records on an expedited basis could reasonably be expected to pose an imminent threat to the life or physical safety of an individual; or

(ii) With respect to a request made by a person primarily engaged in disseminating information, urgency to inform the public concerning actual or alleged Federal Government activity.

(2) A requester shall demonstrate a compelling need by a statement certified by the requester to be true and correct to the best of such person's knowledge and belief.

(3) The procedures of this paragraph (e) for expedited processing apply to both requests for information and to administrative appeals.

Dated: September 17, 1997.

Floyd Fithian,

Secretary, Farm Credit System Insurance Corporation Board.

[FR Doc. 97–25237 Filed 9–22–97; 8:45 am]

BILLING CODE 6710–01–P

DEPARTMENT OF THE TREASURY

Customs Service

19 CFR Part 12

[T.D. 97–80]

RIN 1515–AC22

Import Restrictions Imposed on Archaeological Artifacts From Mali

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

ACTION: Final rule.

SUMMARY: This document amends the Customs Regulations to reflect the imposition of import restrictions on culturally significant archaeological artifacts from the region of the Niger River Valley of Mali and the Bandiagara Escarpment (Cliff), Mali. These restrictions are being imposed pursuant to an agreement between the United States and Mali that has been entered into under the authority of the Convention on Cultural Property Implementation Act in accordance with the United Nations Educational, Scientific and Cultural Organization (UNESCO) Convention on the Means of Prohibiting and Preventing the Illicit Import, Export and Transfer of Ownership of Cultural Property. The document also contains the Designated List of Archaeological Material that describes the articles to which the restrictions apply. These import restrictions imposed pursuant to the bilateral agreement between the United States and Mali continue the import restrictions that were imposed on an emergency basis in 1993. Accordingly, this document amends the Customs Regulations by removing Mali from the listing of countries for which emergency actions imposed the import restrictions and adding Mali to the list of countries for which an agreement has been entered into for imposing import restrictions.

EFFECTIVE DATE: September 23, 1997.

FOR FURTHER INFORMATION CONTACT: (Legal Aspects) Donnette Rimmer, Intellectual Property Rights Branch (202) 482–6960; (Operational Aspects) Joan E. Sebanaler, Trade Operations (202) 927–0402.

SUPPLEMENTARY INFORMATION:

Background

The value of cultural property, whether archaeological or ethnological in nature, is immeasurable. Such items often constitute the very essence of a society and convey important information concerning a people's origin, history, and traditional setting. The importance and popularity of such items regrettably makes them targets of theft, encourages clandestine looting of archaeological sites, and results in their illegal export and import.

The U.S. shares in the international concern for the need to protect endangered cultural property. The appearance in the U.S. of stolen or illegally exported artifacts from other countries where there has been pillage has, on occasion, strained our foreign and cultural relations. This situation, combined with the concerns of museum, archaeological, and scholarly communities, was recognized by the President and Congress. It became apparent that it was in the national interest for the U.S. to join with other countries to control illegal trafficking of such articles in international commerce.

The U.S. joined international efforts and actively participated in deliberations resulting in the 1970 UNESCO Convention on the Means of Prohibiting and Preventing the Illicit Import, Export and Transfer of Ownership of Cultural Property (823 U.N.T.S. 231 (1972)). U.S. acceptance of the 1970 UNESCO Convention was codified into U.S. law as the ''Convention on Cultural Property Implementation Act'' (Pub.L. 97–446, 19 U.S.C. 2601 *et seq.*) (''the Act''). This was done to promote U.S. leadership in achieving greater international cooperation towards preserving cultural treasures that are of importance not only to the nations whence they originate, but also to greater international understanding of mankind's common heritage. The U.S. is, to date, the only major art importing country to implement the 1970 Convention.

During the past several years, import restrictions have been imposed on an emergency basis on archaeological and ethnological artifacts of a number of signatory nations as a result of requests for protection received from those nations as well as pursuant to bilateral agreements between the United States and other countries.

Mali has been one of the countries whose archaeological material has been afforded emergency protection. In T.D. 93–74, § 12.104g(b), Customs Regulations, (19 CFR § 12.104g(b)) was amended to reflect that archaeological material from the region of the Niger River Valley in Mali and the Bandiagara Escarpment (Cliff) in Mali forming part of the remains of the ancient sub-Sahara culture received import protection under the emergency protection provisions of the Act.

Import restrictions are now being imposed on these same archaeological artifacts from Mali as the result of a

bilateral agreement entered into between the United States and Mali. This agreement was entered into on September 19, 1997, pursuant to the provisions of 19 U.S.C. 2602. Protection of the archaeological material from the region of the Niger River Valley in Mali and the Bandiagara Escarpment (Cliff) in Mali previously reflected in § 12.104g(b) will be continued through the bilateral agreement without interruption. Accordingly, § 12.104g(a) of the Customs Regulations is being amended to indicate that restrictions have been imposed pursuant to the agreement between the United States and Mali and the emergency import restrictions on certain archaeological material from Mali is being removed from 12.104g(b) as those restrictions are now encompassed in § 12.104g(a).

Material and Sites Encompassed in Import Restrictions

In reaching the decision to recommend that negotiations for an agreement with Mali should be undertaken to continue the imposition of import restrictions on certain archaeological material from Mali, the Deputy Director of the United States Information Agency made a determination that the cultural patrimony of Mali continues to be in jeopardy from pillage of irreplaceable materials representing Mali heritage and that the pillage is endemic and substantially documented with respect to sites in the region of the Niger River Valley and the Bandiagara Escarpment (Cliff) of Mali. The Deputy Director listed the following archaeological material from the following sites as those that are in need of protection.

Material

Archaeological material from sites in the region of the Niger River Valley and the Bandiagara Escarpment (Cliff), Mali, dating from approximately the Neolithic period to approximately the 18th century, identifiable by unique stylistic features, by medium, and where possible, by historic and cultural context. This archaeological material includes, but is not limited to: terra cotta statues depicting anthropomorphic and zoomorphic figures and terra cotta common vessels; copper and copper alloy materials, such as bronze, from which have been produced figurines and other objects such as pendants, finger bells, bells and bracelets; iron figures; and glass beads. Other archaeological material is identifiable as coming from the Tellem burial caves of the Bandiagara Escarpment (Cliff) and includes, but is not limited to: iron headrests; rings; bracelets; hairpins; fingerbells; bronze pendants; carved wood anthropomorphic and zoomorphic figures; carved wood headrests; wood bowls, spoons, hoes, axes, bows, arrows quivers, flutes, harps and drums; leather sandals, boots, knife-sheaths and plaited bracelets; ritual and utilitarian pottery, three/four-footed ceramic bowls; textiles of cotton and wool that are the remnants of tunics and coifs, blankets, skirts; organic fiber from which belts were made; glass beads; stone (carnelian) beads; and stone (quartz) lip plugs.

Sites

Sites include, but are not limited to: Djenne and Guimbala of the Inland Niger Delta; Bougouni of the Upper Valley of the Niger River; and the Bandiagara Escarpment (Cliff); and are recognized to be of high cultural significance. These sites represent a continuum of civilizations from the Neolithic period to the colonial occupation of the 18th century, and lend an archaeological significance to the region.

Designated List

The bilateral agreement between Mali and the United States covers the material set forth in a Designated List of Archaeological Material from the Region of the Niger River Valley, Mali and the Bandiagara Escarpment (Cliff), Mali, which is set forth below. Importation of articles on this list is restricted unless the articles are accompanied by documentation certifying that the material left Mali legally and not in violation of the export laws of Mali.

Archaeological Material From the Region of the Niger River Valley, Mali and the Bandiagara Escarpment (Cliff), Mali

The following categories of material are restricted from importation into the U.S. unless accompanied by a verifiable export certificate issued by the Government of Mali—archaeological material from the Region of the Niger River Valley, Mali and the Bandiagara Escarpment (Cliff), Mali, that includes, but is not limited to, the categories listed below. As this region is further excavated, other types of material may be found and added to an amended list. The following list is representative only. Any dimensions are approximate.

I. Ceramics/Terra Cotta/Fired Clay

Types of ceramic forms (stylistically known as Djenne-jeno or Jenne, Bankoni, Guimbala, Bambara, Bougouni and other stylistic labels) that are known to come from the region include, but are not limited to:

A. Figures/Statues.

1. Anthropomorphic figures, often incised, impressed and with added motifs, such as scarification marks and serpentine patterns on their bodies, often depicting horsemen or individuals sitting, squatting, kneeling, embracing, or in a position of repose, arms elongated the length of the body or crossed over the chest, with the head tipped backwards. (H: 6–30 in.)
2. Zoomorphic figures, often depicting a snake motif on statuettes or on the belly of globular vases. Sometimes the serpent is coiled in an independent form. A horse motif is common, but is usually mounted. Includes quadrupeds. (H: 6–30 in.)

B. Common Vessels.

1. Funerary jars, ocher in color, often stamped with chevrons. (H: 50 to 80 cm.)
2. Globular vases often stamped with chevrons and serpentine forms. (H: under 10 in.)
3. Bottles with a long neck and a belly that is either globular or streamlined. Some have lids shaped like a bird's head.
4. Ritual pottery of the Tellem culture, decorated with a characteristic plaited roulette.
   a. Pot made on a convex mold built up by coiling.
   b. Hemispherical pot made on three or four legs or feet resting on a stand. (H: 18 cm.)
5. Kitchen pottery of the Tellem culture with the paddle-and-anvil technique decorated with impressions from woven mats. (H: 20 cm.)

II. Leather

Objects of leather found in Tellem funerary caves of the Bandiagara Escarpment include, but are not limited to:

A. Clothing.

1. Sandals often decorated and furnished with a leather ankle protection.
2. Boots profusely painted with geometric designs.
3. Plaited bracelets.
4. Knife-sheaths.
5. Loinskin.
6. Bag.

III. Metal

Objects of metal from the region of the Niger River Valley and the Bandiagara Escarpment include the following components:

A. Copper and Copper Alloy (Such as Bronze).

1. Figures/Statues.
   a. Anthropomorphic figures,

including equestrian figures and kneeling figures. (Some are miniatures no taller than 2 inches; others range from 6 to 30 inches).
b. Zoomorphic figures, such as the bull and the snake.
2. Bells (4–5 in.) and finger bells (2–3 in.).
3. Pendants, known to depict a bull's head or a snake. (H: 2–4 in.)
4. Bracelets, known to depict a snake (5–6 in.).
5. Bracelets, known to be shaped as a head and antelope (3–4 in.).

B. Iron.
1. Figures/Statues.
a. Anthropomorphic figures. (H: 5–30 in.)
b. Zoomorphic figures, sometimes representing a serpent. (H: 5–30 in.)
2. Headrests of the Tellem culture.
3. Ring-bells or fingerbells of the Tellem culture.
4. Bracelets and armlets of the Tellem culture.
5. Hairpins, twisted and voluted, of the Tellem culture.

IV. Stone

Objects of stone usually found in Tellem funerary caves of the Bandiagara Escarpment include, but are not limited to:

A. Carnelian beads (faceted).
B. Quartz lip plugs.

V. Glass Beads

Glass beads have been recovered in the Tellem funerary caves and in archaeological sites in the region of the Niger River Valley.

VI. Textiles

Textile objects, or fragments thereof, have been recovered in the Tellem funerary caves of the Bandiagara Escarpment and include, but are not limited to:

A. Cotton.
1. Tunics.
2. Coifs.
3. Blankets.

B. Vegetable Fiber.
Skirts, aprons and belts—made of twisted and intricately plaited vegetable fiber.

C. Wool.
Blankets.

VII. Wood

Objects of wood may be found archaeologically (in funerary caves of the Tellem or Dogon peoples in the Bandiagara Escarpment, for example).

Archaeological Material of Wood

Following are representative examples of wood objects usually found archaeologically:

A. Figures/Statues.
1. Anthropomorphic figures—usually with abstract body and arms raised standing on a platform, sometimes kneeling. (H: 10–24 in.)
2. Zoomorphic figures—depicting horses and other animals. (H: 10–24 in.)

B. Headrests.

C. Household Utensils.
1. Bowls.
2. Spoons—carved and decorated.

D. Agricultural/Hunting Implements.
1. Hoes and axes—with either a socketed or tanged shafting without iron blades.
2. Bows—with a notch and a hole at one end and a hole at the other with twisted, untanned leather straps for the ''string''.
3. Arrows, quivers.
4. Knife sheaths.

E. Musical Instruments.
1. Flutes with end blown, bi-toned.
2. Harps.
3. Drums.

Inapplicability of Notice and Delayed Effective Date

Because the amendment to the Customs Regulations contained in this document imposing import restrictions on the above-listed Malian cultural property is being made in response to a bilateral agreement entered into in furtherance of the foreign affairs interests of the United States, pursuant to section 553(a)(1) of the Administrative Procedure Act, (5 U.S.C. 553(a)(1)), no notice of proposed rulemaking or public procedure is necessary. For the same reason, a delayed effective date is not required.

Regulatory Flexibility Act

Because no notice of proposed rulemaking is required, the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) do not apply. Accordingly, this final rule is not subject to the regulatory analysis or other requirements of 5 U.S.C. 603 and 604.

Executive Order 12866

This amendment does not meet the criteria of a ''significant regulatory action'' as described in E.O. 12866.

Drafting Information

The principal author of this document was Keith B. Rudich, Esq., Regulations Branch, Office of Regulations and Rulings, U.S. Customs Service. However, personnel from other offices participated in its development.

List of Subjects in 19 CFR Part 12

Customs duties and inspections, Imports, Cultural property.

Amendment to the Regulations

Accordingly, Part 12 of the Customs Regulations (19 CFR part 12) is amended as set forth below:

PART 12—[AMENDED]

1. The general authority and specific authority citation for part 12, in part, continue to read as follows:

Authority: 5 U.S.C. 301, 19 U.S.C. 66, 1202 (General Note 20, Harmonized Tariff Schedule of the United States (HTSUS)), 1624;

* * * * *

Sections 12.104 through 12.104i also issued under 19 U.S.C. 2612;

* * * * *

2. In § 12.104g, paragraph (a) the list of agreements imposing import restrictions on described articles of cultural property of State Parties is amended by adding Mali in appropriate alphabetical order as follows:

§ 12.104g [Amended]

State	Cultural property	T.D. No.
* * *	* * *	*
Mali	Archaeological material from the Niger River Valley Region, Mali, and the Bandiagara Escarpment (Cliff) forming part of the remains of the sub-Sahara culture..	T.D. 97–80
* * *	* * *	*

3. In § 12.104(g), paragraph (b), the list of emergency actions imposing import restrictions on described articles of cultural property of State parties is amended by removing the entry for ''Mali'' in its entirety.

Samuel H. Banks,

Acting Commissioner of Customs.

Dated: September 12, 1997.

John P. Simpson,

Deputy Assistant Secretary of the Treasury.

[FR Doc. 97–25342 Filed 9–19–97; 2:01 pm]

BILLING CODE 4820–02–P

DEPARTMENT OF THE TREASURY

Customs Service Treasury Decisions

19 CFR Part 134

[T.D. 97–79]

Country of Origin Marking Guidance for Containers of Imported Fruit Juice Concentrate

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

ACTION: Policy statement.

SUMMARY: The purpose of this document is to remind the public of the existing Customs Service's interpretation of the application of the country of origin marking law to imported fruit juice concentrate. Customs has previously published guidance on application of the marking law to imported juice concentrate in Treasury Decision (T.D.) 89–66. In recognition of the fact that accounting for all minor foreign sources on the label may make compliance with the marking law prohibitively expensive, fruit juice processors have been permitted to comply with marking requirements by ''major supplier marking.'' Customs permits ''major supplier marking'' as an acceptable method of compliance. Processors may list up to ten countries if they account for at least 75 percent of foreign concentrate used. Additionally, the sources listed on a juice container must indicate the sources actually used in that lot, not the sources used in a representative past importing period. The full name of the country of origin must be used unless Customs has authorized abbreviations which unmistakably reflect the country of origin to the ultimate purchaser.

FOR FURTHER INFORMATION CONTACT: David Cohen, Special Classification and Marking Branch (202–482–6980).

SUPPLEMENTARY INFORMATION:

Background

In accordance with 19 U.S.C. 1304, and 19 CFR Part 134, Customs ensures that imported fruit juice concentrate entering the U.S. in large containers, e.g., tanker cars and multi-gallon drums, is properly marked to show country of origin. However, the country of origin marking requirements set forth in this document are those pertaining to labeling that must appear on packages of concentrated or reconstituted fruit juice containing imported concentrate that reach ultimate purchasers. The purpose of this document is to remind the public of these requirements.

Customs Service Decision (C.S.D.) 85–47 (Headquarters Ruling Letter (HRL) 728557, dated September 4, 1985) held that containers of orange juice in frozen concentrated or reconstituted forms which contain imported concentrate, must be marked on the labels with the foreign country of origin of the products. This decision was based on the determination that the imported foreign orange juice concentrate used in the production of frozen concentrated or reconstituted orange juice is not substantially transformed after undergoing further processing in the U.S., including blending with other batches of orange concentrate, addition of water, oils and essences, pasteurization or freezing, and repacking. Customs determined that the frozen concentrated or reconstituted orange juice did not emerge from the processing as a new article with a new name, character, and use. *United States* v. *Gibson-Thomsen* Co., 27 C.C.P.A. 267, (C.A.D. 98) (1940).

By a notice published in the **Federal Register** on July 30, 1986 (51 FR 27195), Customs announced that the country of origin marking requirements of orange juice set forth in C.S.D. 85–47, later upheld substantively in *National Juice Products Association* v. *United States,* 10 Ct. Int'l Trade 48, 628 F. Supp. 978 (1986), were extended to include all other imported fruit juice concentrate which undergoes processing in the U.S. similar to that performed on orange juice concentrate. Therefore, all frozen concentrated or reconstituted fruit juices made with foreign concentrate processed in a manner similar to that described in C.S.D. 85–47 must be marked to indicate the country of origin of the foreign concentrate. This position has been in effect since February 1, 1987. T.D. 86–120 (51 FR 23045 (June 25, 1986)).

Customs does not require ''all sources marking'' on containers of juice made with imported concentrate. Customs allows ''major supplier marking'' as an acceptable method of compliance for marking of imported juice concentrate. Major supplier marking permits processors to list up to ten foreign sources to account for 75 percent or more of imported concentrate. Customs concluded from previous consultations with those in the juice industry that in the majority of circumstances, five or fewer sources will account for at least 75 percent of foreign concentrate present in a lot, and that in virtually all cases, ten or fewer sources will account for 75 percent of the foreign concentrate. If ten sources do not amount to 75 percent of foreign concentrate, then all foreign sources must be listed. For purposes of complying with this requirement, ''lot'' is defined as it is in Food and Drug Administration regulations, 21 CFR 146.3(h)(1)(i), as ''[a] collection of primary containers or units of the same size, type, and style manufactured or packed under similar conditions and handled as a single unit of trade.'' ''Manufactured or packed under similar conditions'' is defined, for purposes of compliance with 19 U.S.C. 1304, as all the containers or units containing the same blend of foreign concentrates.

The listing of foreign sources must consist of the countries contributing the greatest percentages adding up to at least 75 percent. For example, processors may not skip over an ''undesirable'' source contributing 10 percent in order to list the next two ''unobjectionable'' sources contributing five percent each. However, the order within the list need not change based on ranking. For example, if a processor is blending foreign concentrates from two countries contributing 60 and 15 percent, respectively, and the two countries reversed proportions, the same label could be used on both lots.

In addition, Customs reminds the public that section 134.45, Customs Regulations (19 CFR 134.45), provides that:

> Except as otherwise provided in * * * this section, the markings required by this part shall include the full English name of the country of origin, unless another marking to indicate the English name of the country of origin is specifically authorized by the Commissioner of Customs * * *.

Only authorized abbreviations which unmistakably indicate the name of a country, such as ''Gt. Britain'' for ''Great Britain'' or ''Luxemb'' and ''Luxembg'' for ''Luxembourg'' are acceptable and variant spellings which clearly indicate the English name of the country of origin, such as ''Brasil'' for ''Brazil'' and ''Italie'' for ''Italy,'' are acceptable. Rulings may be obtained from the

Customs Service regarding what country abbreviations are acceptable for purposes of compliance with the marking statute. Customs notes that it is incorrect to abbreviate the word ''concentrate'' to ''conc'' when disclosing the origin of juice concentrate since the ultimate purchaser will not unmistakably identify ''conc'' as an abbreviation for the word ''concentrate.''

Summary

Imported fruit juice concentrate which is imported into the U.S. and used in the production of concentrated or reconstituted fruit juice is not substantially transformed after undergoing further processing in the U.S. Accordingly, all such imported concentrate is subject to the country of origin marking requirements of 19 U.S.C. 1304, and 19 CFR Part 134. Processors may use ''major supplier marking'' in preparing labels for containers of juice made with imported concentrate. If a processor obtains 75 percent or more of the imported concentrate used in a particular lot from ten or fewer countries, only those countries need be revealed. The full name of the country of origin must be used unless Customs has authorized abbreviations which unmistakably indicate the country of origin of the concentrate to the ultimate purchaser.

Drafting Information

The principal author of this document was David E. Cohen, Office of Regulations and Rulings, U.S. Customs Service. However, personnel from other offices participated in its development.

Date: September 17, 1997.

Stuart P. Seidel,

Assistant Commissioner, Office of Regulations and Rulings.

[FR Doc. 97–25134 Filed 9–22–97; 8:45 am]

BILLING CODE 4820–02–P

SOCIAL SECURITY ADMINISTRATION

20 CFR Parts 404 and 416

RIN 0960–AE58

Administrative Review Process, Testing Elimination of the Fourth Step of Administrative Review in the Disability Claim Process (Request for Review by the Appeals Council)

ACTION: Final rules.

SUMMARY: We are amending our rules to establish authority to test elimination of the final step in the administrative review process used in determining claims for Social Security and Supplemental Security Income (SSI) benefits based on disability. Under the final rules, the right of appeal for a claimant who is included in the test procedures and who is dissatisfied with the decision of an administrative law judge (ALJ) will be to file a civil action in Federal district court, rather than to request the Appeals Council to review the decision. We are testing procedures that eliminate the request for Appeals Council review in furtherance of the Plan for a New Disability Claim Process that former Commissioner of Social Security Shirley S. Chater approved in September 1994. Unless specified, all other regulations relating to the disability determination process and the administrative review process remain unchanged.

EFFECTIVE DATE: September 23, 1997.

FOR FURTHER INFORMATION CONTACT: Harry J. Short, Legal Assistant, Division of Regulations and Rulings, Social Security Administration, 6401 Security Boulevard, Baltimore, MD 21235, (410) 965–6243. For information on eligibility or claiming benefits, call our national toll-free number, 1–800–772–1213.

SUPPLEMENTARY INFORMATION:

Background

The Social Security Administration (SSA) currently uses a four-step process in deciding claims for Social Security benefits under title II of the Social Security Act (the Act) and for SSI benefits under title XVI of the Act. Claimants who are not satisfied with the initial determination on their claims may request reconsideration. Claimants who are not satisfied with the reconsidered determination may request a hearing before an ALJ, and claimants who are dissatisfied with an ALJ's decision may request review by the Appeals Council. Claimants who have completed these four steps, and who are dissatisfied with the final decision, may request judicial review of the decision by filing a civil action in Federal district court. 20 CFR 404.900 and 416.1400.

SSA's Plan for a New Disability Claim Process (59 FR 47887, September 19, 1994) anticipates establishment of a redesigned, two-step process for deciding Social Security and SSI claims based on disability. The redesign plan anticipates that the process for determining disability can be significantly improved by strengthening the steps of the process in which we make initial determinations and provide dissatisfied claimants an opportunity for a hearing before an ALJ, and by eliminating the reconsideration step and the step in which claimants request the Appeals Council to review the decisions of ALJs.

In 20 CFR 404.906 and 416.1406 (60 FR 20023, April 24, 1995), we have established authority to test, singly and in combination, several model procedures for modifying the disability claims process. Under that authority, we are testing, in isolation from other possible changes, a modification of the initial determination step in which a single decisionmaker, rather than a team composed of a disability examiner and a medical consultant, makes the initial determination of disability. In addition, under authority established in 20 CFR 404.943 and 416.1443 (60 FR 47469, September 13, 1995), we are also testing, in another model for evaluating a possible change in isolation from other changes, use of an adjudication officer as the focal point for all prehearing activities in disability cases in which a claimant requests a hearing before an ALJ.

To assess how the above changes and other elements of the disability redesign plan would work together in different combinations, we initiated an integrated test on April 7, 1997, that combines model procedures for major elements of the redesign plan. As structured under testing authority established in §§ 404.906, 404.943, 416.1406, and 416.1443 in combination, this integrated model includes, in addition to models for the single decisionmaker and the adjudication officer, a model for procedures to provide a predecision interview conducted by the single decisionmaker (at which a claimant for benefits based on disability will have an opportunity to submit further evidence and have an interview with the initial decisionmaker if the evidence is insufficient to support a fully favorable initial disability determination or would require an initial determination denying the claim), and a model to test eliminating the reconsideration step in disability claims.

In order to increase our ability to assess the effects of possible modifications of the disability claim process in combination, we are, through publication of these final rules, adding new §§ 404.966 and 416.1466 to our regulations to authorize testing of an additional modification in our integrated model. These final rules authorize us to incorporate in the integrated model additional procedures to test elimination of the step in the disability claim process in which a claimant requests the Appeals Council to review the hearing decision of an ALJ.

Our specific goal in testing elimination of the request for Appeals Council review will be to assess the effects of this change, as it functions in

conjunction with other modifications in the disability claim process included in the integrated model, on: (1) judicial workloads, and (2) the legal sufficiency of decisions subjected to judicial review. We consider the effects of the change in those respects to represent the principal, practical issues bearing on the advisability of eliminating the request for review step in connection with the planned, overall redesign of the disability claim process.

Regulatory Provisions

Under new §§ 404.966 and 416.1466, we will randomly select approximately one half of the requests for an ALJ hearing in the integrated model for potential inclusion in the test procedures for eliminating the request for Appeals Council review. The remaining requests for hearing in the integrated model will be processed under our regulations concerning the request for Appeals Council review step and subsequent judicial review. This will enable us to assess other modifications tested in the integrated model in association with both the test procedures for eliminating the request for Appeals Council review and our existing request for review procedures.

The provisions of §§ 404.966 and 416.1466 apply only to those ALJ decisions that have been identified for inclusion in that part of our integrated model in which the request for review by the Appeals Council is eliminated. Under these provisions, we will eliminate the request for review step (which has been established by agency regulations and is not mandated by the Act) in a case in the integrated model if: (1) the case has been randomly selected for inclusion in this aspect of the model, and (2) an ALJ issues a decision in the case that is less than wholly favorable to the claimant (i.e., unfavorable or only partially favorable to the claimant). Cases in the integrated model in which an ALJ issues a wholly favorable decision, dismisses a request for hearing, or issues a recommended decision will not be included in this part of the model. These cases will be processed under our existing procedures for requesting Appeals Council review and judicial review.

In a case to which the new rules apply, the appeal available to a claimant who is dissatisfied with the ALJ's decision will be, as the notice of the decision will advise, filing a civil action in Federal district court. Requesting review by the Appeals Council will be eliminated as an appeal and as a prerequisite to seeking judicial review.

Under §§ 404.966 and 416.1466, the ALJ's decision will be binding unless a party to the decision files a civil action, the Appeals Council decides within a specified time to review the decision on its own motion under the authority provided in 20 CFR 404.969 and 416.1469, or the decision is revised by the ALJ or the Appeals Council under the rules on reopening final decisions in 20 CFR 404.987 and 416.1487. A party to the decision will have the right to request the Appeals Council to grant an extension of time to file a civil action.

Evaluation Procedures

We will evaluate the effect of eliminating the request for review step on judicial workloads by comparing the rate at which civil actions are filed by individuals whose claims are processed under the current administrative review steps in the disability claims process—i.e., the four step process—to the rate at which civil actions are filed in cases selected for processing under the test procedures for eliminating the request for Appeals Council review. We will also consider the rate at which civil actions are filed in cases in the integrated model in which we retain the request for Appeals Council review. In addition, we will collect and evaluate information on the reasons individuals included in the elimination of the request for review decide either to pursue or to forgo appeals to district courts.

We will assess the effect of eliminating the request for review on the legal sufficiency of final decisions by comparing the rates at which, following the filing of civil actions in cases included in the integrated model and in a control sample of cases processed under the current administrative review steps in the disability claims process, we request court-remand of a case within the period during which the Commissioner of Social Security may file his answer to a civil action under section 205(g) of the Act. The Appeals Council, working with agency counsel, will evaluate the claims in the integrated model and in the control sample to identify instances in which a court should be requested (as courts may be under existing procedures) to remand a case for further administrative action. The information we will collect and evaluate will include data on the agency's ability to assess the legal sufficiency of cases on a timely basis without having to file court motions requesting extensions of the time in which the agency's answer may be filed.

Public Comments

These regulatory provisions were published in the **Federal Register** as a notice of proposed rulemaking (NPRM) on May 16, 1997 (62 FR 26997). We provided the public a 30-day comment period. We received statements in response to this notice from 10 individuals, including employees of SSA and attorney and nonattorney representatives of claimants. We also received comments from a legal services organization, the American Bar Association, and the Administrative Office of the United States Courts.

Many of the commenters discussed reasons for believing that the request for Appeals Council review should be retained either as a mandatory or an optional step in the disability claim process. These comments can be viewed as opposing testing of the elimination of the request for review step on the basis that the need for the step, as it now exists or as it might be changed under the commenter's suggestions, is sufficiently clear to rule out testing its elimination. We have summarized these statements in a single comment to this effect that we address below with the other substantive comments received.

The American Bar Association welcomed SSA's proposal to study the Appeals Council's role and endorsed the plan to examine the impact of eliminating the request for review step, without taking a position with respect to the specific procedures proposed for testing that impact. The Administrative Office of the United States Courts reported that the Federal judiciary continues to be seriously concerned about the impact of eliminating the request for review by the Appeals Council on the caseloads of the Federal courts. However, this office supported careful testing of the proposed changes and thorough analysis of the results as consistent with the common interests of SSA and the courts in providing efficient and legally sufficient decisions, and made specific recommendations, which we address below in our responses to the comments received, as to how to ensure such testing and analysis.

Because some of the comments were detailed, we condensed, summarized or paraphrased them. We have, however, tried to summarize the commenters' views accurately and respond to all of the significant issues raised by the commenters that are within the scope of the proposed rules. As we discuss below in responding to the comments, we have made an addition to the proposed rules to clarify their intent. We have also responded to comments received by adding to our planned evaluation design.

Comment: A number of the commenters implicitly or explicitly

opposed testing elimination of the request for review step in the disability claim process on the basis that the step is necessary or worthwhile and should not be eliminated. The wide-ranging reasons cited for this view included the following: that a shorter process is not necessarily a fairer process, that SSA should deal with the increase in the Appeals Council's workloads by increasing its staff and other support, that claimants may drop out of the process prematurely because of the costs and other difficulties involved in filing civil actions, that SSA's workloads will be increased by the filing of new claims by individuals who leave the administrative appeals process prematurely, and that the change will result in large increases in caseloads in the Federal courts.

Response: The reasons cited in support of this comment are generally similar to reasons for not eliminating the request for review step we received and considered in developing and publishing the Plan for a New Disability Claim Process. Many of these reasons have merit, to one degree or another. However, there are also sound reasons for believing that eliminating the request for review step would improve the disability claim process, if carried out in conjunction with other changes to that process. After reviewing these additional statements in opposition to eliminating the request for review step, we continue to believe that we should test eliminating this step in conjunction with other possible changes for the purpose of gaining additional information needed to make a fully informed decision.

Comment: One individual opposed the proposed testing of the elimination of the request for review step on the basis that such testing could itself adversely affect over 30,000 claimants, lessening their chances of receiving a favorable ALJ decision (because ALJs will know in advance that less than wholly favorable decisions in certain cases will not be subject to a request for Appeals Council review), without providing the claimants involved in the testing any offsetting benefits stemming from process unification and changes to the front-end of the disability claim process.

Response: As we stated in the NPRM, these rules will authorize elimination of the request for review in only a relatively small number of cases, which we project at approximately 1900. The test will apply only in those cases in the integrated model that give rise to a request for an ALJ hearing (projected at approximately 10,000 cases), that are then randomly selected for inclusion in the request for review elimination (contingent on an ALJ's issuance of a less than wholly favorable decision), and that result in a less than wholly favorable decision.

We do not know that there would be, as this comment indicates, a reduction in the likelihood of an allowance decision because the ALJ in a case knows that the case will not be subject to a request by the claimant for review by the Appeals Council and will, instead, be subject to the immediate filing of a civil action to secure judicial review. However, we believe that we should maximize the relevant, advance notice that we can give individuals that their cases will be included in these test procedures of the integrated model (if an ALJ issues a decision that is less than wholly favorable) and will, therefore, provide notice of that circumstance in the acknowledgment letter issued by the adjudication officer at the start of the ALJ hearing process. We also believe it is important to test these changes at the ALJ hearing level with the advance knowledge of the participants in that, if the request for review step were ultimately eliminated, all the participants in the hearing process would know that the appeal available to a dissatisfied claimant would be to file a civil action in Federal district court.

The test of eliminating the request for review will be accompanied by changes in the front-end of the disability claim process and by process unification changes. Individuals participating in this test will participate in other changes being tested in the integrated model, including the opportunity for a face-to-face interview with the initial decisionmaker and elimination of the reconsideration step. In addition, like all claims for benefits based on disability, the claims involved in the test of eliminating the request for Appeals Council review will be decided under the significant process unification changes we have already made to the disability claims process. These changes include the publication of a series of Social Security Rulings on some of the most significant issues in disability adjudication (61 FR 34466–34492, July 2, 1996), and the training of all of our adjudicators, at all adjudicative levels, in the correct application of these rulings.

Comment: One individual expressed doubt about the methodology of the proposed test, questioning whether testing elimination of the request for Appeals Council review in only about 1900 cases will provide a statistically valid universe for deriving useful information relative to a process that involves, at the ALJ level, hundreds of thousands of cases and varied factors affecting case outcome.

Response: Prior to implementing the integrated model in April 1997, we secured an independent analytical assessment of the completeness, adequacy, and statistical soundness of our plans for conducting and evaluating the testing to be carried out in that model, including our plans for testing elimination of the request for Appeals Council review. Performed by the Lewin Group, Inc., this assessment concluded that our test design was fundamentally sound and that, even if recommendations for improving the test were not implemented, the test would likely produce valid findings and provide information that decisionmakers and stakeholders need. Final Report, An Independent Assessment of the Proposed Structure, Operation, and Evaluation Plans of the Full Process Model Pilot (hereafter, Final Report), prepared by the Lewin Group, Inc., March 14, 1997, p. 2. (The ''Full Process Model Pilot'' is same test that we are herein referring to as the ''integrated model.'')

We have implemented most of the recommendations the Lewin Group made for improving our test and evaluation procedures. The recommendations implemented include the recommendation the Lewin Group made relative to testing elimination of the request for Appeals Council review (which recommendation concerned when in the process individuals should be notified that they will not have an opportunity to request Council review). Final Report, p. 21.

Comment: The Administrative Office of the United States Courts requested clarification as to which judicial districts will be affected.

Response: The test of eliminating the request for Appeals Council review will affect claims of individuals residing in the following ten States: Arizona, Colorado, Georgia, Kentucky, New York, Pennsylvania, South Carolina, Tennessee, Utah, and Wisconsin. District courts in these States will be affected by procedures for testing and evaluating the request for Appeals Council review elimination.

Comment: The Administrative Office of the United States Courts also recommended that follow-up surveys be conducted with participants in the test of eliminating the request for Appeals Council review to determine what factors went into the decisions of claimants either to pursue or to forgo appeals to district courts.

Response: Under our evaluation design for the integrated model, we

intend to conduct surveys to collect information on multiple issues we are assessing in this model. We believe it would be helpful to collect and evaluate information regarding the factors concerning court filings identified by this commenter, and we will do that. Collecting such information requires no change in the regulatory provisions as proposed.

Comment: The Administrative Office of the United States Courts also thought that it would be advantageous to have a set period for the test, followed by a meaningful review of the results, particularly the impact upon Federal court filings, prior to a determination being made as to whether permanent changes would be made to the Appeals Council review step. This commenter also noted in this regard that the Federal judiciary would like to be made aware of the results of the proposed test.

Response: We project that the operational aspects of the integrated model will be completed within two and a half to three years of our initiation of testing in the front-end parts of the model in April 1997. This projection includes the estimated time we will require to conduct pre-answer assessments of the legal sufficiency of new court cases that arise in cases in the integrated model. No fixed term for the test can be set because completion of its operational aspects will depend on when the last civil action is filed in cases in the integrated model in which the request for review is eliminated or the Appeals Council denies review. We will then require an additional period to conclude our evaluation of the test results.

We agree that we should not decide to propose elimination of the request for review step in the disability claim process until we have undertaken preliminary consultation with key stakeholders, including the Administrative Office of the United States Courts, about the results demonstrated in our testing of the integrated model, and about the multiple issues that would be involved in proposing such a change. If a decision were made to propose elimination of the request for review step after analysis of the test results, we would, of course, publish an NPRM soliciting public comments on the various changes in our regulations that would be required to implement this change.

Comment: A private attorney representative of claimants commented that the proposed regulations are ''contrary to the Act in that they purport to use the first part of sentence six [of § 205(g) of the Act] to reclaim ALJ decisions the agency concludes are indefensible or that the agency does not otherwise want to defend.'' This commenter believes that the first part of sentence six is properly used only in very narrow circumstances, such as when a hearing transcript cannot be prepared, and that Congress did not enact part one of sentence six to provide the agency with a chance to rehear or redo an inadequate ALJ decision for the purpose of avoiding a ruling on the merits of the decision under sentence four of § 205(g).

Response: The agency's procedures for assessing the legal defensibility of cases filed in Federal court will not be affected by the final rules, and any court action requested in light of such assessment will continue to be subject to the relevant provisions of § 205(g) of the Act. We do not, however, agree that the first clause of sentence six of § 205(g) must be construed in the restrictive manner suggested by the commenter, who believed that sentence six allows remands prior to the filing of the answer only in ''very narrow circumstances, such as when a hearing transcript cannot be prepared.'' The first clause of sentence six expressly allows the court to remand cases for further proceedings ''for good cause shown.'' It neither delineates nor limits the circumstances which may be sufficient for a demonstration of good cause. Moreover, the legislative history of this provision recognizes the type of procedural difficulty suggested by the commenter to be an example of ''good cause,'' not an exclusive delineation of the circumstances that may constitute good cause. H.R. Conf. Rep. No. 944, 96th Cong., 2d Sess. 58–59 (1980). Significantly, virtually every court which has addressed the issue has held that the defining characteristic of a sentence six, clause one remand lies in the timing of the remand request, not in its characterization as either substantive or technical, *i.e.*, if the remand is requested by the Commissioner prior to the filing of his answer, it falls under sentence six, and if the Commissioner's request is made subsequent to the filing of an answer, it may fall under sentence four.

Comment: This same individual also commented that the proposed rules represent an implicit assertion by the agency that it may extend the 60 days for taking own motion review to any time before the Commissioner files his answer.

Response: It is our intent that the Appeals Council shall have authority to review a case on its own motion under these final rules only if it decides to review the case, and issues a notice establishing the occurrence of such a decision, within the 60-day period prescribed in §§ 404.969 and 416.1469 (i.e., within 60 days of the date of the hearing decision). We believe this intent is clear in the rules as proposed, which indicate in §§ 404.966(b)(2) and 416.1466(b)(2) that the own-motion authority the Appeals Council will have under these rules is the authority provided in §§ 404.969 and 416.1469.

In test cases in which the request for review by the Appeals Council is eliminated and the notice of the ALJ's decision advises the parties of the right to file a civil action, it is also our intent that the authority of the Appeals Council to decide to review a case on its own motion shall cease to exist, even if 60 days have not yet lapsed after the date of the ALJ's decision, as of the date, if any, upon which the jurisdiction of a Federal district court is established by the filing of a civil action as provided in the Federal Rules of Civil Procedure. We have clarified §§ 404.966(b)(2) and 416.1466(b)(2) to make this intention clearer. The agency's assessment of a case following establishment of the jurisdiction of a Federal court will occur under the provisions of § 205(g) of the Act, 42 U.S.C. § 405(g).

In a case in which we test elimination of the request for Appeals Council review, a decision by the Appeals Council to review an ALJ's decision under §§ 404.969 or 416.1469 will mean that the Council has assumed jurisdiction of the case, thereby causing the decision not to be a final decision of the Commissioner of Social Security subject to judicial review under § 205(g) of the Act. If the Appeals Council decides to review one of these cases on its own motion, it must issue a notice establishing its decision to do so before a civil action is filed establishing the jurisdiction of a Federal district court.

To clarify our intent in these respects, we have revised §§ 404.966(b)(2) and 416.1466(b)(2) in the final rules to include a provision specifying that the Appeals Council must issue a notice announcing its decision to review the case on its own motion before the filing date of any civil action establishing the jurisdiction of a Federal district court.

Comment: This same individual also commented that the proposed regulations invite unnecessary litigation over motions for extension of time to file answer.

Response: As we discussed in the NPRM, our intent is that the Appeals Council, working with agency counsel, will evaluate the legal sufficiency of cases in the integrated model and in a

control sample to determine, within the time in which the Commissioner of Social Security may file his answer, if we should request the court to remand the case. We do not expect that these activities will require the agency frequently to request extensions of time to file answers in these cases. However, our ability to carry out these evaluations in a timely fashion is an important consideration and will be one of the matters we assess in the testing to be conducted under these final rules.

Based on our analysis of the comments, we are adopting the proposed rules with the above-discussed addition to §§ 404.966(b)(2) and 416.1466(b)(2). This addition clarifies the time during which the Appeals Council may decide on its own motion to review a case to which these final rules apply. We have also made the following minor editorial changes in the rules as proposed: we have inserted the words ''in which'' in the final clause of the last sentence of §§ 404.966(a) and 416.1466(a), and we have made technical corrections in the numbering of the subparagraphs of §§ 404.966(b) and 416.1466(b). The additions we have made to our evaluation plans based on consideration of the comments require no changes in the regulatory provisions as proposed.

Regulatory Procedures

We find good cause for dispensing in this instance with the 30-day delay in the effective date of a substantive rule provided for by 5 U.S.C. 553(d). For the reasons set forth below, we find that it is unnecessary and contrary to the public interest to delay the effective date of these final rules.

We find that delay of the effective date is unnecessary because the affected individuals will be notified of the possibility of elimination of the Appeals Council review step more than 30 days before any such elimination actually occurs. Under new §§ 404.966 and 416.1466, we will randomly select cases in the integrated model for contingent inclusion in the test of eliminating the request for Appeals Council review after a request for an ALJ hearing is filed and before the adjudication officer acknowledges receipt of the request for a hearing. In the cases selected, as we have previously discussed, the acknowledgement letter the adjudication officer sends will notify the individual filing the request (and any appointed representative of the individual) that if an ALJ issues a decision that is less than wholly favorable, the right of appeal available to the individual will be to file a civil action in Federal district court.

Elimination of the request for Appeals Council review step will not occur in a case, if it occurs at all, until after the adjudication officer sends the case to an ALJ, a hearing is scheduled and held (except where the parties waive an oral hearing), and the ALJ issues a decision that is less than wholly favorable. Therefore, even with elimination of the 30-day delay in the effective date of these final rules, the substantive change authorized by §§ 404.966 and 416.1466, elimination of the request for Appeals Council review step for test purposes, will not actually occur until after more than 30 days have elapsed from the date of the publication of these final rules in the **Federal Register**.

We also find that delay of the effective date is contrary to the public interest because it would compromise our ability to evaluate the effects of the test. By making the rules effective upon publication, we can immediately implement the planned selection and notice procedures and thereby make it possible to test elimination of the request for Appeals Council review in the greatest number of cases in the integrated model that can be used without reducing our ability also to test, as we believe we should, use of the other new procedures in the integrated model with the request for review step. We believe that maximizing the number of cases in the integrated model in which we can test elimination of the request for Appeals Council review step, while also testing retention of that step in conjunction with the other changes in the integrated model, will contribute to the soundness of our evaluation of the effects of eliminating this step from the disability claim process.

Executive Order 12866

We have consulted with the Office of Management and Budget (OMB) and determined that these rules meet the criteria for a significant regulatory action under Executive Order 12866. Thus, they were subject to OMB review. These rules do not adversely affect State, local or tribal governments. The administrative costs of the test will be covered within budgeted resources. No program costs are expected to result from the processing of the test cases. We have not, therefore, prepared a cost/benefit analysis under Executive Order 12866.

Regulatory Flexibility Act

We certify that these regulations will not have a significant economic impact on a substantial number of small entities because these rules affect only individuals. Therefore, a regulatory flexibility analysis as provided in the Regulatory Flexibility Act, as amended, is not required.

Paperwork Reduction Act

These regulations impose no new reporting or record keeping requirements requiring OMB clearance.

(Catalog of Federal Domestic Assistance Program Nos. 96.001, Social Security-Disability Insurance; 96.006, Supplemental Security Income)

List of Subjects

20 CFR Part 404

Administrative practice and procedure, Death benefits, Disability benefits, Old-Age, Survivors and Disability Insurance, Reporting and recordkeeping requirements, Social Security.

20 CFR Part 416

Administrative practice and procedure, Aged, Blind, Disability benefits, Public assistance programs, Supplemental Security Income (SSI), Reporting and record keeping requirements.

Dated: August 26, 1997.

John J. Callahan,

Acting Commissioner of Social Security.

For the reasons set out in the preamble, subpart J of part 404 and subpart N of part 416 of chapter III of title 20 of the Code of Federal Regulations are amended as set forth below.

PART 404—FEDERAL OLD-AGE, SURVIVORS AND DISABILITY INSURANCE (1950–)

20 CFR part 404, subpart J, is amended as follows:

1. The authority citation for subpart J of part 404 continues to read as follows:

Authority: Secs. 201(j), 205(a), (b), (d)–(h), and (j), 221, 225, and 702(a)(5) of the Social Security Act (42 U.S.C. 401(j), 405(a), (b), (d)–(h), and (j), 421, 425, and 902(a)(5)); 31 U.S.C. 3720A; sec. 5, Pub. L. 97–455, 96 Stat. 2500 (42 U.S.C. 405 note); secs. 5, 6(c)–(e), and 15, Pub. L. 98–460, 98 Stat. 1802 (42 U.S.C. 421 note).

2. New § 404.966 is added under the undesignated center heading ''APPEALS COUNCIL REVIEW'' to read as follows:

§ 404.966 Testing elimination of the request for Appeals Council review.

(a) *Applicability and scope.* Notwithstanding any other provision in this part or part 422 of this chapter, we are establishing the procedures set out in this section to test elimination of the request for review by the Appeals Council. These procedures will apply in randomly selected cases in which we have tested a combination of model

procedures for modifying the disability claim process as authorized under §§ 404.906 and 404.943, and in which an administrative law judge has issued a decision (not including a recommended decision) that is less than wholly favorable to you.

(b) *Effect of an administrative law judge's decision.* In a case to which the procedures of this section apply, the decision of an administrative law judge will be binding on all the parties to the hearing unless —

(1) You or another party file an action concerning the decision in Federal district court;

(2) The Appeals Council decides to review the decision on its own motion under the authority provided in § 404.969, and it issues a notice announcing its decision to review the case on its own motion no later than the day before the filing date of a civil action establishing the jurisdiction of a Federal district court; or

(3) The decision is revised by the administrative law judge or the Appeals Council under the procedures explained in § 404.987.

(c) *Notice of the decision of an administrative law judge.* The notice of decision the administrative law judge issues in a case processed under this section will advise you and any other parties to the decision that you may file an action in a Federal district court within 60 days after the date you receive notice of the decision.

(d) *Extension of time to file action in Federal district court.* Any party having a right to file a civil action under this section may request that the time for filing an action in Federal district court be extended. The request must be in writing and it must give the reasons why the action was not filed within the stated time period. The request must be filed with the Appeals Council. If you show that you had good cause for missing the deadline, the time period will be extended. To determine whether good cause exists, we will use the standards in § 404.911.

PART 416—SUPPLEMENTAL SECURITY INCOME FOR THE AGED, BLIND, AND DISABLED

20 CFR part 416, subpart N, is amended as follows:

1. The authority citation for subpart N continues to read as follows:

Authority: Sec. 702(a)(5), 1631, and 1633 of the Social Security Act (42 U.S.C. 902(a)(5), 1383, and 1383b).

2. New § 416.1466 is added under the undesignated center heading ''APPEALS COUNCIL REVIEW'' to read as follows:

§ 416.1466 Testing elimination of the request for Appeals Council review.

(a) *Applicability and scope.* Notwithstanding any other provision in this part or part 422 of this chapter, we are establishing the procedures set out in this section to test elimination of the request for review by the Appeals Council. These procedures will apply in randomly selected cases in which we have tested a combination of model procedures for modifying the disability claim process as authorized under §§ 416.1406 and 416.1443, and in which an administrative law judge has issued a decision (not including a recommended decision) that is less than wholly favorable to you.

(b) *Effect of an administrative law judge's decision.* In a case to which the procedures of this section apply, the decision of an administrative law judge will be binding on all the parties to the hearing unless —

(1) You or another party file an action concerning the decision in Federal district court;

(2) The Appeals Council decides to review the decision on its own motion under the authority provided in § 416.1469, and it issues a notice announcing its decision to review the case on its own motion no later than the day before the filing date of a civil action establishing the jurisdiction of a Federal district court; or

(3) The decision is revised by the administrative law judge or the Appeals Council under the procedures explained in § 416.1487.

(c) *Notice of the decision of an administrative law judge.* The notice of decision the administrative law judge issues in a case processed under this section will advise you and any other parties to the decision that you may file an action in a Federal district court within 60 days after the date you receive notice of the decision.

(d) *Extension of time to file action in Federal district court.* Any party having a right to file a civil action under this section may request that the time for filing an action in Federal district court be extended. The request must be in writing and it must give the reasons why the action was not filed within the stated time period. The request must be filed with the Appeals Council. If you show that you had good cause for missing the deadline, the time period will be extended. To determine whether good cause exists, we will use the standards in § 416.1411.

[FR Doc. 97–25124 Filed 9–22–97; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR 157

[CGD 91–045]

RIN 2115–AF51

Operational Measures To Reduce Oil Spills From Existing Tank Vessels Without Double Hulls

AGENCY: Coast Guard, DOT.

ACTION: Final rule; response to petitions for rulemaking.

SUMMARY: On July 30, 1996, the Coast Guard published a final rule requiring the owners, masters, or operators of tank vessels of 5,000 gross tons or more that do not have double hulls and that carry oil in bulk as cargo to comply with certain operational measures. This final rule included a provision requiring, in some cases, owner notification of the vessel's calculated anticipated under-keel clearance which was scheduled to go into effect on November 27, 1996. Following issuance of the final rule, the Coast Guard received comments, several in the form of petitions for rulemaking, expressing concern about the implementation of the owner notification portion of the under-keel clearance provision and requesting an additional opportunity to comment on the provision. On November 27, 1996, the Coast Guard granted this request by suspending the provision and giving the public 90 days to comment on the under-keel clearance requirement in general. After reviewing the additional public comments, the Coast Guard issues a final rule which revises the under-keel clearance requirement for single-hull tank vessels and responds to the petitions for rulemaking.

DATES: This final rule is effective on January 21, 1998.

ADDRESSES: Documents as indicated in this preamble are available for inspection or copying at the office of the Executive Secretary, Marine Safety Council (G–LRA/3406), U.S. Coast Guard Headquarters, 2100 Second Street SW., room 3406, Washington, DC 20593–0001, between 9:30 a.m. and 2 p.m., Monday through Friday, except Federal holidays. The telephone number is 202–267–1477.

FOR FURTHER INFORMATION CONTACT: LCDR Suzanne Englebert, Project Manager, Project Development Division, at 202–267–1492 or LT Brian Willis, Vessel Compliance Division, at 202–267–2735.

SUPPLEMENTARY INFORMATION:

Regulatory History

The regulatory history for this rulemaking is recounted in the preamble of the final rule entitled ''Operational Measures to Reduce Oils Spills from Existing Tank Vessels without Double Hulls'' (61 FR 39770; July 30, 1996).

As the result of the petitions from industry, the Coast Guard published a notice in the **Federal Register** on November 27, 1996 suspending the effective date of the owner notification provision in the under-keel clearance requirement entitled ''Operational Measures to Reduce Oil Spills from Existing Tank Vessels without Double Hulls; Partial Suspension of Regulation'' (61 FR 60189) and solicited additional comments on the entire under-keel clearance provision contained in the final rule.

Background and Purpose

Background information on operation measures for existing vessels without double hulls is provided in the preambles to the advance notice of proposed rulemaking (ANPRM) (56 FR 56284; November 1, 1991), the notice of proposed rulemaking (NPRM) (58 FR 54870; October 22, 1993), the supplemental notice of proposed rulemaking (SNPRM) (60 FR 55904; November 3, 1995), and the final rule (61 FR 39770; July 30, 1996).

Discussion of Comments

The Coast Guard received 65 letters containing over 190 comments on the under-keel clearance provision of the operational measures July 1996 final rule. Two comments strongly supported the under-keel clearance requirement as written in the final rule. Two other comments requested an extension of the comment period for the partial suspension. One of these, in addition to the party's original petition, requested specific data from the Coast Guard on the basis for the requirement. A copy of the Coast Guard's response to this request was added to the docket. Thereafter, the Coast Guard notified the public of this addition to the docket and permitted the public an additional 30 days to comment (62 FR 3463; January 23, 1997).

The following discussion summarizes the remaining comments and is divided into the following topics: (1) Removal of the under-keel clearance requirement; (2) Owner notification; (3) Applicability; (4) Economic analysis; (5) Master/pilot relationship; and (6) Calculations.

1. Removal of the Under-Keel Clearance Requirement

Fifty-two comments urged the Coast Guard to eliminate the under-keel clearance requirement from the operational measures rulemaking. Twenty-four comments argued that the under-keel clearance requirement circumvents the knowledge and ability of the master and pilot—parties that have historically policed themselves and have the local expertise to safely command the vessel—and should, therefore, be removed. Nineteen of these comments specifically suggested that it was not necessary for the Coast Guard to regulate under-keel clearance, since current industry practice dictates the responsible performance of under-keel clearance calculations by the master. One comment indicated that the anticipated under-keel clearance requirement contained in the operational measures final rule was similar to the recordkeeping aspects of the International Safety Management (ISM) Code and, therefore, redundant. Another comment contended that the rules regarding under-keel clearance were not only unnecessary, but dangerous, and urged their immediate removal. The comment explained that to require a discussion of under-keel clearance at night could result in the loss of night vision and create the potential for more accidents to occur.

The Coast Guard finds that requiring a master to calculate the anticipated under-keel clearance of the ship, discuss the clearance and the transit with the pilot, and ensure that the decisions being made on the bridge comply with company policy reflects good seamanship. Effective communication and passage planning are critical for a large single-hull tankship entering port. The failure of either can contribute to accidents as was presented in the quantitative risk model for the SNPRM. Thus, an anticipated under-keel clearance provision was required. It was recognized in both the SNPRM and the final rule that many companies, masters, and pilots conduct ''self-imposed'' under-keel clearance planning. The requirement in the final rule ensured all single-hull tankship masters plan, consider, and communicate this crucial aspect of navigation. The current regulations contained in 33 CFR 164.11 require tankship personnel to set the vessel's speed with regard to the vessel's maneuverability when there is small under-keel clearance. They do not require the specific calculation of clearance or the planning of the ship's transit to identify areas of concern. Section 164.11 also does not focus the discussion of the pilot and master on passage planning or under-keel clearance. This final rule amends the original prescriptive calculation requirement of § 157.455 and removes the owner notification provision, but continues to stress the importance of communications between the pilot and the master about the vessel's transit, including its anticipated under-keel clearance.

The ISM code requirements also do not specifically require that tankship masters calculate the anticipated under-keel clearance of their vessels prior to entering or leaving port. Therefore, as required in this final rule, the master's consideration of the vessel's anticipated under-keel clearance and the owner's issuance of company guidance, complement the ISM code. By recognizing the owner's responsibility in providing safety guidance to the master and focusing that guidance to the time single-hull tankships are most at risk of spilling large quantities of oil (while maneuvering to or from a facility or anchorage), this final rule will reduce the likelihood of future casualties.

The Coast Guard disagrees that the calculation of anticipated under-keel clearance or conferring with company personnel or referring to company guidance poses a safety risk. Bridge personnel have checklists, cargo calculations, pilot information cards, chart plots, and several other items that must be completed prior to transiting a port. During night transits, the requirements are the same. Consultation with the company should not pose difficulty to a master of any ship, in daylight or at night. If it does, safety is hindered by other human factors such as a lack of clearly written guidance, no local contact personnel, or an ineffective means of communication on the bridge, not by an under-keel clearance requirement. Regardless, the Coast Guard has amended the anticipated under-keel clearance requirement by simply requiring the owner or operator to provide written guidance to the tankship master rather than allowing the option of either written policy or contacting company personnel. By only requiring written guidance, the Coast Guard is ensuring a tankship master no longer has to worry about not being able to contact company personnel or leaving the bridge in order to comply with the requirement.

Twenty-four comments recommended that the anticipated under-keel clearance provision be removed and replaced with a non-regulatory requirement that the controlling depth and proper under-keel clearance be established by the Captain of the Port

(COTP), the pilot, or the Port Authority. The comments reasoned that these entities are in the best position to develop criteria, because of their in-depth knowledge of port conditions and their ability to specify the limiting factors applicable to a port.

The Coast Guard does not prohibit the Port Authority or any other port group from meeting and developing guidance for tankships. OPA 90 required the Coast Guard to implement regulatory measures that were both economically and technologically feasible for single-hull tankship prior to their phase-out dates. This final rule implements a planning tool termed ''anticipated under-keel clearance'' for single-hull tank vessels in order to implement the requirements of section 4115(b) of OPA 90. This rule does not conflict with any existing prescribed port authority under-keel clearance guidance.

One comment argued that the Coast Guard did not properly substantiate the operational measures final rulemaking. The comment proposed that the administrative record constructed by the Coast Guard lacked the factual basis to support a determination to implement an anticipated under-keel clearance requirement for single-hull tankships. The comment argued that an anticipated under-keel clearance requirement was not necessary, because lack of clearance has not been documented as a contributing factor in any oil spills to this date. In addition, the comment contended that the Coast Guard neglected to give the public due notice of the anticipated under-keel clearance owner notification requirement and its assessment in the final rule.

The regulatory analysis for the SNPRM was based on a subjective review of single-hull vessel casualties. Generally, there are multiple causes for each accident which are commonly termed ''chain of events.'' As explained in the SNPRM and the final rule assessment, if a contributory cause of the reviewed casualty was a lack of passage planning, including the failure of the master to review the vessel's draft, depth, or route prior to a port transit, a portion of the spilled oil was documented as being preventable by use of an under-keel clearance requirement. Using the SNPRM's quantitative risk assessment, this spilled oil amount was then reduced by a range of 10 to 23 percent of the original amount to reflect the predicted effectiveness of the proposed anticipated under-keel clearance provision. Predicting the future avoidance of casualties based on a risk assessment is an accepted analytical tool. The fact that a major oil spill cannot be attributed solely to a lack of under-keel clearance, does not indicate that potential benefits from a focused effort on under-keel clearance do not exist. The lack of calculating anticipated under-keel clearance and discussing the vessel's route prior to entering or leaving a port have partially contributed to past casualties. This past history is enough to substantiate the benefits of a passage planning requirement that focuses on anticipated under-keel clearance to prevent groundings by single-hull tankships.

The Coast Guard contends that the public was afforded due notice and the opportunity to comment on the anticipated under-keel clearance provisions. In the SNPRM the Coast Guard discussed both the mandatory passage planning requirement and the need to involve the vessel's owner in making navigation decisions. In fact, every relevant regulatory document associated with operational measures has stressed the importance the Coast Guard places on owner involvement. In response to adverse comments to the SNPRM's proposed ½ meter anticipated under-keel clearance minimum, the Coast Guard removed the uniform under-keel clearance requirement and replaced it with a logical outgrowth of that concept. Both the assessments and the source documents for every incident documented in the assessments were in the public record and were available to the public during this rulemaking. The Coast Guard nevertheless suspended the under-keel clearance requirement and allowed an additional comment period to guarantee that every pubic concern was thoroughly considered and addressed before it took this final action on under-keel clearance for single-hull tank vessels.

2. Owner Notification

Fifty-four comments urged the Coast Guard to remove the owner notification provisions contained in §§ 157.455(a)(5) and (6) of the operational measures regulation. The comments argued that shore-based personnel contacted for a decision regarding anticipated under-keel clearance could be located thousands of miles away from the port and unfamiliar with the maneuvering characteristics and behavior of the vessel in a loaded condition. In essence, they argued that the master may have to rely on the ''expertise'' of an unqualified party in another part of the world, who may never have been to sea, and may be half asleep when contacted to make a decision as to whether a vessel should proceed. However, ten comments indicated that, if the Coast Guard deemed it necessary to regulate under-keel clearance, they would support a requirement that owners or operators provide under-keel guidance through a prescribed policy which could be consulted by the master during transit. One comment fully supported the approach taken by the Coast Guard in the final rule and endorsed it as valid. The comment stated that conscientious operators do, and all operators should, take under-keel clearance into account when planning a voyage. The comment further explained that the pilot's job is made easier knowing that the ship has been loaded with due regard for local draft limitations and that the master and the ship's owner have considered the limitations in planning the vessel's transit.

In the final rule, the Coast Guard issued a requirement that involved the owner or operator at the policy level. In addition, an alternative to supplying written company policy on under-keel clearance was provided allowing the master to contact company personnel. This measure ensured that company policy was checked or management was informed of the vessel's passage situation. This final rule removes the owner notification provision and simply requires company policy to be provided to the master. The responsibility for estimating the anticipated under-keel clearance along the transit route of the vessel, including the facility or anchorage, is now placed on the master. However, the company policy should provide the master the guidance needed to pre-plan the transit and the direct authority to delay the transit or take any action necessary to ensure the vessel's safe navigation.

Three comments noted what they perceived as a ''technical defect'' in the drafting of § 157.455(a)(6). The provision states that an owner should not allow a vessel to proceed if transit ''would not be prudent considering, but not limited to, the anticipated under-keel clearance, any Captain of the Port (COTP) under-keel clearance guidance, and the pilot's recommended clearance.'' The comments contended that the ''but not limited to'' phrasing contained in this section implies that the owner's decision to allow a vessel to proceed could be based on unspecified criteria in addition to the specified factors. They argued that since the provision effectively places legal responsibility for imprudence in making under-keel clearance determinations on the owner or operator of a vessel, the Coast Guard should be specific as to the criteria to be applied.

The Coast Guard has removed the phrase ''but not limited to'' from the anticipated under-keel clearance provision in this final rule. The phrase

was meant to include such things as anticipated traffic, ship-specific maneuvering characteristics with respect to small under-keel clearances, or other existing company policies that may be affected. The company guidance required in this final rule should cover these types of contingencies.

3. Applicability

Twenty-one comments requested that the Coast Guard explicitly limit the application of the anticipated under-keel clearance requirement to single-hull tankships, and exclude all other carriers, including, but not limited to, bulk carriers, general cargo carriers, container ships, and Roll-on, Roll-off container ships. In contrast, one comment recommended use of under-keel clearance guidance for all ships, not just tankships without double hulls. The comment explained that some other types of vessels (e.g., dry cargo vessels) routinely carry more oil in bunkers than many tank vessels carry as cargo. Consequently, the comment argued that whatever increased protection to the environment results from requiring under-keel clearance for single-hull tankships should be amplified if such measures are applied to all vessels using the waterways.

The Coast Guard is acting under the authority of section 4115(b) of OPA 90 and does not intent to extend implementation of operational measures to vessels other than vessels of 5,000 gross tons (GT) or more that do not have double hulls and that carry oil in bulk as cargo in this final rule. Implementing the pre-planning guidance and communication requirements of this final rule is prudent on all vessels. However, this rule only prescribes an anticipated under-keel requirement for single-hull tank vessels. If the Coast Guard deemed it appropriate to expand the applicability of this rule to other vessel types, a notice would be issued in the **Federal Register** and the public would be allowed an opportunity to comment. Currently, many COTPs and port authorities are working together to develop non-regulatory solutions to reducing risk within their waterways. The public is encouraged to contact their local COTPs to discuss ongoing port efforts and become involved in these issues.

4. Economic Analysis

Eighteen comments questioned the results of the regulatory analysis completed by the Coast Guard and requested that the General Accounting Office study the economic impact of a requirement for the establishment of a minimum under-keel clearance for single-hull tankships prior to implementation of a final rule. In addition, the comments requested that a small working group, comprised of representatives from industry and the Coast Guard, be established specifically for the purpose of studying the issue of under-keel clearance. Another comment also expressed concern about the potential financial impact of the anticipated under-keel clearance requirement, and contended that the Coast Guard should impose new regulations only after an attempt to enforce current regulations fails and a reasonable risk of harm exists. In contrast, one comment stated that the original anticipated under-keel clearance requirement was reasonable and consistent with modern practice.

The Coast Guard has revised the anticipated under-keel clearance requirement in this final rule to make it less prescriptive. Because the requirement in this final rule contains the original communication and pre-planning under-keel clearance focus for single-hull tank vessels, the Coast Guard estimates that the benefits from this rule will remain as originally predicted until 2015 when these vessels no longer transit in U.S. ports. Because this requirement reflects current industry practice and ensures all single-hull tankships, at the very least, take the time to plan the vessel's passage with respect to under-keel clearance and discuss it with the pilot, the Coast Guard does not agree that an additional economic analysis is needed. If a COTP deems it necessary to require under-keel clearance or draft requirements, a cost analysis would be done and presented to the public for comment prior to implementation. Individual or small industry group participation in local determinations of this sort are used extensively by the Coast Guard to help it develop port requirements.

One comment expressed concern that Protection and Indemnity (P & I) Clubs might decline claims resulting from oil spills based on a determination that an owner, operator, or representative employee was privy to an unsafe practice under the Marine Insurance Act of 1906. Consequently, the company holding the Certificate of Financial Responsibility (COFR), as guarantor, would be obligated to pay the claim, causing insurance rates to rise significantly. As a result, the comment argued that the cost of obtaining a COFR should have been included in the cost calculations for the operational measures final rule.

The Coast Guard developed the original anticipated under-keel clearance requirement to ensure owners and operators were fully informed of vessel operations prior to transiting port. Although this final rule removes the owner notification provision, it remains a preventive measure and focuses on ensuring the master follows company guidance that contains appropriate information to navigate safely. All of the anticipated under-keel clearance requirements discussed in this rulemaking have focused on planning and prevention. Therefore, the original final rule's cost analysis has not been amended to include the cost of insurance rate increases to those companies who may be found liable for future spills due to their own imprudence.

A separate comment maintained that the imposition of an anticipated under-keel clearance requirement on the single-hull tanker fleet would cause a substantial loss of cargo-carrying capacity, forcing either an increase in the fleet size serving U.S. markets, or an increase in the number of trips required to move a specific quantity of oil. According to the comment, the Coast Guard failed to quantify the cargo loss factor or evaluate its effects in the final rule regulatory assessment. The original final rule assessment estimated the cost of cargo shut-out for single-hull tankships. Because industry indicated that prudent under-keel clearances were already the standard ''best practice'' for the majority of single-hull vessels, the Coast Guard found that single-hull tankship traffic would not be notably increased by the anticipated under-keel clearance requirement. Therefore, this cost was not included in the assessment.

5. Master/Pilot Relationship

One comment requested that the Coast Guard consider allowing the master to discuss draft, anticipated under-keel clearance, and passage planning with the boarding pilot by radio, cellular phone, or some other method, prior to the pilot coming on board. The comment explained that in most ports, the current pilot boarding stations are too close, leaving no time for the pilot to discuss passage planning prior to proceeding to the channel or river.

The Coast Guard encourages masters to contact pilots prior to boarding stations. The operational measure requiring pilot cards (§ 157.450) ensures that discussions between the master and the pilot occur prior to entering port or getting underway. This anticipated under-keel clearance requirement also requires a discussion between the pilot and the master. It is the responsibility of the master to take the time to discuss the vessel's passage with the pilot. Safe

navigation of the vessel hinges on this discussion as well as the competence of the bridge team. There is no regulation that prohibits a master from requesting the pilot to board early or from conferring with the pilot by radio or other means prior to boarding, or engaging in any other communication that helps clarify conditions prior to a port transit.

6. Calculations

Twelve comments expressed dissatisfaction with the anticipated under-keel clearance provision relating to the calculation of squat. Two comments contended that if squat characteristics are to be taken into account for the anticipated under-keel clearance calculation, the regulations should incorporate generic squat equations to avoid the inaccuracies associated with using empirical formulas. One comment specifically recommended that the Coast Guard establish speed curves for various sizes and types of vessels to be used in calculating anticipated under-keel clearance. Another comment suggested that the local COTP, in coordination with the pilots, officially predetermine the transit speed at each critical geographical point for each ship type, size, and draft. The comment contended that if the COTP did not dictate the transit speed for the purpose of calculating squat, artificially low transit speeds that disregard the steering effect could be used in order to obtain a minimum squat value and reduce the ship's calculated navigational draft.

Another comment urged the Coast Guard to prescribe the form of all required calculations in order to ensure uniformity of usage throughout industry, and to facilitate Coast Guard inspections for compliance. One comment recommended that § 157.455(a)(1)(iii) be amended to allow masters to rely on calculations or experience in determining the corresponding effects of the intended transit speed on the vessel. The comment explained that the available formulas for squat are inaccurate for vessels in confined channels and tend to yield a much greater squat than the vessel actually realizes. Three comments suggested that the issue of squat should be a matter of discussion between master and pilot and not required to be determined at the commencement of a voyage. Three other comments argued that unless the Coast Guard was prepared to designate a methodology for determining squat, the calculation of squat should not be required by regulations.

One comment supported the requirement to include squat in the anticipated under-keel clearance calculation. If, according to the comment, § 157.450 requires maneuvering characteristics (including squat characteristics) to be recorded on the wheelhouse poster in accordance with Appendix 2 of IMO Resolution A.601(15), then § 157.455 should be amended by removing the ''if known'' from the tankship's deepest draft calculation. The comment explained that based on § 157.450, squat characteristics should be known, and that, therefore, the ''if known'' phrasing should be deleted from § 157.455, in order to make the provisions consistent.

The Coast Guard has removed the prescriptive calculation criteria for the anticipated under-keel clearance requirement in this final rule. Consideration of squat and how it may affect the vessel's maneuverability during a transit is required by § 164.11 for all vessels. This final rule ensures that the master and the pilot discuss the passage plan, including the anticipated under-keel clearance. This discussion should include speed, squat, and maneuverability criteria, as found in the wheelhouse poster in accordance with Appendix 2 of IMO Resolution A.601(15) and their effect on the vessel's safe transit. While the Coast Guard could implement speed restrictions for all single-hull tankships in this rulemaking or provide empirical formulas for squat calculations, it has not. Diverse port needs, vessel characteristics, and port hydrography make such requirements difficult to develop and keep current. Local COTPs, who have knowledge of port-specific needs, may choose to implement these types of requirements. However, if a COTP deems if necessary to require speed restrictions or the calculation of squat formulas, a cost analysis would be done and presented to the public for comment prior to implementation.

Regulatory Assessment

This rule is a significant regulatory action under section 3(f) of Executive Order 12866 and has been reviewed by the Office of Management and Budget under that Order. It required an assessment of potential costs and benefits under section 6(a)(3) of that Order, and is significant under the regulatory policies and procedures of the Department of Transportation (44 FR 11040; February 26, 1979). An Assessment has been prepared and is available in the docket for inspection or copying where indicated under **ADDRESSES**. Revisions to the Assessment completed for the final rule (61 FR 39770; July 30, 1996) are summarized as follows:

The amended anticipated under-keel clearance requirement in this final rule is less prescriptive than the provision the Coast Guard evaluated in the Operational Measures final rule (61 FR 39770). However, because it contains the essential elements contained in the original anticipated under-keel clearance provision—communication, planning, and acting to ensure safe navigation—this amended anticipated under-keel clearance requirement should be effective as the original, more prescriptive, requirement. Therefore, the costs and benefits for this final rule remain as calculated in the original final rule regulatory assessment. The estimated cost of implementing this amended anticipated under-keel clearance requirement remains at $43.97 million. Implementing this adjusted anticipated under-keel clearance requirement would still yield a 10 to 23 percent risk effectiveness factor in preventing grounding or casualties of single-hull tank vessels. The estimated benefit range remains at 5,279 to 12,142 barrels of unspilled oil in the 19 years this requirement will be in effect. The estimated cost-benefit range for the amended anticipated under-keel clearance in this final rule is $3,223–$7,931 per barrel of unspilled oil.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), the Coast Guard considered whether this rule will have a significant economic impact on a substantial number of small entities. ''Small entities'' include 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.

This final rule does not change the cost or benefit estimates of the anticipated under-keel clearance requirement contained in the original final rule. For the reasons discussed in the final rule for operational measures (61 FR 39786), the Coast Guard certifies under section 605(b) of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) that this final rule will not have a significant economic impact on a substantial number of small entities.

Assistance for Small Entities

In accordance with section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), the Coast Guard will provide assistance to small entities to determine how this rule applies to them. If you are a small business and

need assistance understanding the provisions of this rule, please contact the Coast Guard Captain of the Port (COTP) closest to your vessel's operational area.

Unfunded Mandate

Under the Unfunded Mandate Reform Act (Pub. L. 104–4), the Coast Guard must consider whether this rule will result in an annual expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million (adjusted annually for inflation). The Act also requires (in Section 205) that the Coast Guard identify and consider a reasonable number of regulatory alternatives and, from those alternatives, select the least costly, most cost-effective, or least burdensome alternative that achieves the objective of the rule.

The cost-benefit analysis done for the original anticipated under-keel clearance requirement remains unchanged for this final rule. The anticipated under-keel clearance requirement contained in this final rule is less prescriptive while achieving the same objective. The anticipated under-keel clearance requirement, as amended in this final rule, does not result in costs of $100 million or more to either State, local, or tribal governments, in the aggregate, or to the private sector and is the least burdensome alternative that achieves the objective of the rule.

Collection of Information

This final rule contains no new collection-of-information requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). As stated in a notice published on December 6, 1996 (61 FR 64618), the Office of Management and Budget (OMB) has approved the collection requirements under OMB control number 2115–0629.

Federalism

The Coast Guard has analyzed this final rule under the principles and criteria contained in Executive Order 12612 (October 26, 1987) and has determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Environment

The Coast Guard considered the environmental impact of this rule for the original operational measures final rulemaking and concluded that preparation of an Environmental Impact Statement was not necessary. An Environmental Assessment and a Finding of No Significant Impact are available in the docket for inspection or copying where indicated under **ADDRESSES**.

List of Subjects in 33 CFR Part 157

Cargo vessels, Oil Pollution, Reporting and recordkeeping requirements.

For the reasons set out in the preamble, the Coast Guard amends 33 CFR part 157 as follows:

PART 157—RULES FOR THE PROTECTION OF THE MARINE ENVIRONMENT RELATING TO TANK VESSELS CARRYING OIL IN BULK

1. The authority citation for part 157 continues to read as follows:

Authority: 33 U.S.C. 1903; 46 U.S.C. 3703, 3703a (note); 49 CFR 1.46. Subparts G, H, and I are also issued under section 4115(b), Pub. L. 101–380, 104 Stat. 520; Pub. L. 104–55, 109 Stat. 546.

2. The stay announced at 61 FR 60189, November 27, 1996, is lifted and § 157.455 is revised to read as follows:

§ 157.455 Minimum under-keel clearance.

(a) The owner or operator of a tankship, that is not fitted with a double bottom that covers the entire cargo tank length, shall provide the tankship master with written under-keel clearance guidance that includes—

(1) Factors to consider when calculating the ship's deepest navigational draft;

(2) Factors to consider when calculating the anticipated controlling depth;

(3) Consideration of weather or environmental conditions; and

(4) Conditions which mandate when the tankship owner or operator shall be contacted prior to port entry or getting underway; if no such conditions exist, the guidance must contain a statement to that effect.

(b) Prior to entering the port or place of destination and prior to getting underway, the master of a tankship that is not fitted with the double bottom that covers the entire cargo tank length shall plan the ship's passage using guidance issued under paragraph (a) of this section and estimate the anticipated under-keel clearance. The tankship master and the pilot shall discuss the ship's planned transit including the anticipated under-keel clearance. An entry must be made in the tankship's official log or in other onboard documentation reflecting discussion of the ship's anticipated passage.

(c) The owner or operator of a tank barge, that is not fitted with a double bottom that covers the entire cargo tank length, shall not permit the barge to be towed unless the primary towing vessel master or operator has been provided with written under-keel clearance guidance that includes—

(1) Factors to consider when calculating the tank barge's deepest navigational draft;

(2) Factors to consider when calculating the anticipated controlling depth;

(3) Consideration of weather or environmental conditions; and

(4) Conditions which mandate when the tank barge owner or operator shall be contacted prior to port entry or getting underway; if no such conditions exist, the guidance must contain a statement to that effect.

Dated: September 15, 1997.

Robert E. Kramek,

Admiral, U.S. Coast Guard Commandant.

[FR Doc. 97–25208 Filed 9–22–97; 8:45 am]

BILLING CODE 4910–14–M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[ME–046–6996a; A–1–FRL–5894–8]

Approval and Promulgation of Air Quality Implementation Plans; Maine (General Conformity Rule)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is approving the State Implementation Plan (SIP) revision submitted by the State of Maine for the purpose of implementing General Conformity (Section 176(c)(4)(C) of the Clean Air Act (CAA), and its regulations, 40 CFR part 51, subpart W), which requires federal actions to conform to all applicable implementation plans developed pursuant to section 110 and part D of the CAA. The Maine SIP incorporates by reference the criteria and procedures set forth at 40 CFR part 51, subpart W. This general conformity SIP revision will enable the State of Maine to implement and enforce the Federal general conformity requirements in Maine's nonattainment and maintenance areas at the State and local level. This action is being taken in accordance with the Clean Air Act.

DATES: This action is effective November 24, 1997, unless EPA receives adverse or critical comments by October 23, 1997. If the effective date is delayed, timely notice will be published in the **Federal Register**.

ADDRESSES: Comments may be mailed to Susan Studlien, Deputy Director, Office

of Ecosystem Protection (mail code CAA), U.S. Environmental Protection Agency, Region I, JFK Federal Building, Boston, MA 02203. Copies of the documents relevant to this action are available for public inspection during normal business hours, by appointment at the Office of Ecosystem Protection, U.S. Environmental Protection Agency, Region I, One Congress Street, 11th floor, Boston, MA; Air and Radiation Docket and Information Center, U.S. Environmental Protection Agency, 401 M Street, SW. (LE–131), Washington, DC 20460; and the Bureau of Air Quality Control, Department of Environmental Protection, 71 Hospital Street, Augusta, ME 04333.

FOR FURTHER INFORMATION CONTACT: Donald O. Cooke, (617) 565–3508, at the EPA Region I address above.

SUPPLEMENTARY INFORMATION: Section 176(c) of the Clean Air Act, as amended (the Act), requires the EPA to promulgate criteria and procedures for demonstrating and ensuring conformity of Federal actions to an applicable implementation plan developed pursuant to section 110 and part D of the Act. EPA promulgated a final rulemaking on November 30, 1993 consisting of 40 CFR part 93, subpart B, ''Determining Conformity of General Federal Actions to State or Federal Implementation Plans,'' which applied to Federal agencies immediately (hereafter referred to as the General Conformity rule); and 40 CFR part 51, subpart W, ''Determining Conformity of General Federal Actions to State or Federal Implementation Plans,'' which established requirements for States in submitting SIPs. The general conformity rules, except for the 40 CFR 51.851(a) language requiring State submission of a SIP revision, are repeated at 40 CFR part 93, subpart B. The General Conformity rule establishes the criteria and procedures governing the determination of conformity for all Federal actions, except Federal highway and transit actions.

The General Conformity rule also establishes the criteria for EPA approval of SIPs. See 40 CFR 51.851 and 93.151. These criteria provide that the state provisions must be at least as stringent as the requirements specified in EPA's General Conformity rule, and that they can be more stringent only if they apply equally to Federal and non-Federal entities (§ 51.851(b)). The federal General Conformity rule has been incorporated by reference so Maine's rule is no more stringent than the federal rule and does not impose any additional controls on non-federal entities.

On October 11, 1996, the State of Maine submitted a formal revision to its State Implementation Plan (SIP). The SIP revision consists of incorporating by reference 40 CFR 51.850, 51.852, 51.853, 51.854, 51.855, 51.856, 51.857, 51.858, 51.859 and 51.860 thereby establishing general conformity criteria and procedures in the Maine SIP. This proposed SIP revision was the subject of a public hearing held on August 14, 1996 in accordance with federal and state administrative requirements. The Maine Board of Environmental Protection adopted ''State Chapter 141—Conformity of General Federal Actions,'' that became effective September 28, 1996. The Maine Office of the Attorney General has certified Chapter 141 as to form and legality.

I. Summary of SIP Revision

The purpose of the General Conformity Rule is to ensure that all Federal actions [except for Federal actions related to transportation projects funded or approved under Title 23 U.S.C. or the Federal Transit Act (49 U.S.C. 1601 *et seq.*) which are regulated under Transportation Conformity], conform to the appropriate SIP developed pursuant to Section 110 and part D of the CAA. Section 176(c) of the CAA, 42 U.S.C. 7506(c), provides that no Federal department, agency, or instrumentality shall engage in, support in any way or provide financial assistance for, license or permit, or approve any activity which does not conform to a SIP that has been approved or promulgated pursuant to the CAA. Conformity is defined in section 176(c) of the CAA as conformity to the SIP's purpose of eliminating or reducing the severity and number of violations of the National Ambient Air Quality Standards (NAAQS) and achieving expeditious attainment of such standards, and that such activities will not: (1) Cause or contribute to any new violation of any standard in any area; (2) interfere with provisions in the applicable SIP for maintenance of any standard; (3) increase the frequency or severity of any existing violation of any standard in any area; or (4) delay timely attainment of any standard or any required interim emission reductions or other milestones in any area.

The CAA ties conformity to attainment and maintenance of the NAAQS. Conformity therefore applies only in areas that are non-attainment or maintenance with respect to any of the criteria pollutants under the CAA: carbon monoxide (CO), lead (Pb), nitrogen dioxide (NO_2), ozone (O_3), particulate matter (PM_{10}), and sulfur dioxide (SO_2). The rule covers direct and indirect emissions of criteria pollutants or their precursors that are reasonably foreseeable and caused by a Federal action.

II. Evaluation of the State's Submittal

Pursuant to the requirements under Section 176(c)(4)(C) of the CAA the Maine DEP submitted a SIP revision to the EPA on October 11, 1996. The EPA found this submittal to be complete on November 14, 1996. In its submittal, the State adopted through incorporation by reference, ''EPA's general conformity rule 40 CFR part 51, subpart W, §§ 51.850, 51.852, 51.853, 51.854, 51.855, 51.856, 51.857, 51.858, 51.859, and 51.860'' (as published on November 30, 1996 at 58 FR 63247–63253), in Chapter 141 of the Maine Department of Environmental Protection Air Regulation entitled, ''Conformity of General Federal Actions''.

General conformity is required for all areas which are designated nonattainment or maintenance for any NAAQS criteria pollutant. The State of Maine currently has six areas where the general conformity rule must be implemented: three areas designated ozone nonattainment; one area designated ozone maintenance; one designated particulate matter (PM_{10}) maintenance area; and one designated sulfur dioxide (SO_2) maintenance area. The ozone areas for which conformity determinations are required and which are governed by general conformity include the following counties: Hancock; Waldo; Knox; Lincoln; Androscoggin; Kennebec; Cumberland, Sagadahoc; York. The PM_{10} maintenance area for which conformity determinations are required and which is governed by general conformity includes a portion of Aroostock County (within city of Presque Isle). And finally, the SO_2 maintenance area for which conformity determinations are required and which is governed by general conformity is the municipality of Millinocket.

III. Statutory and Regulatory References

The Maine Office of Attorney General determined that this SIP revision will be enforceable pursuant to Maine statutory law (i.e., 38 M.R.S.A. Section 585 which states ''The board may establish and may amend standards, herein called ''emission standards,'' limiting and regulating in a just and equitable manner the amount and type of air contaminants which may be emitted to the ambient air within a region. Such emission standards shall be designated to prevent air pollution and to achieve and maintain the ambient air quality

standards within the region in which applicable'' and 38 M.R.S.A. Section 585–A which states ''The Board may establish and amend regulations to implement ambient air quality standards and emission standards''). Finally, Section 110 of the Clean Air Act Amendments requires each state to adopt and submit to the Administrator a plan providing for the implementation, maintenance and enforcement of air quality standards and control programs.

IV. EPA Action

The EPA is approving the general conformity SIP revision for the State of Maine. The EPA has evaluated this SIP revision and has determined that the State has fully adopted the provisions of the Federal general conformity rules set forth at 40 CFR part 51, subpart B. The appropriate public participation and comprehensive interagency consultations have been undertaken during development and adoption of this SIP revision.

The EPA is publishing this action without prior proposal because the Agency views this as a noncontroversial amendment and anticipates no adverse comments. However, in a separate document in this **Federal Register** publication, the EPA is proposing to approve the SIP revision should adverse or critical comments be filed. This action will be effective November 24, 1997, unless, by October 23, 1997, adverse or critical comments are received.

If the EPA receives such comments, this action will be withdrawn before the effective date by publishing a subsequent document that will withdraw the final action. All public comments received will be addressed in a subsequent final rule based on this action serving as a proposed rule. The EPA will not institute a second comment period on this action. Any parties interested in commenting on this action should do so at this time. If no such comments are received, the public is advised that this action will be effective November 24, 1997.

Nothing in this action should be construed as permitting or allowing or establishing a precedent for any future request for revision to any State implementation plan. Each request for revision to the State implementation plan shall be considered separately in light of specific technical, economic, and environmental factors and in relation to relevant statutory and regulatory requirements.

V. Administrative Requirements

A. Executive Order 12866

The Office of Management and Budget (OMB) has exempted this regulatory action from E.O. 12866 review.

B. Regulatory Flexibility Act

Under the Regulatory Flexibility Act, 5 U.S.C. 600 *et seq.*, EPA must prepare a regulatory flexibility analysis assessing the impact of any proposed or final rule on small entities. 5 U.S.C. 603 and 604. Alternatively, EPA may certify that the rule will not have a significant impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and government entities with jurisdiction over populations of less than 50,000.

SIP approvals under section 110 and subchapter I, part D of the Clean Air Act do not create any new requirements but simply approve requirements that the State is already imposing. Therefore, because the Federal SIP approval does not impose any new requirements, the Administrator certifies that it does not have a significant impact on any small entities affected. Moreover, due to the nature of the Federal-State relationship under the CAA, preparation of a flexibility analysis would constitute Federal inquiry into the economic reasonableness of state action. The Clean Air Act forbids EPA to base its actions concerning SIPs on such grounds. *Union Electric Co.* v. *U.S. EPA*, 427 U.S. 246, 255–66 (1976); 42 U.S.C. 7410(a)(2).

C. Unfunded Mandates Act

Under sections 202 of the Unfunded Mandates Reform Act of 1995 (''Unfunded Mandates Act''), signed into law on March 22, 1995, EPA must prepare a budgetary impact statement to accompany any proposed or final rule that includes a Federal mandate that may result in estimated costs to State, local, or tribal governments in the aggregate; or to the private sector, of $100 million or more. Under Section 205, EPA must select the most cost-effective and least burdensome alternative that achieves the objectives of the rule and is consistent with statutory requirements. Section 203 requires EPA to establish a plan for informing and advising any small governments that may be significantly or uniquely impacted by the rule.

EPA has determined that the approval action proposed does not include a Federal mandate that may result in estimated costs of $100 million or more to either State, local, or tribal governments in the aggregate, or to the private sector. This Federal action approves pre-existing requirements under State or local law, and imposes no new Federal requirements. Accordingly, no additional costs to State, local, or tribal governments, or to the private sector, result from this action.

D. Submission to Congress and the General Accounting Office

Under 5 U.S.C. 801(a)(1)(A) as added by the Small Business Regulatory Enforcement Fairness Act of 1996, EPA submitted 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 General Accounting Office prior to publication of the rule in today's **Federal Register**. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

E. Petitions for Judicial Review

Under Section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by November 24, 1997. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See Section 307(b)(2).) EPA encourages interested parties to comment in response to the proposed rule rather than petition for judicial review, unless the objection arises after the comment period allowed for in the proposal.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Hydrocarbons, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides.

Dated: September 9, 1997.

John P. DeVillars,

Regional Administrator, Region I.

Part 52 of chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 52—[AMENDED]

1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401–7671q.

Subpart U—Maine

2. Section 52.1020 is amended by adding paragraph (c)(44) to read as follows:

§ 52.1020 Identification of plan.

* * * * *

(c) * * *

(44) Revisions to the State Implementation Plan submitted by the Maine Department of Environmental Protection on October 11, 1996.

(i) Incorporation by reference.

(A) Letter from the Maine Department of Environmental Protection dated October 11, 1996 submitting a revision to the Maine State Implementation Plan.

(B) Chapter 141 of the Maine Department of Environmental Protection Air Regulation entitled, ''Conformity of General Federal Actions,'' effective in the State of Maine on September 28, 1996.

3. In § 52.1031 Table 52.1031 is amended by adding a new entry for state citation Chapter 141: General Conformity Rule to read as follows:

§ 52.1031 EPA-approved Maine regulations.

* * * * *

TABLE 52.1031.—EPA-APPROVED RULES AND REGULATIONS

State citation	Title/subject	Date adopted by State	Date approved by EPA	Federal Register citation	52.1020	
*	*	*	*	*	*	*
141	Conformity of General Federal Actions.	9/11/96	September 23, 1997.	62 FR 49611	(c)(44)	''Chapter 141: Conformity of General Federal Actions''.
*	*	*	*	*	*	*

[FR Doc. 97–25230 Filed 9–22–97; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[MD 039–3019; FRL–5896–1]

Approval and Promulgation of Air Quality Implementation Plans; Maryland; 15% Rate of Progress Plan for the Maryland Portion of the Metropolitan Washington, D.C. Area

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is granting conditional approval of the State Implementation Plan (SIP) revision submitted by the State of Maryland, for the Maryland portion of the Metropolitan Washington, D.C. serious ozone nonattainment area, to meet the 15 percent reasonable further progress (RFP, or 15% plan) requirements of the Clean Air Act (the Act). EPA is granting conditional approval of the 15% plan, submitted by the State of Maryland, because on its face the plan achieves the required 15% emission reduction, but additional documentation to verify the emission calculations is necessary for full approval. Additionally, the plan relies upon Maryland's inspection and maintenance (I/M) program that received final conditional approval on July 31, 1997 (62 FR 40938). This action is being taken under section 110 of the Clean Air Act.

EFFECTIVE DATE: This final rule is effective on October 23, 1997.

ADDRESSES: Copies of the documents relevant to this action are available for public inspection during normal business hours at the Air, Radiation, and Toxics Division, U.S. Environmental Protection Agency, Region III, 841 Chestnut Building, Philadelphia, Pennsylvania 19107; and the Maryland Department of the Environment, 2500 Broening Highway, Baltimore, Maryland 21224.

FOR FURTHER INFORMATION CONTACT: Carolyn M. Donahue, Ozone/Carbon Monoxide and Mobile Sources Section (3AT21), USEPA—Region III, 841 Chestnut Building, Philadelphia, Pennsylvania 19107, or by telephone at (215) 566–2095 or via e-mail, at the following address: donahue.carolyn@epamail.epa.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Section 182(b)(1) of the Act requires ozone nonattainment areas classified as moderate or above to develop plans to reduce volatile organic compounds (VOC) emissions by 15% from 1990 baseline levels. The Metropolitan Washington, D.C. area is classified as a serious ozone nonattainment area and is subject to the 15% plan requirement. The Metropolitan Washington, D.C. ozone nonattainment area consists of the entire District of Columbia (''the District''), five counties in the Northern Virginia area and five counties in Maryland. The Maryland portion consists of Calvert, Charles, Frederick, Montgomery and Prince George's Counties.

Virginia, Maryland, and the District all must demonstrate reasonable further progress for the Metropolitan Washington, D.C. nonattainment area. These three jurisdictions, in conjunction with municipal planning organizations, collaborated on a coordinated 15% plan for the nonattainment area. This was done with the assistance of the regional air quality planning committee, the Metropolitan Washington Air Quality Committee (MWAQC), and the local municipal planning organization, the Metropolitan Washington Council of Governments (MWCOG), to ensure coordination of air quality and transportation planning.

The State of Maryland submitted the 15% plan SIP revision for the Maryland portion of the Metropolitan Washington, D.C. nonattainment area on July 12, 1995. On June 5, 1997, EPA published a notice of proposed rulemaking (NPR) in the **Federal Register** proposing conditional approval of the 15% plan (62 FR 30821). EPA's rationale for granting conditional approval to this Maryland 15% plan, and the details of the July 12, 1995 submittal are contained in the June 5, 1997 NPR and the accompanying technical support document and will not be restated here.

II. Public Comments and EPA Responses

EPA received a letter in response to the June 5, 1997 NPR from the Sierra Club Legal Defense Fund (SCLDF). The

following discussion summarizes and responds to the comments received.

Comment 1

SCLDF commented that the Maryland 15% plan must be disapproved because it failed to produce the 15% emission reduction of 60.7 tons/day identified in the plan as prescribed by section 182(b)(1)(A)(I) of the Act. EPA's argument that it believes that Maryland's required 15% reduction ''may be lower than the 56.4 tons per day'' is flawed. EPA took no action on 6.3 tons of additional measures.

Response 1

Under section 110(k)(4) of the Act, EPA may conditionally approve a plan based on a commitment from the state to adopt specific enforceable measures within one year from the date of approval. EPA believes that the 15% required reduction in the Maryland portion of the Metropolitan Washington, D.C. nonattainment area may be lower than the 60.7 tons/day estimated in the July 12, 1995 SIP submittal based on new information supplied by the State. Although this information has not been established through an official SIP submittal, this information is contained in Maryland's rate-of-progress SIP for the 1996–1999 time period (known as the Post-1996 plan). Maryland has held a public hearing on this SIP, which EPA provided comments on for the public record, and expects to submit it to EPA shortly. Under these circumstances—including the fact that the amount of emissions at issue is a relatively small percentage of the 15% requirement—EPA has the authority to conditionally approve Maryland's 15% SIP, on the condition that Maryland submit the requisite documentation. The State of Maryland has agreed to meet this condition to document that the amount of reduction needed to meet the 15% requirement is less than 56.4 tons/day, and submitted such commitment in writing on July 3, 1997.

Comment 2

SCLDF commented that the Maryland 15% plan, which takes credit for federal control measures such as architectural and industrial maintenance coating, consumer/commercial products and autobody refinishing, should not be approved because those federal control measures have not yet been promulgated. SCLDF states that allowing such credit violates section 182(b)(1)(C) of the Act. SCLDF further commented that EPA cannot lawfully base SIP decisions on unpromulgated rules because it does not know what these final rules will say. SCLDF contends that allowing credit on as yet unpromulgated rules, even with the caveat that the states must revisit the rule later if the federal rules turn out differently than predicted, amounts to an unlawful extension of a SIP submission deadline. SCLDF stated that EPA must base its decision on the record before it at the time of its decision; not on some record that the agency hopes will exist in the future.

Response 2

Section 182(b)(1)(A) of the Act requires states to submit their 15% SIP revisions by November 1993. Section 182(b)(1)(C) of the Act provides the following general rule for creditability of emissions reductions towards the 15% requirement: ''Emissions reductions are creditable toward the 15 percent required * * * to the extent they have actually occurred, as of (November 1996), from the implementation of measures required under the applicable implementation plan, rules promulgated by the Administrator, or a permit under Title V.''

This provision further indicates that certain emissions reductions are not creditable, including reductions from certain control measures required prior to the 1990 Amendments. This creditability provision is ambiguous. Read literally, it provides that although the 15% SIPs are required to be submitted by November 1993, emissions reductions are creditable as part of those SIPs only if ''they have actually occurred, as of (November 1996)''. This literal reading renders the provision internally inconsistent.

Accordingly, EPA believes that the provision should be interpreted to provide, in effect, that emissions reductions are creditable ''to the extent they will have actually occurred, as of (November 1996), from the implementation of (the specified measures)'' (the term ''will'' is added). This interpretation renders the provision internally consistent.

Sec. 182(b)(1)(C) of the Act explicitly includes as creditable reductions those resulting from ''rules promulgated by the Administrator''. This provision does not state the date by which those measures must be promulgated, i.e., does not indicate whether the measures must be promulgated by the time the 15% SIPs were due (November 1993), or whether the measures may be promulgated after this due date.

Because the statute is silent on this point, EPA has discretion to develop a reasonable interpretation, under *Chevron U.S.A. Inc.* v. *NRDC,* 467 U.S. 837, 104 S.Ct. 2778, 81 L.Ed.2d 694 (1984). EPA believes it reasonable to interpret section 182(b)(1)(C) of the Act to credit reductions from federal measures as long as those reductions are expected to occur by November 1996, even if the Federal measures are not promulgated by the November 1993 due date for the 15% SIPs.

EPA's interpretation is consistent with the congressionally mandated schedule for promulgating regulations for consumer and commercial products, under section 182(e) of the Act. This provision requires EPA to promulgate regulations controlling emissions from consumer and commercial products that generate emissions in nonattainment areas. Under the schedule, by November 1993—the same date that the States were required to submit the 15% SIPs—EPA was to issue a report and establish a rulemaking schedule for consumer and commercial products. Further, EPA was to promulgate regulations for the first set of consumer and commercial products by November 1995. It is reasonable to conclude that Congress anticipated that reductions from these measures would be creditable as part of the 15% SIPs, as long as those reductions were to occur by November 1996.

Crediting reductions from federal measures promulgated after the due date for the 15% SIPs is also sensible from an administrative standpoint. Crediting the reductions allows the states to plan accurately to meet the 15% reduction target from the appropriate level of state and federal measures. Not crediting such reductions would mean that the states would have to implement additional control requirements to reach the 15% mark; and that SIPs would result in more than a 15% level of reductions once the federal measures in question were promulgated and implemented. At that point in time, the state may seek to eliminate those additional SIP measures on grounds that they would no longer be necessary to reach the 15% level. Such constant revisions to the SIP to demonstrate 15% is a paper exercise that exhausts both the states' and EPA's time and resources.

The fact that EPA cannot determine precisely the amount of credit available for the federal measures not yet promulgated does not preclude granting the credit. The credit can be granted as long as EPA is able to develop reasonable estimates of the amount of VOC reductions from the measures EPA expects to promulgate. EPA believes that it is able to develop reasonable estimates, particularly because is has already proposed and taken comment on the measures at issue, and expects to

promulgate final rules by the spring of 1998. Many other parts of the SIP, including state measures, typically include estimates and assumptions concerning VOC amounts, rather than actual measurements. For example, EPA's document to estimate emissions, ''Compilation of Air Pollutant Emission Factors,'' January 1995, AP–42, provide emission factors used to estimate emissions from various sources and source processes. AP–42 emission factors have been used, and continue to be used, by states and EPA to determine base year emission inventory figures for sources and to estimate emissions from sources where such information is needed. Estimates in the expected amount of VOC reductions are commonly made in air quality plans, even for those control measures that are already promulgated.

Moreover, the fact that EPA is occasionally delayed in its rulemaking is not an argument against granting credits from these measures. The measures are statutorily required, and states and citizens could bring suit to enforce the requirements that EPA promulgate them. If the amount of credit that EPA allows the state to claim turns out to be greater than the amount EPA determines to be appropriate when EPA promulgates the federal measures, EPA intends to take appropriate action to require correction of any shortfall in necessary emissions reductions that may occur.

The above analysis focuses on the statutory provisions that include specific dates for 15% SIP submittals (November 1993), and implementation (November 15, 1996). These dates have expired, and EPA has developed new dates for submittal and implementation. EPA does not believe that the expiration of the statutory dates, and the development of new ones, has implications for the issue of whether reductions from federal measures promulgated after the date of 15% SIP approval may be counted toward those 15% SIPs. Although the statutory dates have passed, EPA believes that the analysis described above continues to be valid.

Comment 3

EPA has improperly suggested that SIPs can be approved if the state has failed to demonstrate approvability. In this regard, EPA has not been able to verify Maryland's emission reduction credit claims for Tier I or Stage II vapor recovery, but has nonetheless stated that it has no reason to dispute the credit claimed by Maryland and is therefore approving the 15% plan. An absence of statutorily required documentation requires disapproval.

Response 3

EPA believes Maryland has demonstrated that it has appropriately modeled its mobile source program benefits, through proper use of EPA's MOBILE emissions factor estimation model, combined with state vehicle miles of travel estimates. It is not practical to submit the hundreds or even thousands of modeling input and output runs needed to evaluate the mobile source-related portions of the 15% rate-of-progress SIP. Maryland instead submitted to EPA a list of the variables and assumptions utilized in its MOBILE modeling analysis, along with sample model input and output scenarios.

While the SIP does not contain sufficient data to reconstruct the analysis and, therefore, to independently verify the State's claims, EPA believes the State's methodology is sound. However, EPA has deferred the specific results of that methodology, in part, to the State.

Comment 4

SCLDF commented that it is unlawful for EPA to allow substantial credit from an I/M program that is not before the agency. The 15% plan before EPA was submitted on July 12, 1995, and thus does not incorporate Maryland's current I/M plan which was submitted in March 1996. Also, it is unlawful to allow postponements under the National Highway System Designation Act (NHSDA) for an area that did not submit an NHSDA-type program.

Response 4

Maryland's March 1996 I/M submittal was an amendment to the I/M program submitted to EPA on July 11, 1995. The March I/M submittal does not supercede the July 1995 program; thus Maryland's current I/M program is before EPA. EPA granted conditional approval of Maryland's I/M program on July 31, 1997. If the rules submitted from Maryland to EPA are valid, they do not have to be submitted in a particular order.

EPA believes that test-only I/M programs like the one in Maryland should be treated in the same manner as NHSDA state programs (test and repair programs) with regard to 15% plan requirements. In a letter from Mary Nichols to MDE Secretary Jane Nishida dated January 30, 1996, EPA stated this position is justified in light of administrative and statutory changes in the I/M requirements and the extent to which states relied on I/M programs in their 15% submittals. EPA's approach would have the effect of keeping a level playing field by assuring that Maryland would not be penalized for adopting a test-only program.

Comment 5

SCLDF commented that EPA cannot postpone the deadline for achieving the required 15% reduction any further than the current deadline of November 15, 1999. It contends that, without conceding the legality of a 3-year postponement of the statutory deadline of November 15, 1996 allowed by EPA, any longer postponement would be unlawful. Once a compliance date has expired, compliance must occur in the shortest time possible. The commenter cited various court decisions in an effort to demonstrate that a postponement longer than three years would not adhere to the strict standard of compliance. Also, SCLDF claimed that postponing a requirement for reasonable further progress until after the deadline for attainment would be unlawful.

Response 5

The case law cited by the commenter considers various circumstances, such as failure by EPA to promulgate rules on the statutorily mandated deadline or to take action on state failures to make SIP submissions on the statutorily mandated deadline. See, e.g., *Natural Resources Defense Council* v. *EPA*, 22 F.3d 1125 (D.C. Cir. 1994), *Natural Resources Defense Council* v. *Train*, 510 F.2d 692 (D.C. Cir. 1975). These cases articulate various formulations of the standards by which the courts establish new deadlines. EPA believes that its formulation of the standard by which States must achieve the 15% reductions—''as soon as practicable''—is generally consistent with the case law.

Further, EPA believes that Maryland has demonstrated that it has met this standard. The notice of proposed rulemaking and the TSD accompanying that proposal establish that implementation of the I/M program is as soon as practicable. The main reason for the delays in the development and implementation of Maryland's 15% SIP relate to its enhanced I/M plan. Most recently, these enhanced I/M delays were closely associated with the enactment, in November 1995, of the NHSDA. The NHSDA afforded states the opportunity to revise their I/M plans in a manner that would be treated as meeting certain EPA requirements on an interim basis. The NHSDA provided additional time for the State and EPA to develop and process the revised I/M plans. In the January 1996 letter to Secretary Nishida from Mary Nichols,

EPA states it will credit Maryland's test-only enhanced I/M program for purposes of the 15% requirement. This approach enables states with test-only programs to enhance those programs starting in 1997 while applying credit for those programs to satisfy the 1996 15% VOC reduction plan requirements. Maryland acted expeditiously in developing and implementing a revised enhanced I/M program. However, the amount of time necessary to develop and implement the I/M program rendered impossible achieving the 15% reduction target by the end of 1996. The addendum to the TSD showing the chronology of Maryland's I/M program development demonstrates the necessity of the extension.

Moreover, EPA has reviewed other VOC SIP measures that are at least theoretically available to Maryland, and has concluded that implementation of any such measures that might be appropriate would not accelerate the date of achieving the 15% reductions. For reasons indicated elsewhere in the record, EPA considers the biennial I/M program selected by Maryland to be as soon as practicable, notwithstanding the fact that other states may choose to implement an annual program.

Comment 6

SCLDF commented that any further delays in achieving the mandate 15% reduction from VOC control measures, including most prominently, enhanced I/M, must not be tolerated. Furthermore, missing the November 15, 1996 deadline unlawfully rewards states for failure to meet the deadline by giving them increased credits under national programs such as the Tier I Federal Motor Vehicle Control Program. SCLDF argues that such an approach unlawfully delays the achievement of clean air by allowing the states to reduce their own emission control efforts by the amount of the post-November 1996 fleet turnover benefits. Consequently, EPA must deny the post-November 1996 Tier I credit and require states to adopt emission reductions to compensate for post-1996 growth in vehicle miles traveled (VMT).

SCLDF further argues that EPA cannot delay the section 182(b)(1) requirement for states to account for growth in the 15% plans to the Post-1996 rate-of-progress plans, particularly because the Post-1996 plans involve potential NO_X substitution that is not permitted in the VOC-only 15% plans.

Response 6

EPA disagrees with this comment. The NHSDA was enacted by Congress in November of 1995. Section 348 of this statute provided states' renewed opportunity to satisfy the Clean Air Act requirements related to the network design for I/M programs. States were not only granted the flexibility to enact test-and-repair programs, but were provided additional time to develop those programs and to submit proposed regulations for interim SIP approval. Maryland moved rapidly to propose I/M regulations and to submit to EPA on March 27, 1996 an amendment to the I/M SIP containing those regulations. EPA granted conditional approval of the Maryland I/M program on July 31, 1997 (62 FR 40938).

Under the terms of the 15% requirement in section 182(b)(1)(A)(I) of the Act, the SIP must—''provide for (VOC) emission reductions, within 6 years after the date of enactment of the Clean Air Act Amendments of 1990, of at least 15 percent from baseline emissions, accounting for any growth in emissions after (1990).''

EPA interprets this provision to require that a specific amount of VOC reductions occur, and has issued guidance for computing this amount. Maryland, complying with this guidance, has determined the amount of the required VOC reductions needed to meet the 15% goal. It is no longer possible for Maryland to implement measures to achieve this level of reduction as the November 15, 1996 date provided under the 15% provisions has passed. Accordingly, EPA believes that Maryland will comply with the statutory mandate as long as it achieves the requisite level of reductions on an as-soon-as-practicable basis after 1996. In computing the reductions, EPA believes it acceptable for states to count reductions from federal measures, such as vehicle turnover, that occur after November 15, 1996, as long as they are measures that would be creditable had they occurred prior to that date. These measures result in VOC emission reductions as directed by Congress in the Act; therefore, these measures should count towards the achievement—however delayed—of the 15% VOC reduction goal.

EPA does not believe states are obligated as part of the 15% SIP to implement further VOC reductions to offset increases in VOC emissions due to post-1996 growth. As noted above, the 15% requirement mandates a specific level of reductions. By counting the reductions that occur through measures implemented pre-and post-1996, SIPs may achieve this level of reductions. Although section 182(b)(1)(A)(I), quoted above, mandates that the SIPs account for growth after 1990, the provision does not, by its terms, establish a mechanism for how to account for growth, or indicate whether, under the present circumstances, post-1996 growth must be accounted for. EPA believes that its current requirements for the 15% SIPs meet section 182(b)(1)(A)(I). In addition, although post-1996 VOC growth is not offset under the 15% SIPs, such growth must be offset in the Post-1996 plans required for serious and higher classified areas to achieve 9% in VOC reductions every three years after 1996 (until the attainment date). Maryland's Post-1996 plan for the Maryland portion of the Metropolitan Washington, D.C. area, which is nearing completion, does appear to achieve the 9% emissions reductions required between 1996 and 1999, taking into account growth in VOCs during that time. The fact that these Post-1996 SIPs may substitute NO_X reductions for VOC reductions in the 1996 to 1999 period does not undermine the integrity of the 15% SIPs. Allowing NO_X substitution is fully consistent with the health goals of the Clean Air Act.

Under EPA's approach, post-1996 growth will be accounted for in the plans that Congress intended to take account of such growth—the Post-1996 ''rate of progress'' SIPs. To shift the burden of accounting for such growth to the 15% plans, as commenters would have EPA do, would impose burdens on states above and beyond what Congress contemplated would be imposed by the 15% requirement (which was intended to have been achieved by November 15, 1996). In the current situation, where it is clearly impossible to achieve the target level of VOC reductions (a 15% reduction taking into account growth through November 1996) by November 1996, EPA believes that its approach is a reasonable and appropriate one. It will still mean that post-1996 growth is taken into account in the SIP revisions Congress intended to take into account such growth and it means that the target level of VOC reductions will be achieved as soon as practicable. Once the Post-1996 rate of progress plans are approved and implemented, areas will have achieved the same level of progress that they were required to have achieved through the combination of the 15% and rate of progress requirements as originally intended by Congress.

Comment 7

SCLDF commented that EPA proposed disapproval of the Philadelphia 15% plan in 1996 because the plan assumed credit from control strategies either not fully adopted, not creditable under the Clean Air Act, or which had not been adequately quantified. Furthermore, EPA proposed

disapproval of the plan because Pennsylvania switched I/M programs yet did not revise the 15% plan to reflect the differences in the I/M program description and projected emission reductions. EPA set precedence with this rulemaking and to propose approval of the Maryland 15% plan when the same deficiencies exist is acting in an arbitrary and capricious manner of treating similar situations in such a diametrically opposed fashion.

Response 7

EPA's proposed approval of the Maryland 15% plan is not inconsistent with the proposed disapproval of the Philadelphia 15% plan. On July 10, 1996, EPA proposed to disapprove Pennsylvania's 15% plan for the Philadelphia area because it would not have achieved sufficient reductions to meet the requirements of section 182(b)(1) of the Act (61 FR 36320). EPA did not credit any reductions from Pennsylvania's enhanced I/M program because at the time of the July 10, 1996 rulemaking EPA had disapproved Pennsylvania's I/M submittal. In a letter dated April 13, 1995, EPA converted the August 31, 1994 conditional approval of Pennsylvania I/M submittal to a disapproval. As discussed above, on July 31, 1997, EPA granted conditional approval of Maryland's I/M program in the Maryland SIP (62 FR 40938). Therefore, the factual basis for EPA's conditional approval of Maryland's 15% plan is not similar to that of the Philadelphia 15% plan. In the July 10, 1996 proposed disapproval, EPA credited the measures in Pennsylvania's 15% plan towards meeting the rate of progress requirements of the Act even though they were insufficiently documented to qualify for full approval. See 61 FR 36322. That action is wholly consistent with EPA's conditional approval of the Maryland 15% plan.

III. Conditional Approval

EPA has evaluated Maryland's July 12, 1995 submittal for consistency with the Act, applicable EPA regulations, and EPA policy and has determined, as documented in the June 5, 1997 NPR, that, on its face, the 15% plan for the Maryland portion of the Metropolitan Washington, D.C. nonattainment area achieves the required 15% VOC emission reduction to meet Maryland's portion of the regional multi-state plan to satisfy the requirements of section 182(b)(1) of the Act. However, there are measures included in the Maryland 15% plan, which may be creditable towards the Act requirement, but which are insufficiently documented for EPA to take action on at this time. While the amount of creditable reductions for certain control measures has not been adequately documented to qualify for Clean Air Act approval, EPA has determined that Maryland's submittal contains enough of the required structure to warrant conditional approval. EPA cannot grant full approval of the Maryland 15% rate-of-progress plan under section 110(k)(3) and Part D of the Clean Air Act. Instead, EPA is granting conditional approval of this SIP revision under section 110(k)(4) of the Act, because the State must meet the specified conditions and supplement its submittal to satisfy the requirements of section 182(b)(1) of the Act regarding the 15% rate-of-progress plan, and because the State must supplement its submittal and demonstrate it has achieved the required emission reductions.

The June 5, 1997 NPR listed the conditions that Maryland must meet in order to convert the conditional approval to full approval. In a July 3, 1997 letter to EPA, the State committed to meet all the conditions listed in the NPR within 12 months of final conditional approval. The conditions from the NPR are restated here. The State of Maryland must fulfill the following conditions by no later than September 23, 1998:

1. Maryland's 15% plan must be revised to account for growth in point sources from 1990–1996.

2. Maryland must meet the conditions listed in the October 31, 1996 proposed conditional I/M rulemaking notice, and the I/M reductions using the following two EPA guidance memos: ''Date by which States Need to Achieve all the Reductions Needed for the 15 Percent Plan from I/M and Guidance for Recalculation,'' Note from John Seitz and Margo Oge, dated August 13, 1996, and ''Modeling 15 Percent VOC Reductions from I/M in 1999—Supplemental Guidance'', memorandum from Gay MacGregor and Sally Shaver, dated December 23, 1996.

3. Maryland must remodel to determine affirmatively the creditable reductions from RFG, and Tier 1 in accordance with EPA guidance.

4. Maryland must submit a SIP revision amending the 15% plan with a demonstration using appropriate documentation methodologies and credit calculations that the 56.4 tons/day reduction, supported through creditable emission reduction measures in the submittal, satisfies Maryland's 15% ROP requirement for the Metropolitan Washington, D.C. nonattainment area.

After making all the necessary corrections to establish the creditability of chosen control measures, Maryland must demonstrate that 15% emission reduction is obtained in the Maryland portion of the Metropolitan Washington, D.C. nonattainment area as required by section 182(b)(1) of the Act and in accordance with EPA's policies and guidance issued pursuant to section 182(b)(1).

IV. Final Action

EPA is today granting conditional approval of the Maryland 15% plan as a revision to the Maryland SIP. This rulemaking action will not convert to full approval until Maryland has met conditions 1 through 4 of this rulemaking. If the conditions are not met within 12 months of today's rulemaking, this rulemaking will convert to a disapproval. Once Maryland satisfies the conditions of the I/M rulemaking and receives final approval of I/M, EPA will grant final approval of the 15% plan (assuming that the other conditions have been met). Conversely, if EPA disapproves the Maryland I/M program, EPA's conditional approval of the 15% plan would also convert to a disapproval. EPA would notify Maryland by letter that the conditions have not been met and that the conditional approval of the 15% plan has converted to a disapproval. Each of the conditions must be fulfilled by Maryland and submitted to EPA as an amendment to the SIP. If Maryland corrects the deficiencies within one year of conditional approval, and submits a revised 15% plan as a SIP revision, EPA will conduct rulemaking on that revision.

Further, EPA makes this conditional approval of the 15% plan contingent upon Maryland maintaining a mandatory I/M program. EPA will not credit any reductions toward the 15% ROP requirement from a voluntary enhanced I/M program. Any changes to I/M which would render the program voluntary or discontinued would cause a shortfall of credits in the 15% reduction goal. Therefore, this action will convert automatically to a disapproval should the State make the enhanced I/M program a voluntary measure.

Nothing in this action should be construed as permitting or allowing or establishing a precedent for any future request for revision to any state implementation plan. Each request for revision to the state implementation plan shall be considered separately in light of specific technical, economic, and environmental factors and in relation to relevant statutory and regulatory requirements.

The Office of Management and Budget (OMB) has exempted this regulatory action from E.O. 12866 review.

Under the Regulatory Flexibility Act, 5 U.S.C. 600 *et seq.*, EPA must prepare a regulatory flexibility analysis assessing the impact of any proposed or final rule on small entities. 5 U.S.C. 603 and 604. Alternatively, EPA may certify that the rule will not have a significant impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and government entities with jurisdiction over populations of less than 50,000.

SIP approvals under section 110 and subchapter I, part D of the Clean Air Act do not create any new requirements but simply approve requirements that the State is already imposing. Therefore, because the Federal SIP approval does not impose any new requirements, the EPA certifies that it does not have a significant impact on any small entities affected. Moreover, due to the nature of the Federal-State relationship under the Act, preparation of a flexibility analysis would constitute Federal inquiry into the economic reasonableness of state action. The Clean Air Act forbids EPA to base its actions concerning SIPs on such grounds. *Union Electric Co.* v. *U.S. EPA*, 427 U.S. 246, 255–66 (1976); 42 U.S.C. 7410(a)(2).

Conditional approvals of SIP submittals under section 110 and subchapter I, part D of the Act do not create any new requirements but simply approve requirements that the State is already imposing. Therefore, because the Federal SIP approval does not impose any new requirements, EPA certifies that it does not have a significant impact on any small entities affected. Moreover, due to the nature of the Federal-State relationship under the Act, preparation of a flexibility analysis would constitute Federal inquiry into the economic reasonableness of state action. The Clean Air Act forbids EPA to base its actions concerning SIPs on such grounds. *Union Electric Co.* v. *U.S. EPA*, 427 U.S. 246, 255–66 (1976); 42 U.S.C. 7410(a)(2).

If the conditional approval is converted to a disapproval under section 110(k), based on the State's failure to meet the commitment, it will not affect any existing state requirements applicable to small entities. Federal disapproval of the state submittal does not affect its state-enforceability. Moreover, EPA's disapproval of the submittal does not impose a new Federal requirement. Therefore, EPA certifies that this disapproval action does not have a significant impact on a substantial number of small entities because it does not remove existing requirements nor does it substitute a new federal requirement.

Under section 202 of the Unfunded Mandates Reform Act of 1995 (''Unfunded Mandates Act''), signed into law on March 22, 1995, EPA must prepare a budgetary impact statement to accompany any proposed or final rule that includes a Federal mandate that may result in estimated costs to State, local, or tribal governments in the aggregate; or to private sector, of $100 million or more. Under section 205, EPA must select the most cost-effective and least burdensome alternative that achieves the objectives of the rule and is consistent with statutory requirements. Section 203 requires EPA to establish a plan for informing and advising any small governments that may be significantly or uniquely impacted by the rule.

EPA has determined that the approval action promulgated does not include a Federal mandate that may result in estimated costs of $100 million or more to either State, local, or tribal governments in the aggregate, or to the private sector. This Federal action approves pre-existing requirements under State or local law, and imposes no new requirements. Accordingly, no additional costs to State, local, or tribal governments, or to the private sector, result from this action.

Under 5 U.S.C. 801(a)(1)(A) as added by the Small Business Regulatory Enforcement Fairness Act of 1996, EPA submitted 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 General Accounting Office prior to publication of the rule in today's **Federal Register**. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action, pertaining to the final conditional interim approval of the 15% plan for the Maryland portion of the Metropolitan Washington D.C. serious ozone nonattainment area, must be filed in the United States Court of Appeals for the appropriate circuit by November 24, 1997. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Hydrocarbons, Incorporation by reference, Ozone.

Dated: September 12, 1997.

W. Michael McCabe,

Regional Administrator, Region III.

Chapter I, title 40, of the Code of Federal Regulations is amended as follows:

PART 52—[AMENDED]

1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401–7671q.

Subpart V—Maryland

2. Section 52.1072 is amended by adding paragraph (b) to read as follows:

§ 52.1072 Conditional approval.

* * * * *

(b) The State of Maryland's July 12, 1995 submittal for the 15 Percent Rate of Progress Plan (15% plan) for the Maryland portion of the Metropolitan Washington, DC ozone nonattainment area, is conditionally approved based on certain contingencies. The conditions for approvability are as follows:

(1) Maryland's 15% plan must be revised to account for growth in point sources from 1990–1996.

(2) Maryland must meet the conditions listed in the October 31, 1996 proposed conditional I/M rulemaking notice, remodel the I/M reductions using the following two EPA guidance memos: ''Date by which States Need to Achieve all the Reductions Needed for the 15 Percent Plan from I/M and Guidance for Recalculation,'' note from John Seitz and Margo Oge, dated August 13, 1996, and ''Modeling 15 Percent VOC Reductions from I/M in 1999—Supplemental Guidance,'' memorandum from Gay MacGregor and Sally Shaver, dated December 23, 1996.

(3) Maryland must remodel to determine affirmatively the creditable reductions from RFG, and Tier 1 in accordance with EPA guidance.

(4) Maryland must submit a SIP revision amending the 15% plan with a demonstration using appropriate documentation methodologies and credit calculations that the 56.4 tons/day reduction, supported through creditable emission reduction measures in the submittal, satisfies Maryland's 15% ROP requirement for the

Metropolitan Washington, DC nonattainment area.

[FR Doc. 97–25228 Filed 9–22–97; 8:45 am]
BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[Region 2 Docket No. NY24–2–172b, FRL–5892–5]

Approval and Promulgation of Implementation Plans; Reasonably Available Control Technology for Oxides of Nitrogen for Specific Sources in the State of New York

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: The EPA is announcing approval of three (3) revisions to the State Implementation Plan (SIP) for ozone submitted by the State of New York. These revisions consist of source-specific reasonably available control technology (RACT) determinations for controlling oxides of nitrogen (NO_X) from these sources in New York. The intended effect of this action is to approve the source-specific RACT determinations made by New York in accordance with State provisions. This action is being taken in accordance with section 110 of the Clean Air Act (the Act).

DATES: This rule is effective on November 24, 1997 unless adverse or critical comments are received by October 23, 1997. If the effective date is delayed, timely notice will be published in the **Federal Register**.

ADDRESSES: All comments should be addressed to: Ronald J. Borsellino, Chief, Air Programs Branch, Environmental Protection Agency, Region 2 Office, 290 Broadway, New York, New York 10007–1866.

Copies of the State submittals are available at the following addresses for inspection during normal business hours:

Environmental Protection Agency, Region 2 Office, Air Programs Branch, 290 Broadway, 25th Floor, New York, New York 10007–1866.

New York Department of Environmental Conservation, Division of Air Resources, 50 Wolf Road, Albany, New York 12233.

Environmental Protection Agency, Air and Radiation Docket and Information Center, Air Docket (6102), 401 M Street, SW., Washington, DC 20460.

FOR FURTHER INFORMATION CONTACT: Ted Gardella or Rick Ruvo, Air Programs Branch, Environmental Protection Agency, 290 Broadway, 25th Floor, New York, New York 10007–1866, (212) 637–4249.

SUPPLEMENTARY INFORMATION:

A. Background

The air quality planning requirements for the reduction of NO_X emissions through RACT are set out in section 182(f) of the Act. Section 182(f) requirements are described by EPA in a **Federal Register**, ''State Implementation Plans; Nitrogen Oxides Supplement to the General Preamble; Clean Air Act Amendments of 1990 Implementation of Title I; Proposed Rule,'' published November 25, 1992 (57 FR 55620). The November 25, 1992 **Federal Register** should be referred to for detailed information on the NO_X requirements. Additional guidance memoranda which have been released subsequent to the NO_X Supplement should also be referred to.

The EPA has defined RACT as the lowest emission limitation that a particular source is capable of meeting by the application of control technology that is reasonably available considering technological and economic feasibility (44 FR 53762, September 17, 1979).

Section 182(f) of the Act requires states within ozone nonattainment areas classified moderate or above or areas within the ozone transport region to apply the same requirements to major stationary sources of NO_X ''major'' as defined in section 302 and section 182(c), (d), and (e)) as are applied to major stationary sources of volatile organic compounds (VOCs). For more information on what constitutes a major source, see section 2 of the NO_X Supplement to the General Preamble.

Section 182(b)(2) requires submittal of RACT rules for major stationary sources of VOC emissions (not covered by a pre-enactment control technique guidelines (CTG) document or a post-enactment CTG document) by November 15, 1992. There were no NO_X CTGs issued before enactment and EPA has not issued a CTG document for any NO_X sources since enactment. States, in their RACT rules, are expected to require final installation of the actual NO_X controls by May 31, 1995 from those sources for which installation by that date is practicable.

States within the Northeast ozone transport region established by section 184(a) should have revised their SIPs to include the RACT measures by November 15, 1992. Because major sources in states in an ozone transport region are generally subject to at least the same level of control as sources in moderate ozone nonattainment areas, EPA believes that the schedule for implementing these RACT rules in the ozone transport region should be consistent with the requirements of section 182(b)(2) which requires the state to provide for implementation of the actual NO_X controls as expeditiously as practicable but no later than May 31, 1995. Based on sections 182(f)and 184(a) and (b), New York is required to apply the NO_X RACT requirements Statewide.

B. New York's NO_X RACT Regulations

New York held public hearings in April 1993 on 6 NYCRR subpart 227–2, the State's NO_X RACT plan entitled ''Reasonably Available Control Technology For Oxides of Nitrogen (NO_X RACT)—Stationary Combustion Installations.'' Following the public hearings and the comment period, the plan was adopted and signed on January 19, 1994. On January 20, 1994, the plan was submitted to EPA as a revision to the SIP and EPA found it to be administratively and technically complete on April 15, 1994. Proposed EPA action on the January 20, 1994 submittal is expected to be published in the **Federal Register** soon.

C. Case-by-Case RACT Determinations

Provisions within subpart 227–2 establish a procedure for a case-by-case determination of what represents RACT for an item of equipment or source operation. This procedure is applicable in two situations: (1) If the major NO_X facility contains any source operation or item of equipment of a category not specifically regulated in subpart 227–2, or (2) if the owner or operator of a source operation or item of equipment of a category that is regulated in subpart 227–2 seeks approval of an alternative maximum allowable emission limit.

Subpart 227–2 requires the owners and/or operators of the affected facility to submit either a RACT proposal if they are not covered by specific emission limitations or a request for an alternative maximum allowable emission limit if they are covered by specific emission limitations. For each situation, the owners/operators must include a technical and economic feasibility analysis of the possible alternative control measures. RACT determinations for an alternative maximum allowable emission limit must consider alternative control strategies (i.e., system wide averaging and fuel switching) in addition to considering control technologies (e.g., low NO_X burners). In either case, subpart 227–2 provides for New York to

establish emission limits based upon a RACT determination specific to the facility. The resulting alternative maximum allowable emission limit must be submitted to EPA for approval as a SIP revision.

D. Analysis of State Submittals

The three (3) source-specific SIP revisions that are the subject of this action were all adopted by New York at different times during 1995 and 1996 and were found by EPA to be administratively and technically complete. Each of the three SIP revisions were requests by New York for EPA approval of alternative emission limits in accordance with provisions of subpart 227–2 for stationary combustion sources. Prior to adoption, New York published their proposed RACT determinations in local newspapers and/or their *Environmental Notice Bulletin* and provided 30 days for public comment and an opportunity to request a public hearing. There were no requests for public hearings and New York reviewed and responded to all comments made. New York determined that the alternative maximum allowable emission limits proposed by the owners conform with the applicable provisions of Subpart 227–2. New York has issued to each owner a permit to construct and/or certificate to operate incorporating approved permit conditions which are fully enforceable by the State and which contain conditions consistent with subpart 227–2. These permitted documents are identified in the ''Incorporation by reference'' section at the end of this rulemaking.

EPA has determined that the NO_X emission limits identified in New York's approved permits to construct and/or certificates to operate represent RACT for each source identified in this action. The permit conditions include emission limits, work practice standards, testing, monitoring, and recordkeeping/reporting requirements. These permit conditions are consistent with the NO_X RACT requirements specified in subpart 227–2 and conform to EPA's NO_X RACT guidance. Therefore, EPA is approving the three source-specific SIP revisions submitted by New York dated February 22, 1996, June 21, 1996 and June 25, 1996 as identified in this **Federal Register**.

EPA's evaluation of each RACT submittal is detailed in a document dated June 19, 1997, entitled ''Technical Support Document-NO_X RACT Source-Specific SIP Revisions-State of New York.'' A copy of that document is available, upon request, from the EPA Regional Office listed in the ADDRESSES section of this document.

The following is a summary of EPA's findings of each source-specific SIP revision where the owner or operator of a source operation or item of equipment seeks approval of a RACT emission limit different from that which is established in subpart 227–2. This rulemaking takes action only on the permitted emission limits and conditions of approval related to emissions of NO_X; action is not being taken on any other pollutants which may be permitted by New York with regard to these sources.

1. University of Rochester

The University of Rochester operates two oil-fired boilers in Rochester, Monroe County. Boiler # 3 is categorized as a mid-size boiler and Boiler # 5 is categorized as a large boiler. The facility's RACT analysis concluded, and New York agreed, that RACT for each boiler is the application of burner tuning with oxygen trim and limiting the annual fuel consumption to 1,000,000 gallons per boiler. The alternative NO_X emission limit is 0.425 pounds NO_X per million BTUs (lbs/MM BTU).

2. Morton International, Incorporated

Morton International, Incorporated operates a mid-size standby gas-fired boiler at its Silver Springs facility in Wyoming County. The facility's RACT analysis concluded, and New York agreed, that RACT is limiting the hours of operation to 500 during any consecutive twelve (12) month period. A rolling 12-month total is to be computed monthly. The alternative NO_X emission limit is 3.1 tons per year, equivalent to 0.135 lbs/MM BTU.

3. Algonquin Gas Transmission Company

Algonquin Gas Transmission Company operates four 2700-horsepower natural gas-fired, reciprocating lean-burn internal combustion engines at its Stony Point Compressor Station in Rockland County. The facility's RACT analysis concluded, and New York agreed, that RACT is the use of a high energy ignition system combined with air-to-fuel ratio control for each engine. The alternative NO_X emission limit for each engine is 5.1 grams per horsepower-hour (g/hp-hr).

Final Action

EPA is approving three source-specific RACT determinations as described above as RACT for the control of NO_X emissions and the corresponding permit conditions for the sources identified.

The EPA is publishing this direct final rule without prior proposal because the Agency views this as a noncontroversial amendment and anticipates no adverse comments. However, in a separate document in this **Federal Register** publication, the EPA is publishing a proposal to approve these same three source-specific SIP revisions. The final rule will be effective November 24, 1997 unless adverse or critical comments are received by October 23, 1997 in which case this direct final rule will be withdrawn. EPA will make all efforts to have the final action withdrawing this direct final rule published in the **Federal Register** prior to the effective date of the direct final action. All public comments received will be addressed in a subsequent final rule based on the proposed rule and the rationale in the preamble of this direct final rule. The EPA will not institute a second comment period on these actions. Any parties interested in commenting on this action should do so at this time. If no such comments are received, the public is advised that this direct final rule will be effective November 24, 1997.

Nothing in this action should be construed as permitting or allowing or establishing a precedent for any future request for revision to any SIP. Each request for revision to the SIP shall be considered separately in light of specific technical, economic, and environmental factors and in relation to relevant statutory and regulatory requirements.

Administrative Requirements

Executive Order 12866

This action has been classified as a Table 3 action for signature by the Regional Administrator under the procedures published in the **Federal Register** on January 19, 1989 (54 FR 2214–2225), as revised by a July 10, 1995 memorandum from Mary Nichols, Assistant Administrator for Air and Radiation. The Office of Management and Budget (OMB) has exempted this regulatory action from E.O. 12866 review.

Regulatory Flexibility Act

Under the Regulatory Flexibility Act, 5 U.S.C. 600 *et seq.*, EPA must prepare a regulatory flexibility analysis assessing the impact of any proposed or final rule on small entities. 5 U.S.C. 603 and 604. Alternatively, EPA may certify that the rule will not have a significant impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and government entities with jurisdiction over populations of less than 50,000.

SIP approvals under section 110 and subchapter I, part D of the Act do not create any new requirements but simply approve requirements that the state is already imposing. Moreover, this action does not involve generally applicable requirements, but specific requirements for each facility which both the source owner and the State have determined to be economically and technologically reasonable. This action only affects the sources which have requested the SIP revision and which are not small entities. Therefore, EPA certifies that this approval action does not have a significant impact on small entities.

Unfunded Mandates Act

Under section 202 of the Unfunded Mandates Reform Act of 1995 (''Unfunded Mandates Act''), signed into law on March 22, 1995, EPA must prepare a budgetary impact statement to accompany any proposed or final rule that includes a Federal mandate that may result in estimated annual costs to state, local, or tribal governments in the aggregate; or to private sector, of $100 million or more. Under section 205, EPA must select the most cost-effective and least burdensome alternative that achieves the objectives of the rule and is consistent with statutory requirements. Section 203 requires EPA to establish a plan for informing and advising any small governments that may be significantly or uniquely impacted by the rule.

EPA has determined that the approval action promulgated does not include a Federal mandate that may result in estimated annual costs of $100 million or more to either state, local, or tribal governments in the aggregate, or to the private sector. This Federal action approves pre-existing requirements under state or local law, and imposes no new Federal requirements. Accordingly, no additional annual costs to state, local, or tribal governments, or to the private sector, result from this action.

Submission to Congress and the General Accounting Office

Under 5 U.S.C. 801(a)(1)(A) as added by the Small Business Regulatory Enforcement Fairness Act of 1996, EPA submitted 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 General Accounting Office prior to publication of the rule in today's **Federal Register**. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Petitions for Judicial Review

Under section 307(b)(1) of the Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by November 24, 1997. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Nitrogen dioxide, Ozone, Reporting and recordkeeping requirements.

Dated: September 2, 1997.

William J. Muszynski,

Acting Regional Administrator.

Part 52, chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 52—[AMENDED]

1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401–7671q.

Subpart HH—New York

2. Section 52.1670 is amended by adding new paragraph (c)(91) to read as follows:

§ 52.1670 Identification of plan.

* * * * *

(c) * * *

(91) Revisions to the State Implementation Plan submitted by the New York State Department of Environmental Conservation on February 22, 1996, June 21, 1996 and June 25, 1996.

(i) *Incorporation by reference.*

(A) Permits to Construct and/or Certificates to Operate: The following facilities have been issued permits to construct and/or certificates to operate by New York State and such permits and/or certificates are incorporated for the purpose of establishing NO_X emission limits consistent with Subpart 227–2:

(*1*) Morton International Inc.'s mid-size gas-fired boiler, emission point 00027, Wyoming County; New York permit approval dated September 1, 1995 and Special Conditions letter dated August 23, 1995.

(*2*) University of Rochester's two oil fired boilers, emission points 00003 and 00005, Monroe County; New York permit approval dated April 25,1996 and Special Permit Conditions issued March 19, 1996.

(*3*) Algonquin Gas Transmission Company's four gas-fired reciprocating internal combustion engines, emission points R0100, R0200, R0300, and R0400, Rockland County; New York permit and Special Conditions approval dated September 23, 1991; New York Special Conditions documents dated March 18, 1996 for emission points RO100, RO200, and RO300; and March 29, 1996 for emission point RO400; and Permit Correction dated August 8, 1996.

(ii) *Additional information.* Documentation and information to support NO_X RACT alternative emission limits in three letters addressed to EPA from New York State Department of Environmental Conservation and dated as follows:

(A) February 22, 1996 letter to Regional Administrator Jeanne Fox from Commissioner Michael D. Zagata for a SIP revision for Morton International, Inc.

(B) June 21, 1996 letter to Mr. Conrad Simon, Director of the Air and Waste Management Division from Deputy Commissioner David Sterman for a SIP revision for the Algonquin Gas Transmission Company.

(C) June 25, 1996 letter to Mr. Conrad Simon, Director of the Air and Waste Management Division from Deputy Commissioner David Sterman for a SIP revision for the University of Rochester.

[FR Doc. 97–25232 Filed 9–22–97; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 167

[FRL–5897–3]

Change of Address for Submission of Certain Reports; Technical Amendment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; technical amendment.

SUMMARY: This document announces a technical amendment revising the address to be used by foreign pesticide producing establishments when submitting applications for registration and annual reports to EPA.

DATES: This document is effective September 23, 1997.

FOR FURTHER INFORMATION CONTACT: Foreign pesticide producing establishments should contact: Carol

Buckingham, FIFRA, Section 7 Registration Contact, Agriculture and Ecosystems Division (2225A), Office of Compliance, Office of Enforcement and Compliance Assurance, U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460, (202) 564–5008; Fax: (202) 564–0085.

SUPPLEMENTARY INFORMATION: Section 7 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) requires that pesticides subject to the Act be produced only in establishments registered with EPA, and requires that registered establishments file annual reports with the Agency. The Agency has established regulations at 40 CFR part 167 to implement the requirements of section 7 of FIFRA. Section 167.90 of those regulations directs that applications for registration of establishments and annual reports be sent to the appropriate EPA regional office (if a registered establishment is located in the United States) or to a specified address at EPA headquarters (if a registered establishment is located in any other country). The Agency is, by this document, amending 40 CFR 167.90(b) by revising the address to be used by foreign establishments when submitting applications or annual reports to the Agency. This technical amendment to the regulations will become effective upon publication of this document in the **Federal Register**.

List of Subjects in 40 CFR Part 167

Environmental protection, Pesticides and pests, Pesticide company, Pesticide producing establishment, Reporting and recordkeeping requirements.

Dated: September 17, 1997.

Elaine G. Stanley,

Director, Office of Compliance, Office of Enforcement and Compliance Assurance.

Therefore, 40 CFR part 167 is amended as follows:

PART 167—[AMENDED]

1. The authority citation for part 167 continues to read as follows:

Authority: 7 U.S.C. 136 (e) and (w).

2. In § 167.90(b), by revising the address at the end of the paragraph to read as follows:

§ 167.90 Where to obtain and submit forms.

* * * * *

(b) * * *

U.S. Environmental Protection Agency, Office of Enforcement and Compliance Assurance, Office of Compliance, Agriculture and Ecosystems Division (2225A), 401 M Street, SW, Washington, DC 20460, ATTN: Foreign Registration Clerk.

[FR Doc. 97–25223 Filed 9–22–97; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 281

[FRL–5896–7]

West Virginia; Final Approval of State Underground Storage Tank Program

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of final determination on West Virginia's application for program approval.

SUMMARY: The State of West Virginia has applied for approval of its underground storage tank program under Subtitle I of the Resource Conservation and Recovery Act (RCRA). The Environmental Protection Agency (EPA) has reviewed the State of West Virginia's application and has made a final determination that the State of West Virginia's underground storage tank program satisfies all of the requirements necessary to qualify for approval. Thus, EPA is granting final approval to the State of West Virginia to operate its program.

EFFECTIVE DATES: Program approval for West Virginia shall be effective on October 23, 1997.

FOR FURTHER INFORMATION CONTACT: Joanne Cassidy, State Programs Branch (3HW60), U.S. EPA Region III, 841 Chestnut Building, Philadelphia, Pennsylvania 19107, (215) 566–3381.

SUPPLEMENTARY INFORMATION:

A. Background

Section 9004 of the Resource Conservation and Recovery Act (RCRA) authorizes EPA to approve State underground storage tank programs to operate in the State in lieu of the Federal underground storage tank (UST) program. To qualify for approval, a State's program must be ''no less stringent'' than the Federal program in all seven elements set forth at section 9004(a) (1) through (7) of RCRA, 42 U.S.C. 6991c(a) (1) through (7), as well as the notification requirements of section 9004(a)(8) of RCRA, 42 U.S.C. 6991c(a)(8) and must provide for adequate enforcement of compliance with UST standards (section 9004(a) of RCRA, 42 U.S.C. 6991c(a)).

On July 7, 1997, the State of West Virginia submitted an official application for approval to administer its underground storage tank program. On August 1, 1997, EPA published a tentative determination announcing its intent to approve the District's program. Further background on the tentative decision to grant approval appears at 62 FR 41326, (August 1, 1997).

Along with the tentative determination, EPA announced the availability of the application for public review and comment, and the date of a tentative public hearing on the application and EPA's tentative determination. EPA requested advance notice for testimony and reserved the right to cancel the public hearing in the event of insufficient public interest. Since there were no requests to hold a public hearing, it was cancelled.

B. Final Decision

I conclude that the State of West Virginia's application for program approval meets all of the statutory and regulatory requirements established by Subtitle I of RCRA and 40 CFR part 281. Accordingly, the State of West Virginia is granted approval to operate its underground storage tank program in lieu of the Federal program.

Compliance With Executive Order 12866

The Office of Management and Budget has exempted this action from the requirements of section 6 of Executive Order 12866.

Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), P.L. 104–4, establishes requirements for Federal agencies to assess the effects of certain regulatory actions on State, local, and tribal governments and the private sector. Under sections 202 and 205 of the UMRA, EPA generally must prepare a written statement of economic and regulatory alternatives analyses for proposed and final rules with Federal mandates, as defined by the UMRA, 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. The section 202 and 205 requirements do not apply to today's action because it is not a ''Federal mandate'' and because it does not impose annual costs of $100 million or more.

Today's rule contains no Federal mandates for State, local or tribal governments or the private sector for two reasons. First, today's action does not impose new or additional enforceable duties on any State, local or tribal governments or the private sector because the requirements of the West Virginia program are already imposed

by the State and subject to State law. Second, the Act also generally excludes from the definition of a ''Federal mandate'' duties that arise from participation in a voluntary Federal program. West Virginia's participation in an authorized UST program is voluntary.

Even if today's rule did contain a Federal mandate, this rule will not result in annual expenditures of $100 million or more for State, local, and/or tribal governments in the aggregate, or the private sector. Costs to State, local and/or tribal governments already exist under the West Virginia program, and today's action does not impose any additional obligations on regulated entities. In fact, EPA's approval of state programs generally may reduce, not increase, compliance costs for the private sector.

The requirements of section 203 of UMRA also do not apply to today's action. Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, section 203 of the UMRA requires EPA to develop a small government agency plan. This rule contains no regulatory requirements that might significantly or uniquely affect small governments. The Agency recognizes that although small governments may own and/or operate USTs, they are already subject to the regulatory requirements under existing state law which are being authorized by EPA, and, thus, are not subject to any additional significant or unique requirements by virtue of this program approval.

Certification Under the Regulatory Flexibility Act

EPA has determined that this authorization will not have a significant economic impact on a substantial number of small entities. Such small entities which own and/or operate USTs are already subject to the regulatory requirements under existing State law which are being authorized by EPA. EPA's authorization does not impose any additional burdens on these small entities. This is because EPA's authorization would simply result in an administrative change, rather than a change in the substantive requirements imposed on these small entities.

Therefore, EPA provides the following certification under the Regulatory Flexibility Act, as amended by the Small Business Regulatory Enforcement Fairness Act. Pursuant to the provision at 5 U.S.C. 605(b), I hereby certify that this authorization will not have a significant economic impact on a substantial number of small entities. This authorization approves regulatory requirements under existing State law to which small entities are already subject. It does not impose any new burdens on small entities. This rule, therefore, does not require a regulatory flexibility analysis.

Submission to Congress and the General Accounting Office

Under 5 U.S.C. 801(a)(1)(A) as added by the Small Business Regulatory Enforcement Fairness Act of 1996, EPA submitted 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 General Accounting Office prior to publication of the rule in today's **Federal Register**. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 281

Administrative practice and procedure, Hazardous materials, State program approval, and Underground storage tanks.

Authority: This notice is issued under the authority of section 9004 of the Resource Conservation and Recovery Act, as amended, 42 U.S.C. 6991c.

Dated: September 15, 1997.

W. Michael McCabe,

Regional Administrator.

[FR Doc. 97–25132 Filed 9–22–97; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 300

[FRL–5895–3]

National Oil and Hazardous Substances Pollution Contingency Plan; National Priorities List Update

AGENCY: Environmental Protection Agency.

ACTION: Notice of deletion of the Spokane Junkyard and Associated Properties site from the National Priorities List.

SUMMARY: The Environmental Protection Agency (EPA) Region 10 announces the deletion of the Spokane Junkyard and Associated Properties Site from the National Priorities List (NPL). 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 of 1980, as amended (CERCLA). EPA and the State of Washington Department of Ecology (Ecology) have determined that no further cleanup under CERCLA is appropriate and that the selected remedy has been protective of human health and the environment.

EFFECTIVE DATE: September 23, 1997.

FOR FURTHER INFORMATION CONTACT: Kevin Rochlin, U.S. EPA Region 10, 1200 Sixth Avenue, Mail Stop: ECL–111, Seattle, Washington 98101, (206) 553–2106.

SUPPLEMENTARY INFORMATION: The site to be deleted from the NPL is: Spokane Junkyard and Associated Properties, Spokane, Washington.

A Notice of Intent to Delete for this site was published on August 7, 1997, (62 FR 42414). The closing date for comments on the Notice of Intent to Delete was September 7, 1997. EPA received no comments.

EPA identifies sites which appear to present a significant risk to human health, welfare or the environment, and it maintains the NPL as the list of those sites. Sites on the NPL may be the subject of Hazardous Substances Response Trust Fund-financed remedial actions. Any site deleted from the NPL remains eligible for Fund-financed remedial actions in the unlikely event that conditions at the site warrant such action. Section 300.425 of the NCP states that Fund-financed actions may be taken at sites deleted from the NPL. Deletion of a site from the NPL does not affect responsible party liability or impede Agency efforts to recover costs associated with response efforts.

List of Subjects in 40 CFR Part 300

Environmental protection, Air pollution control, Chemicals, Hazardous substances, Hazardous waste, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements, Superfund, Water pollution control, and Water supply.

For the reasons set out in the preamble, 40 CFR part 300 is amended as follows:

PART 300—[AMENDED]

1. The authority citation for Part 300 continues to read as follows:

Authority: 33 U.S.C. 1321(c)(2); 42 U.S.C. 9601–9657; E.O. 12777, 56 FR 54757, 3 CFR 1991 Comp., p. 351; E.O. 12580, 52 FR 2923, 3 CFR, 1987 Comp., p. 193.

Appendix B—[Amended]

2. Table 1 of Appendix B to part 300 is amended by removing the entry for ''Spokane Junkyard/Associated Properties, Spokane, Washington.''

Dated: September 9, 1997.

Chuck Clarke,

Regional Administrator, Region 10.

[FR Doc. 97–24943 Filed 9–22–97; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MM Docket No. 96–219; RM–8881]

Radio Broadcasting Services; Temple, Taylor and Hutto, TX

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The Commission, at the request of Stellar Communications, Inc., reallots Channel 282C2 from Temple to Taylor, Texas, and modifies Station KKIK(FM)'s license accordingly. *See* 61 FR 58361, November 14, 1996. Channel 282C2 can be allotted to Taylor in compliance with the Commission's minimum distance separation requirements with a site restriction of 6.4 kilometers (4.0 miles) southwest. The coordinates for Channel 282C2 at Taylor are 30–31–18 and 97–26–40. The Commission also pursuant to the grant of the major change application (BPH–821203AD) reallots Channel 221A from Taylor to Hutto, Texas. With this action, this proceeding is terminated.

EFFECTIVE DATE: October 27, 1997.

FOR FURTHER INFORMATION CONTACT: Pam Blumenthal, Mass Media Bureau, (202) 418–2180.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Report and Order, MM Docket No. 96–219, adopted September 3, 1997, and released September 12, 1997. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Reference Center (Room 239), 1919 M Street, NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractor, ITS, Inc., (202) 857–3800, 1231 20th Street, NW., Washington, DC 20036.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

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: Secs. 303, 48 Stat., as amended, 1082; 47 U.S.C. 154, as amended.

§ 73.202 [Amended]

2. Section 73.202(b), the Table of FM Allotments under Texas, is amended by removing Channel 282C2 at Temple and by adding Channel 282C2 at Taylor; and by removing Channel 221A at Taylor and by adding Hutto, Channel 221A.

Federal Communications Commission.

John A. Karousos,

Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 97–24934 Filed 9–22–97; 8:45 am]

BILLING CODE 6712–01–F

Proposed Rules

Federal Register
Vol. 62, No. 184
Tuesday, September 23, 1997

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.

FARM CREDIT ADMINISTRATION

12 CFR Parts 611, 615, 620 and 627

RIN 3052–AB58

Organization; Funding and Fiscal Affairs, Loan Policies and Operations, and Funding Operations; Disclosure to Shareholders; Title V Conservators and Receivers; Capital Provisions

AGENCY: Farm Credit Administration.

ACTION: Proposed rule.

SUMMARY: The Farm Credit Administration (FCA or Agency), through the FCA Board (Board), issues a proposed rule to amend its capital adequacy and related regulations to address interest rate risk as it pertains to Farm Credit System (System) institutions, the definition of insolvency for the purpose of appointing a receiver, the establishment of capital and bylaw requirements for System service corporations, and changes to risk-weighting categories. In addition, the proposed regulations address the retirement of other allocated equities included in core surplus, deferred-tax assets, the treatment of intra-System investments for capital computation purposes, various other computational issues, and other technical issues. The rule is intended to add safety and soundness requirements deferred from prior rulemakings, provide more consistency with capital requirements of other financial regulators, and make technical corrections.

DATES: Written comments should be received on or before November 24, 1997.

ADDRESSES: Comments may be mailed or delivered to Patricia W. DiMuzio, Director, Regulation Development Division, Office of Policy Development and Risk Control, Farm Credit Administration, 1501 Farm Credit Drive, McLean, Virginia 22102–5090 or sent by facsimile transmission to (703) 734–5784. Comments may also be submitted via electronic mail to ''reg-comm@fca.gov.'' Copies of all communications received will be available for review by interested parties in the Office of Policy Development and Risk Control, Farm Credit Administration.

FOR FURTHER INFORMATION CONTACT:
Dennis K. Carpenter, Senior Policy Analyst, Office of Policy Development and Risk Control, Farm Credit Administration, McLean, VA 22102–5090, (703) 883–4498, TDD (703) 883–4444,
or
Rebecca S. Orlich, Senior Attorney, Office of General Counsel, Farm Credit Administration, McLean, VA 22102–5090, (703) 883–4020, TDD (703) 883–4444.

SUPPLEMENTARY INFORMATION:

I. General

Capital adequacy and customer eligibility regulations, adopted in January and effective in March 1997, added surplus and net collateral ratios for System institutions and established procedures for setting individual institution capital ratios and issuing capital directives. *See* 62 FR 4429, January 30, 1997. The purpose of these proposed regulations is to build on previous regulatory efforts by addressing discrete issues related to capital that were deferred during the FCA's consideration of its newly effective capital adequacy regulations. The issues in this proposed rulemaking include: (1) Interest rate risk; (2) the definition of insolvency for the purpose of appointing a conservator or receiver; (3) the establishment of capital and bylaw requirements for service corporations; and (4) various computational issues, and other issues involving the capital regulations. The objectives of these proposed amendments are:

1. To add provisions where the FCA believes significant capital issues have not been previously addressed in the regulations. Expressly addressing such issues in the regulations accords more certainty to both the Agency and System institutions regarding supervisory expectations and standards for enforcement.

2. To achieve consistency with the capital requirements of other Federal banking regulatory agencies (the Office of the Comptroller of the Currency, the Federal Deposit Insurance Corporation, the Federal Reserve Board, and the Office of Thrift Supervision) in areas of similar risk, such as risk-weighting of assets. In proposing changes, the FCA is cognizant that circumstances unique or special to System institutions may appropriately be addressed in a manner that differs from the treatment of commercial banks and thrifts by the other Federal banking regulators.

3. To make revisions and clarifications in the regulations that address concerns raised by FCA examiners and System institutions.

4. To make technical corrections including removing some inconsistencies in the computations of the core surplus and total surplus ratios.

II. Interest Rate Risk

For the past several years, the FCA has studied the feasibility of modifying the capital adequacy regulations to include a specific interest rate risk exposure component. The current regulations take a risk-based approach that addresses credit risk exposures but does not specifically address other potential exposures. Of particular concern to the FCA is the potentially adverse effect interest rate risk may have on net interest income and the market value of an institution's equity. Specifically, it is the risk of loss of net interest income or the market value of on- and off-balance sheet positions caused by a change in market interest rates. Similar actions to address interest rate risk have been undertaken by the other Federal banking agencies, which were required by section 305 of the Federal Deposit Insurance Corporation Improvement Act of 1991 (FDICIA) (Pub. L. 102–242, 105 Stat. 2236, 2354 (12 U.S.C. 1828 note)) to revise their risk-based capital guidelines to take adequate account of interest rate risk.

The FCA suspended development of the interest rate risk component until completion of higher priority capital adequacy regulations. The FCA is now proposing to add new §§ 615.5180 and 615.5181 to require banks to establish an interest rate risk management program and to provide that the banks' boards of directors and senior management are responsible for maintaining effective oversight. In addition, proposed § 615.5182 would require any other System institution (excluding the Federal Agricultural

Mortgage Corporation [1]) with significant interest rate risk to establish a risk management program.

The proposed rule reflects the FCA's belief that an institution's board and senior management are responsible for ensuring that risks are adequately identified, measured, monitored and controlled. Additionally, proposed §§ 615.5350(b)(7) and 615.5355(a)(4) provide that the FCA may take action against an institution for failure to maintain sufficient capital for interest rate risk exposures. Institutions found to have high levels of exposure or weak management practices may be directed by the FCA to take corrective action, including raising additional capital, strengthening management expertise, improving management information and measurement systems, reducing levels of exposure, or a combination thereof.

The requirements of the proposed rule are similar to interest rate risk management requirements in § 615.5135 of the investment regulations. The existing regulation provides more specific criteria regarding the interest rate risk management process. The proposed rule is general in nature and sets forth the FCA's expectations regarding board and management oversight, particularly maintaining adequate capital for interest rate risk exposures. As a result, the proposed rule provides a flexible regulatory approach to interest rate risk that encourages innovations in risk management practices while ensuring that the FCA can respond to emerging risks in an increasingly complex financial marketplace.

The FCA intends to provide additional guidance on specific criteria and guidelines in the form of a Board Policy Statement or Bookletter in the future. The guidelines will establish a risk assessment approach for the evaluation of capital adequacy specifically addressing interest rate risk, similar to the approach taken by the other Federal banking agencies, and would set forth the FCA's expectations for certain aspects of the institution's ongoing internal control process. These guidelines will address fundamental management practices for identifying, managing, controlling, monitoring, and reporting interest rate risk exposures. The guidelines will reflect the FCA's belief that all institutions should establish a risk management program appropriate for the level of an institution's overall interest rate risk exposure and complexity of its holdings and activities.

[1] Regulations affecting the Federal Agricultural Mortgage Corporation will be issued separately.

III. Definition of Insolvency

The FCA proposes several changes to § 627.2710, which sets forth the grounds for appointing a conservator or receiver for a System institution. First, the FCA proposes to amend the definition of ''insolvency'' as a ground for appointing a conservator or receiver in paragraph (b)(1) to clarify that any stock or allocated equities held by current or former borrowers are not ''obligations to members.'' The FCA believes that this approach for determining insolvency is consistent with financial statements based on generally accepted accounting principles (GAAP) [2] and more appropriately reflects the at-risk character of borrower stock and allocated equities. There would be no change in the treatment of obligations to members such as investment bonds and uninsured accounts. Second, the FCA would revise paragraph (b)(3), which currently provides that a conservator or receiver may be appointed if ''[t]he institution is in an unsafe or unsound condition to transact business.'' The revision would add that ''having insufficient capital or otherwise'' is a circumstance that the FCA could consider to be an unsafe or unsound condition. The proposed addition also identifies capital and collateral benchmarks below which an institution could be considered to be operating unsafely, as well as other conditions. The benchmarks and conditions are:

1. For banks, a net collateral ratio (as defined by § 615.5301(d)) of 102 percent.
2. For associations, collateral insufficient to meet the requirements of the association's general financing agreement with its affiliated bank.
3. For all institutions, permanent capital (as defined in § 615.5201) of less than one-half the minimum required level for the institution.
4. For all institutions, a relevant total surplus ratio (as defined by § 615.5301(i)) of less than 2 percent.
5. For associations, stock impairment.

The first two benchmarks address situations where an institution's continued liquidity is in doubt. In setting the proposed net collateral ratio benchmark at 102 percent, the FCA reviewed the requirements of the System's Market Access Agreement (MAA), as well as the collateral positions of the banks. The FCA also considered a 101-percent standard because the MAA has a 101-percent eligible collateral benchmark below which a bank's market access is restricted.[3] After deliberations, the FCA decided to propose a higher 102-percent benchmark to allow time to appoint a conservator or receiver before a bank is effectively unable to maintain normal funding activities. The Agency requests comment on the appropriateness of the 102-percent benchmark.

The third and fourth benchmarks identify situations where an institution is substantially undercapitalized. The last condition addresses a situation where an association could be exposed to significant customer and marketing uncertainties that may have a significant impact on financial viability or may affect other System institutions.

These benchmarks and conditions are intended to be examples of what the FCA would consider to be an unsafe or unsound condition to transact business but are not exclusive. The Agency would continue to have the discretion to deem an institution to be in an unsafe or unsound condition to transact business based on other activities or circumstances that are not enumerated in the regulation. The FCA notes that, under this proposal, it also retains the discretion not to appoint a conservator or receiver in the event that any of the enumerated circumstances exist. The Agency would evaluate the totality of circumstances before deciding what action, if any, to take.

In developing the proposed revision to this ground for appointing a conservator or receiver, the FCA reviewed the prompt corrective action benchmarks and tripwires used by the other Federal banking regulators with respect to commercial banks and thrifts. The other agencies' prompt corrective action regulations implement provisions of the FDICIA requiring such agencies to take certain supervisory actions, including the appointment of a conservator or receiver, well before insolvency is reached, if an institution's capital declines to unacceptable levels. Although the FCA is not subject to the FDICIA and continues to have supervisory discretion when System institutions are in troubled circumstances, the FCA supports the underlying philosophy of the FDICIA to take supervisory action before an institution is insolvent. It has been the experience of the FCA and the other Federal banking regulators that the longer a failing institution is allowed to remain open, the more difficult it will

[2] GAAP does not define insolvency. However, for the purposes of this regulation, insolvency means total liabilities greater than total assets based upon GAAP financial statements.

[3] The regulation's net collateral ratio is calculated net of any association investments counted as permanent capital by associations and determined using total liabilities, whereas eligible collateral is determined by dividing available collateral by obligations requiring collateralization.

ultimately be to resolve the affairs of the institution. Early intervention is even more important in the Farm Credit System where joint and several liability exists and where the financial health of one institution can affect the public image of other System institutions. The FCA notes that, for this reason, it is very likely that the Agency would appoint a conservator or receiver well before GAAP-based insolvency is reached.

IV. Service Corporations

A. Capital Requirements for Service Corporations

Section 4.25 of the Farm Credit Act of 1971, as amended (Act), requires System institutions to submit proposals to form service corporations to the FCA for issuance of a charter. Current regulations require the submission of bylaws and proposed amounts and sources of capitalization pursuant to § 611.1135(b)(3)(vii), (4), and (5). However, current regulations do not set standard capital requirements for all service corporations. The FCA proposes to amend § 611.1135(c) to address the establishment of capital requirements for service corporations.

Service corporations vary widely in their purpose and structure and present different types of risks to their parent banks or associations. The capital requirements for banks and associations would have little relevance for most service corporations because most service corporations have a small asset base and entirely different risks. Nor does the FCA believe that any single minimum capital adequacy standard is appropriate for all service corporations. The FCA instead proposes to set minimum capital adequacy requirements in the corporate charter approval process as a condition of approval. The FCA would monitor compliance through the examination process.

B. Application of Bylaw Regulations to Service Corporations

The capitalization bylaw provisions in § 615.5220 currently do not apply to service corporations, including the Farm Credit Services Leasing Corporation (FCL or Leasing Corporation). The FCA believes that all institutions, including service corporations, should have capital bylaws that meet the relevant requirements of that provision. The FCA, therefore, proposes to amend § 615.5220 by adding a new paragraph (b) requiring all service corporations to have relevant capitalization provisions in their bylaws. A conforming amendment to § 611.1135(b)(4) is also proposed.

V. Deferred-Tax Assets

A. The Proposed Rule

The FCA proposes to amend § 615.5201 to add new paragraph (d) to define deferred-tax assets that are dependent on future income or future events. The FCA also proposes to amend § 615.5210 to add a new paragraph (e)(11) establishing a requirement to exclude certain deferred-tax assets in capital calculations. Under the proposed rule, deferred-tax assets that can be realized through carrybacks to taxes paid on income earned in prior periods will not be excluded for regulatory capital purposes. However, deferred-tax assets that can be realized only if an institution earns sufficient taxable income in the future or that are dependent on the occurrence of other future events for realization will be partly excluded for regulatory capital purposes. The proposed exclusion is the amount in excess of the amount that the institution is expected to realize within 1 year of the most recent calendar quarter-end date, based on the institution's financial projections of taxable income and other events for that year, or the amount in excess of 10 percent of core surplus capital existing before the deduction of any disallowed tax assets, whichever is greater. Excluded deferred-tax assets will be deducted from capital and from assets for purposes of calculating capital ratios. This proposed exclusion is consistent with requirements of the other Federal banking agencies in response to the issuance by the Financial Accounting Standards Board (FASB) of the Statement of Financial Accounting Standards (SFAS) No. 109, ''Accounting for Income Taxes,'' in February 1992.

B. Discussion

Deferred-tax assets are assets that reflect, for financial reporting purposes, amounts that will be realized as reductions of future taxes or as refunds from a taxing authority. Deferred-tax assets may arise because of limitations under tax laws that provide that certain net operating losses or tax credits be carried forward if they cannot be used to recover taxes previously paid. These ''tax carryforwards'' are realized only if the institution generates sufficient future taxable income during the carryforward period.

Deferred-tax assets may also arise from deductible temporary differences in the tax and financial reporting of certain events. For example, institutions may report higher income to taxing authorities than they reflect in their financial records because their loan loss provisions are expensed for reporting purposes but are not deducted for tax purposes until the loans are charged off.

Deferred-tax assets arising from deductible temporary differences may be ''carried back'' and recovered from taxes previously paid. However, when deferred-tax assets arising from deductible temporary differences exceed such previously paid tax amounts, they will be realized only if there is sufficient future taxable income during the carryforward period.

Another type of deferred-tax assets arises from deductible temporary differences that are dependent on the occurrence of other future events.[4] These deferred-tax assets are not generally available for ''carried back or carry forward'' treatment, but rather are realized in the year the event occurs.

As with the other Federal banking agencies, the FCA has certain concerns about including in capital deferred-tax assets that are dependent upon future taxable income. Realization of such assets depends on whether a System institution that is subject to income tax has sufficient future taxable income during the carryforward period. Since an institution that is in a net operating loss carryforward position is often experiencing financial difficulties, its prospects for generating sufficient taxable income in the future are uncertain. In addition, the future prospects for a financial services organization can change rapidly. This raises concerns about the realization of deferred-tax assets that are dependent upon future taxable income, even when an institution appears to be sound and well managed. Thus, there is considerable uncertainty in determining whether deferred-tax assets will be realized. Many institutions are able to make reasonably accurate projections of future taxable income for relatively short periods of time, but beyond these short time periods, the reliability of the projections tends to decrease significantly.

Certain deferred-tax assets are realized upon the occurrence of certain future events other than taxable income. The same supervisory concerns exist regarding these tax assets as regarding tax assets dependent on future income. Several System institutions have significant amounts of deferred-tax assets that represent the expected refund of income taxes previously paid on earnings distributed in the form of nonqualified allocations of patronage to

[4] The regulations of the other Federal banking agencies do not address this type of deferred-tax assets because it is not applicable to the operations of commercial banks or thrifts, but SFAS No. 109 does encompass all types of such assets.

their stockholders. The realization of these deferred-tax assets is dependent not on future taxable income but rather on actions of the institutions to retire stock or allocated surplus associated with the nonqualified distributions. However, an institution might be unable to retire this stock and allocated equities during periods of financial difficulties when conversion of these deferred-tax assets to cash would be needed.

In addition, as it becomes less likely that deferred-tax assets will be realized, an institution is required under SFAS 109 to reduce its deferred-tax assets through increases to the asset's valuation allowance. Additions to this allowance would reduce an institution's regulatory capital at precisely the time it likely needs additional capital support.

C. Determination of the Deferred-Tax Exclusion

The FCA proposes to require the exclusion of the greater of the amount of deferred-tax assets dependent on future income or events that are not expected to be realized within 1 year, or the amount by which the deferred-tax assets exceed 10 percent of core surplus capital before the exclusion. To determine the deferred-tax exclusion, an institution would assume that all temporary differences fully reverse as of the calculation date. The amount of deferred-tax assets that are dependent upon future taxable income that is expected to be realized within 1 year means the amount of such deferred-tax assets that could be absorbed by the amount of income taxes that are expected to be payable based upon the institution's projected future taxable income for the next 12 months. Estimates of taxable income for the next year should include the effect of tax-planning strategies that the institution intends to implement to realize tax carryforwards that will otherwise expire during the year. Consistent with the other banking agencies and SFAS No. 109, the FCA believes that tax planning strategies are often carried out to prevent the expiration of such carryforwards. Deferred taxes that are dependent on other future events (other than future taxable income) and that are not expected to be realized within 1 year are to be deducted in the determination of the institution's capital measurements.

The FCA believes that institutions will not have significant difficulty in implementing these proposed limits. System institutions routinely make financial projections as part of their annual business planning process. Both the 1-year and 10-percent computations are straightforward and relatively simple. The Agency also believes that most System institutions would not be negatively affected by the implementation of this exclusion of deferred-tax assets. A small number of institutions that have significant tax-deferred assets may be initially unable to satisfy the core surplus ratio but should be able to comply within a relatively short time frame.

The proposed partial exclusion is intended to balance the continued concerns of the Agency about deferred-tax assets that are dependent upon future taxable income and other future events against the fact that such assets will, in many cases, be realized. The exclusion based on 10 percent of core surplus also would ensure that System institutions could not place excessive reliance on deferred-tax assets to satisfy the minimum capital standards.

D. Additional Guidance

The following additional guidance is provided to assist System institutions' understanding of how the FCA proposes to implement the deferred-tax exclusion.

1. Projecting Future Taxable Income and Other Events

Institutions may use the financial projections for planning the current fiscal year (adjusted for any significant changes that have occurred or are expected to occur) when applying the exclusion at an interim date within each fiscal year. In addition, while the proposed rule does not specify how originating temporary differences should be treated for purposes of projecting taxable income and other events for the next year, each institution should decide whether to adjust its financial projections for originating temporary differences and should follow a reasonable and consistent approach.

2. Tax Jurisdictions

Under this proposed rule, an institution would not be required to determine its exclusion of deferred-tax assets on a jurisdiction-by-jurisdiction basis. While an approach that looks at each jurisdiction separately may be more accurate from a theoretical standpoint, the FCA is in agreement with the other Federal banking agencies that the greater precision achieved by mandating such an approach would not outweigh the complexities involved and the inherent cost to institutions. Therefore, to limit regulatory burden, an institution would have the option to calculate one overall exclusion of deferred-tax assets that covers all tax jurisdictions in which it operates.

3. Available-for-Sale Securities

Under SFAS No. 115, ''Accounting for Certain Investments in Debt and Equity Securities'' (SFAS No. 115), available-for-sale securities are reported at fair value, with unrealized holding gains and losses on such securities, net of tax effects, included in a separate component of stockholders' equity. The Agency's current regulations exclude from regulatory capital the amount of net unrealized holding gains and losses on available-for-sale securities. It would be consistent to exclude the deferred tax effects relating to unrealized holding gains and losses on these available-for-sale securities from the calculation of the allowable amount of deferred-tax assets for regulatory capital purposes. However, requiring the exclusion of such deferred tax effects may add significant complexity to the regulatory capital standards and in most cases would not have a significant impact on regulatory capital ratios.

The FCA proposes to permit, but not require, institutions to adjust the amount of deferred-tax assets and liabilities arising from marking-to-market available-for-sale debt securities. This choice should reduce the implementation burden for institutions not wanting to contend with the complexity arising from such adjustments, while permitting those institutions that want to achieve greater precision to make such adjustments. However, institutions must follow a consistent approach with respect to such adjustments.

VI. Computational Issues

Following the implementation of the new capital adequacy provisions, various System institution representatives and FCA examiners have identified certain capital computational concerns and interpretive issues. Such issues primarily involved the computation of the total surplus and core surplus capital requirements. These issues are addressed below as technical corrections to the existing capital adequacy regulations.

A. Average Daily Balance Requirement

The FCA has received comments from System institutions voicing concern with the requirement to calculate the total and core surplus ratios using month-end balances. Institutions have commented that using month-end balances results in significant variability in the ratios due simply to seasonal lending trends. They recommended that

the total and core surplus ratios be calculated using the same basis as permanent capital. The permanent capital ratio is computed using average daily balances for the most recent 3-month period.

The FCA proposes to amend § 615.5330(c) to require computation of the total surplus, core surplus, and risk-adjusted asset base using average daily balances for the most recent 3 months in the same way they are used for the calculation of permanent capital. The FCA is proposing this change for the following reasons:

1. The change will smooth out seasonal fluctuations in month-end balances that may result in undue volatility of the total and core surplus ratios;

2. The requirement is not a burden on System institutions because they already have the information-processing capability to compute the 3-month average of daily balances for various balance sheet accounts;

3. The change achieves consistency in the calculation methodology with regulatory permanent capital requirements; and

4. The 3-month average daily balance methodology is less susceptible to adjustment by delaying or advancing the recognition of various business activities compared to the month-end balances methodology.

Existing § 615.5205 requires institutions to maintain at all times a permanent capital ratio of at least the minimum required level. The FCA proposes to amend § 615.5330(a) and (b) to extend this requirement to the total and core surplus ratios as well. In each case the ratios would be calculated as described above. This change would also ensure ongoing compliance with the requirements of § 615.5240(c), which allows an institution's board of directors to delegate borrower stock retirements to management under certain conditions, including the maintenance of capital ratios at or above the minimum requirements.

The FCA is not proposing to change the requirement in § 615.5335(b) to compute the net collateral ratio using month-end balances at a specific point in time. However, the FCA proposes that banks expressly be required to achieve and maintain at all times a net collateral ratio at or above the regulatory minimum. In addition, banks must have the capability to calculate the net collateral ratio at any time using the balances outstanding at the computation date. Having this capability is important to banks to support daily issuances of debt securities to meet their funding needs.

B. Treatment of Intra-System Investments and Other Adjustments

1. Reciprocal Investments

The FCA proposes to clarify § 615.5210(e)(1) of the capital adequacy regulations that addresses the treatment of reciprocal holdings between two System institutions. The current regulation has not consistently been interpreted by institutions to require that the cross-elimination of reciprocal holdings be made before making the other required adjustments relating to intra-System investments. The FCA intended that elimination of investments between two System institutions be applied on a net basis after adjusting for reciprocal holdings (*see* 53 FR 16956, May 12, 1988). As an example, if institution A has a $100 equity investment in institution B, and institution B has a $25 equity investment in institution A, the net investment after offsetting reciprocal holdings is $75 (*i.e.*, $100—$25). The regulatory offsetting requirement results in the elimination of $25 from the capital and assets of both institutions. This ''netting effect'' ensures that double-counted cross-capital investments made by System institutions are eliminated prior to other adjustments required by the capital regulations. In the example above, the remaining $75 net investment is then the amount used when applying the other intra-System investment-related provisions of the regulations to the computation of permanent capital, total surplus, and core surplus. The FCA believes this clarification is necessary to avoid possible misinterpretations that may result in incorrect deductions.

2. Computation of Total and Core Surplus

The FCA proposes to clarify the treatment of intra-System equity investments and other deductions for the computation of total and core surplus. For the calculation of total surplus, the FCA proposes to amend § 615.5301(i)(7) to more clearly require the same deductions made in the computation of permanent capital. When calculating total surplus, System institutions should eliminate intra-System investments and other deductions from total surplus in a manner consistent with the elimination of such investments when an institution calculates its permanent capital. These eliminations are necessary to ensure that the investing institution does not include certain intra-System investments when computing total surplus and makes similar deductions such as elimination of certain tax-deferred assets. The FCA views most intra-System investments as a commitment of capital between related entities. From a regulatory capital adequacy perspective, elimination of most intra-System investments by the investing institution appropriately reflects that the capital commitment is in the related issuing institution.[5]

The FCA also proposes to eliminate § 615.5330(a)(2) and (a)(3) because these paragraphs are no longer necessary. As previously discussed, the FCA is proposing to amend § 615.5301(i)(7) to require the same deductions to be made in computing total surplus as are required for the calculation of permanent capital. With this revision to § 615.5301(i)(7), the existing requirements of § 615.5330 (a)(2) and (a)(3) are redundant.

With respect to core surplus, some institutions have interpreted the existing regulation as not requiring the elimination of an investment in another System institution (except for associations' investments in their affiliated banks), as is required in the calculation of other regulatory capital measurements. The FCA believes that the elimination of most intra-System investments from core surplus is also appropriate. For this reason, the FCA is proposing to amend § 615.5301(b)(4) to require the elimination of most intra-System investments from the computation of the core surplus of both the investing and the issuing institutions. However, investments to capitalize loan participations would not be eliminated from the investing institution's core surplus. The FCA views investments between System institutions resulting from loan participations as a pass-through of member-purchased or allocated equity. Because the issuing institution does not count such equities as core surplus, the FCA believes that elimination of such pass-through investments from the investing institution's core surplus would be unnecessary. The FCA invites comment on this approach and the alternative approach of eliminating intra-System investments relating to loan participations from the core surplus of the investing institution.

For the core surplus computation, existing § 615.5301(b)(3) requires institutions to make the deductions set forth in § 615.5210(e)(6) and (e)(7) for investments in the Leasing Corporation and for goodwill. The Agency intended for other relevant adjustments required for permanent capital to be made in the

[5] Only the issuing institution may include such equities in its total surplus, and only to the extent such equities qualify pursuant to § 615.5301(i).

core surplus ratio as well. Therefore, the FCA proposes to amend the core surplus computation also to require adjustments for loss-sharing agreements and for deferred-tax assets.

3. Investments in Service Corporations

Existing § 615.5210(e)(6) requires an institution to deduct its investment in the FCL from total capital for purposes of computing its permanent capital. The FCA proposes to require institutions to deduct their investments in all other service corporations as well. This change would be in conformity with the FCA's view that the capital is committed to support risks at the service corporation level and would clarify that such capital would be available to meet any capital requirements imposed by the Agency on service corporations. The required deductions would also be made in the investing institution's core and total surplus computations.

C. Counting Farm Credit System Financial Assistance Corporation (FAC) Obligations as a Liability on an Institution's Balance Sheet

Section 615.5210(a) of the existing regulations provides that no FAC obligations shall be included in the balance sheets of any Farm Credit institution. The FCA proposes to restrict this treatment to only those FAC obligations that were issued to pay capital preservation and loss-sharing agreements.

System institutions are obligated under the Act to: (1) Repay Treasury-paid interest from direct assistance and general Systemwide FAC debt; (2) pay interest on direct assistance FAC obligations; and (3) pay principal and interest on capital preservation-related FAC debt. Section 6.9(e)(3)(E) of the Act provides that certain obligations of the FAC issued in connection with the capital preservation and loss-sharing agreements not be included in the obligations of any institution for reporting purposes. In 1988, when the FCA determined that this exception to GAAP should also be included in the capital regulations, it made the exception broader than the statute by applying it to all FAC obligations. Since the relevant provision of the Act refers only to the obligations of the FAC that were issued in connection with the repayment of capital preservation agreements, the FCA proposes to conform the language of the regulation to the statute.

D. Changes in Risk-Weighting Categories and Credit Conversion Factors for Calculating Risk-Adjusted Assets

The FCA proposes modifications to the risk-weighting categories for on-and off-balance-sheet assets in § 615.5210(f). The purposes of the modifications are to provide a more accurate weighting of assets relative to their risk and to incorporate recent changes to the Basle Accord,[6] as well as to provide consistency with the requirements of the other Federal banking agencies. The following changes are proposed:

1. Elimination of the 10-Percent Category

The FCA proposes to eliminate this risk-weight category as set forth in existing § 615.5210(f)(2)(ii). The assets in this category would be reassigned to other categories that more accurately reflect their credit risks, consistent with the risk-weighting treatment by the other Federal banking agencies. Securities issued by the U.S. Government or its agencies and portions of loans and other assets guaranteed by the full faith and credit of the U.S. Government or its agencies would be risk-weighted at 0 percent in § 615.5210(f)(2)(i). Cash items in the process of collection and portions of loans and other assets collateralized by securities of the U.S. Government or its agencies would be risk-weighted at 20 percent in new § 615.5210(f)(2)(ii). These changes would make the FCA's risk-weighting of these items consistent with that of the other financial regulators.

2. Risk-Weighting of Assets That Are Conditionally Guaranteed by the U.S. Government or Its Agencies at 20 Percent

Such assets are not specifically distinguished from unconditional guarantees in the FCA's current weighting scheme. However, the FCA is now proposing to differentiate between unconditional guarantees, which have a risk-weighting of 0 percent, and conditional guarantees, which are proposed to be risk-weighted at 20 percent, in new § 615.5210(f)(2)(ii)(B). Government-sponsored agency securities not backed by the full faith and credit of the U.S. Government would also be risk-weighted at 20 percent. In developing the proposed revisions, the FCA believes that such guarantees pose some risk and that 20 percent is the appropriate risk-weighting for the general credit risk and would conform to the treatment of such assets by the other financial regulators.

3. Modification of the Definitions of Two Items Involving Foreign Banks

Claims on foreign banks with an original maturity of 1 year or less are now risk-weighted at 20 percent, and those with an original maturity of more than 1 year are weighted at 100 percent. For risk-weighting purposes, the FCA proposes to make a distinction between the Organization for Economic Cooperation and Development (OECD)-based group of countries[7] and non-OECD-based countries in the same fashion as the other Federal banking agencies. Generally, membership in the OECD indicates that such member countries have lower levels of sovereign risk and, therefore, justifies a lower risk-weighting. The FCA proposes to risk-weight all claims on OECD banks at 20 percent in new § 615.5210(f)(2)(ii), regardless of maturity, and claims on non-OECD banks at 20 percent when the remaining maturity is 1 year or less. Claims on non-OECD banks with a remaining maturity of more than 1 year would be risk-weighted at 100 percent in new § 615.5210(f)(2)(iv). The FCA has added a definition of OECD in § 615.5201(j).

4. Risk-Weighting of Unused Commitments With an Original Maturity of Less Than 14 Months at 0 Percent

Unused commitments with an original maturity of more than 1 year now have a 50-percent credit conversion factor, which means that 50 percent of the face amount of such commitments must be added to the appropriate risk-weighting category, usually 100 percent. Many loans made by Farm Credit institutions are on annual renewal cycles. It is the established practice of

[6] Agreed to by the Committee on Banking Regulations and Supervisory Practices, under the auspices of the Bank for International Settlements in Basle, Switzerland (Basle Committee). Under this agreement the other Federal banking agencies that are signatories to the Accord are bound to consider such direction and revise their regulations accordingly. The FCA, for consistency purposes, also chooses to consider and revise its regulations, as appropriate to the System.

[7] OECD means countries that are full members of the Organization for Economic Cooperation and Development. As of August 1997, the OECD includes the following countries: Australia, Austria, Belgium, Canada, the Czech Replublic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Japan, South Korea, Luxembourg, Mexico, the Netherlands, New Zealand, Norway, Poland, Portugal, Spain, Sweden, Switzerland, Turkey, the United Kingdom, and the United States. Saudia Arabia has concluded special lending arrangements with the International Monetary Fund (IMF) associated with the IMF's General Arrangements to Borrow which, together with the aforementioned countries that are full members of the OECD, comprise the OECD-based group of countries.

many of these institutions that, in order to have loan commitments in place at the beginning of each annual cycle, the credit review and subsequent commitment are typically done 30 to 60 days prior to the end of the current loan commitment. Consequently, such ''advance'' commitments have been classified in the 50-percent credit conversion category. The FCA has concluded that these annual advance commitments do not differ substantially from commitments made with an original maturity of 1 year or less.

The FCA proposes in § 615.5210(f)(3)(ii) to classify in the 0-percent credit conversion category those binding commitments with an original maturity of 14 months or less. This change is intended to recognize that the timing of the issuance of binding commitments is appropriately related to the annual operating cycle of borrowers, so that institutions can continue current practices and be able to risk-weight such loans at 0 percent.

5. Revision of Credit Conversion Factors for Derivative Transactions

In September 1995, the other Federal banking agencies adopted final amendments to their risk-based capital regulations relating to derivative transactions based on the Basle Committee's recommendations. *See* 60 FR 46171, September 5, 1995.[8] Their final rule amended the matrix of conversion factors used to calculate potential future exposure and permitted institutions to recognize the effects of qualifying bilateral netting arrangements in the calculation of potential future exposure. The matrix of conversion factors used to calculate potential future exposure was expanded to take into account innovations in the derivatives markets. Specifically, the matrix was modified by adding higher conversion factors to address long-dated transactions (*e.g.*, contracts with remaining maturities over 5 years), and new conversion factors were added to cover certain types of derivative transactions not previously covered.

In conformity with the other Federal banking agencies, the FCA proposes to amend § 615.5210(f)(3)(iii) to permit institutions to net positive and negative mark-to-market values of derivatives contracts entered into with a single counterparty subject to a qualifying, legally enforceable bilateral netting arrangement for purposes of determining credit equivalent amounts. The FCA is adding a definition of ''qualifying bilateral netting contract'' in new § 615.5201(m). The FCA also proposes to adopt the formula used by the other Federal banking agencies for current and potential future exposure for contracts subject to qualifying bilateral netting agreements. The formula is expressed as $A_{net} = (0.4 \times A_{gross}) + 0.6(NGR \times A_{gross})$ where:

a. A_{net} is the adjusted potential future credit exposure;

b. A_{gross} is the sum of potential future credit exposures determined by multiplying the notional principal amount by the appropriate credit conversion factor; and

c. NGR is the ratio of the net current credit exposure divided by the gross current credit exposure determined as the sum of only the positive mark-to-markets for each derivative contract with the single counterparty.

In addition, the FCA proposes to amend the conversion factor matrix as set forth in the following table:

CONVERSION FACTOR MATRIX

[In percent]

Remaining maturity	Interest rate	Exchange rate	Commodity
1 year or less	0.0	1.0	10.0
Over 1 to 5 years	0.5	5.0	12.0
Over 5 years	1.5	7.5	15.0

The FCA would further require that, for any derivative contracts that do not fall into one of the categories above, the potential future credit exposure must be determined using the commodity conversion factors.

VII. Other Issues

A. Retirement of Other Allocated Equities Included in Core Surplus

The FCA's recently adopted capital adequacy regulations permit associations to include, subject to limitations, both nonqualified and qualified allocated equities in core surplus. The regulations permit the inclusion of nonqualified allocated equities that are not distributed according to an established plan or practice. The regulations further allow associations to include in core surplus other allocated equities (*i.e.*, qualified or nonqualified notices of allocation) with an original maturity of at least 5 years and not scheduled for revolvement during the next 3 years. The preamble to the Capital Adequacy and Customer Eligibility final rule (62 FR 4429, January 30, 1997) discussed disallowing a series or class of allocated equities from treatment as core surplus in the event of partial retirements. The preamble also described exceptions to the disallowance requirement if an institution retires allocated equities in the event of loan default or the death of the equityholder. However, in the regulation the disallowance for partial retirements, as well as the exceptions, appeared to apply only to the nonqualified allocated equities without a plan or practice of revolvement.

Several System associations have asked the FCA whether the other allocated equities includible in core surplus would also be disallowed in the event of partial retirement. The remaining equities would be disallowed, and the related exceptions would apply in such circumstances. The FCA is now proposing to amend § 615.5310(b)(2)(ii) in order to ensure consistent treatment of all allocated equities counted as core surplus in the event of partial retirements.

[8] In July 1994 the Basle Accord was revised to permit institutions to net positive and negative mark-to-market values of rate contracts entered into with a single counterparty subject to a qualifying, legally enforceable, bilateral netting agreement. Based upon this revision to the Basle Accord, the other Federal banking agencies revised their risk-based capital regulations accordingly.

B. Ensuring Two Nominees for Each Bank Director's Position and Ensuring Representation on the Board of all Types of Agriculture in the District

Section 4.15 of the Act requires associations to ''endeavor to assure'' that, when directors are elected, there are at least two nominees for each position and that representation of all types of agriculture practiced in the territory is achieved to the extent possible. The statute goes on to say that ''[r]egulations of the Farm Credit Administration governing the election of bank directors shall similarly assure a choice of two nominees for each elective office to be filled and that the bank board represent as nearly as possible all types of agriculture in the district.'' The FCA interprets the provision to require banks to make a good faith effort to locate at least two nominees and to try to assure representation on the board that is reflective of the bank's territory. The Agency proposes to add a new paragraph (5) to § 615.5230(b) to require documentation of that effort. In the event that a bank is unable to find at least two nominees for each position, the bank would be required to keep written documentation of its efforts to do so. The bank would also be required to keep a record of the type of agriculture engaged in by each director on its board.

In addition, the FCA proposes to add § 611.350 to add a reference in the subpart on director elections to the cooperative principles set forth in § 615.5230 that apply to such elections.

C. Statement of SFAS No. 130, Reporting Comprehensive Income

The FASB recently issued SFAS No. 130, Reporting Comprehensive Income (Statement). This Statement sets forth standards for reporting and display of comprehensive income in a full set of financial statements. For fiscal years beginning after December 15, 1997, this Statement will require financial statements to display a balance representing the accumulation of other comprehensive income. This new balance will be displayed separately from retained earnings and additional paid-in capital in the equity (capital) section of the statement of financial position. For the most part, the FCA believes that the Statement represents only a change in display of existing financial transactions and, therefore, does not introduce any new issues that have an effect on the Agency's current regulatory capital standards. The FCA believes that current standards in the capital regulations already address the transactional items that comprise the newly separated component of equity. Accordingly, the FCA has determined that there are no compelling reasons to change the capital standards to take into account the changes in the display of financial transactions resulting from this Statement. The Agency invites any parties with an interest in this issue to submit comments.

E. Conforming Amendments

The FCA proposes to amend § 620.5 to require institutions to disclose information on their surplus and collateral ratios in the annual report to shareholders. Conforming, nonsubstantive changes are also proposed in § 615.5201(h) to replace ''allocation'' with ''allotment'' and in §§ 615.5210(b) and 615.5260(a)(3)(ii) to remove obsolete language.

List of Subjects

12 CFR Part 611

Agriculture, Banks, banking, Rural areas.

12 CFR Part 615

Accounting, Agriculture, Banks, banking, Government securities, Investments, Rural areas.

12 CFR Part 620

Accounting, Agriculture, Banks, banking, Reporting and recordkeeping requirements, Rural areas.

12 CFR Part 627

Agriculture, Banks, banking, Claims, Rural areas.

For the reasons stated in the preamble, parts 611, 615, 620, and 627 of chapter VI, title 12 of the Code of Federal Regulations are proposed to be amended to read as follows:

PART 611—ORGANIZATION

1. The authority citation for part 611 continues to read as follows:

Authority: Secs. 1.3, 1.13, 2.0, 2.10, 3.0, 3.21, 4.12, 4.15, 4.21, 5.9, 5.10, 5.17, 7.0—7.13, 8.5(e) of the Farm Credit Act (12 U.S.C. 2011, 2021, 2071, 2091, 2121, 2142, 2183, 2203, 2209, 2243, 2244, 2252, 2279a—2279f–1, 2279aa–5(e)); secs. 411 and 412 of Pub. L. 100–233, 101 Stat. 1568, 1638; secs. 409 and 414 of Pub. L. 100–399, 102 Stat. 989, 1003, and 1004.

Subpart C—Election of Directors

2. Section 611.350 is added to read as follows:

§ 611.350 Application of cooperative principles to the election of directors.

In the election of directors, each System institution shall comply with the applicable cooperative principles set forth in § 615.5230 of this chapter.

Subpart I—Service Organizations

3. Section 611.1135 is amended by revising paragraphs (b)(4) and (c) to read as follows:

§ 611.1135 Incorporation of service organizations.

* * * * *

(b) * * *

(4) The proposed bylaws, which shall include the provisions required by § 615.5220(b) of this chapter.

* * * * *

(c) *Approval.* The Farm Credit Administration may condition the issuance of a charter, including imposing minimum capital requirements, as it deems appropriate. For good cause, the Farm Credit Administration may deny the application. Upon approval by the Farm Credit Administration of a completed application, which shall be kept on file at the Farm Credit Administration, the Agency shall issue a charter for the service corporation which shall thereupon become a corporate body and a Federal instrumentality.

* * * * *

PART 615—FUNDING AND FISCAL AFFAIRS, LOAN POLICIES AND OPERATIONS, AND FUNDING OPERATIONS

4. The authority citation for part 615 continues to read as follows:

Authority: Secs. 1.5, 1.7, 1.10, 1.11, 1.12, 2.2, 2.3, 2.4, 2.5, 2.12, 3.1, 3.7, 3.11, 3.25, 4.3, 4.3A, 4.9, 4.14B, 4.25, 5.9, 5.17, 6.20, 6.26, 8.0, 8.3, 8.4, 8.6, 8.7, 8.8, 8.10, 8.12 of the Farm Credit Act (12 U.S.C. 2013, 2015, 2018, 2019, 2020, 2073, 2074, 2075, 2076, 2093, 2122, 2128, 2132, 2146, 2154, 2154a, 2160, 2202b, 2211, 2243, 2252, 2278b, 2278b–6, 2279aa, 2279aa–3, 2279aa–4, 2279aa–6, 2279aa–7, 2279aa–8, 2279aa–10, 2279aa–12); sec. 301(a) of Pub. L. 100–233, 101 Stat. 1568, 1608.

Subpart E—Investment Management

5. Section 615.5135 is amended by revising the introductory paragraph to read as follows:

§ 615.5135 Management of interest rate risk.

The board of directors of each Farm Credit Bank, bank for cooperatives, and agricultural credit bank shall develop and implement an interest rate risk management program as set forth in subpart G of this part. The board of directors shall adopt an interest rate risk management section of an asset/liability management policy which establishes

interest rate risk exposure limits as well as the criteria to determine compliance with these limits. At a minimum, the interest rate risk management section shall establish policies and procedures for the bank to:

* * * * *

6. A new subpart G is added to read as follows:

Subpart G—Risk Assessment and Management

Sec.

Subpart G—Risk Assessment and Management

§ 615.5180 Interest rate risk management by banks—general.

The board of directors of each Farm Credit Bank, bank for cooperatives, and agricultural credit bank shall develop and implement an interest rate risk management program tailored to the needs of the institution and consistent with the requirements set forth in § 615.5135 of this part. The program shall establish a risk management process that effectively identifies, measures, monitors, and controls interest rate risk.

§ 615.5181 Bank interest rate risk management program.

(a) The board of directors of each Farm Credit Bank, bank for cooperatives, and agricultural credit bank is responsible for providing effective oversight to the interest rate risk management program and must be knowledgeable of the nature and level of interest rate risk taken by the institution.

(b) Senior management is responsible for ensuring that interest rate risk is properly managed on both a long-range and a day-to-day basis.

§ 615.5182 Interest rate risk management by associations and other Farm Credit System institutions other than banks.

Associations and other Farm Credit System institutions other than banks, excluding the Federal Agricultural Mortgage Corporation, with interest rate risk that could lead to significant declines in net income or in the market value of capital shall comply with the requirements of §§ 615.5180 and 615.5181. The interest rate risk program shall be commensurate with the level of direct interest rate exposure under the management control of the institution.

Subpart H—Capital Adequacy

7. Section 615.5201 is amended by removing the word ''allocation'' and adding in its place, the word ''allotment'' in paragraph (h); redesignating paragraphs (d), (e), (f), (g), (h), (i), (j), (k), (l), (m), and (n) as paragraphs (e), (f), (g), (h), (i), (k), (l), (n), (o), (p), and (q) respectively; and adding new paragraphs (d), (j), and (m) to read as follows:

§ 615.5201 Definitions.

* * * * *

(d) *Deferred-tax assets that are dependent on future income or future events* means:

(1) Deferred-tax assets arising from deductible temporary differences dependent upon future income that exceed the amount of taxes previously paid that could be recovered through loss carrybacks if existing temporary differences (both deductible and taxable and regardless of where the related tax deferred effects are recorded on the institution's balance sheet) fully reverse;

(2) Deferred-tax assets dependent upon future income arising from operating loss and tax carryforwards; or

(3) Deferred-tax assets arising from temporary differences that could be recovered if existing temporary differences that are dependent upon other future events (both deductible and taxable and regardless of where the related tax deferred effects are recorded on the institution's balance sheet) fully reverse.

* * * * *

(j) *OECD* means the group of countries that are full members of the Organization for Economic Cooperation and Development, regardless of entry date, as well as countries that have concluded special lending arrangements with the International Monetary Fund's General Arrangement to Borrow, excluding any country that has rescheduled its external sovereign debt within the previous 5 years.

* * * * *

(m) *Qualifying bilateral netting contract* means a bilateral netting contract that meets at least the following conditions:

(1) The contract is in writing;

(2) The contract is not subject to a walkaway clause;

(3) The contract creates a single obligation either to pay or to receive the net amount of the sum of positive and negative mark-to-market values for all derivative contracts subject to the qualifying bilateral netting contract;

(4) The institution receives a legal opinion that represents, to a high degree of certainty, that in the event of legal challenge the relevant court and administrative authorities would find the institution's exposure to be the net amount;

(5) The institution establishes a procedure to monitor relevant law and to ensure that the contracts continue to satisfy the requirements of this section; and

(6) The institution maintains in its files adequate documentation to support the netting of a derivatives contract.

* * * * *

6. Section 615.5210 is amended by adding new paragraph (e)(11); removing paragraph (f)(2)(v); and revising paragraphs (a), (b), (e) introductory text, (e)(1), (e)(6), (f)(2)(i), (f)(2)(ii), heading of (f)(2)(iii), (f)(2)(iv), (f)(3) introductory text, (f)(3)(ii)(A), and (f)(3)(iii) to read as follows:

§ 615.5210 Computation of the permanent capital ratio.

(a) The institution's permanent capital ratio shall be determined on the basis of the financial statements of the institution prepared in accordance with generally accepted accounting principles except that the obligations of the Farm Credit System Financial Assistance Corporation issued to repay banks in connection with the capital preservation and loss-sharing agreements described in section 6.9(e)(1) of the Act shall not be considered obligations of any institution subject to this regulation prior to their maturity.

(b) The institution's asset base and permanent capital shall be computed using average daily balances for the most recent 3 months.

* * * * *

(e) For the purpose of computing the institution's permanent capital ratio, the following adjustments shall be made prior to assigning assets to risk-weight categories and computing the ratio:

(1) Where two Farm Credit System institutions have stock investments in each other, such reciprocal holdings shall be eliminated to the extent of the offset. If the investments are equal in amount, each institution shall deduct from its assets and its total capital an amount equal to the investment. If the investments are not equal in amount, each institution shall deduct from its total capital and its assets an amount equal to the smaller investment. The elimination of reciprocal holdings required by this paragraph shall be made prior to making the other adjustments required by this subsection.

* * * * *

(6) The double-counting of capital between a service corporation chartered

under section 4.25 of the Act and its owner institutions shall be eliminated by deducting an amount equal to their investment in the service corporation from their total capital.

* * * * *

(11) For purposes of calculating capital ratios under this part, deferred-tax assets are subject to the conditions, limitations, and restrictions described in this paragraph.

(i) Each institution shall deduct an amount of deferred-tax assets, net of any valuation allowance, from its assets and its total capital that is equal to the greater of:

(A) The amount of deferred-tax assets that are dependent on future income or future events in excess of the amount that is reasonably expected to be realized within 1 year of the most recent calendar quarter-end date, based on financial projections for that year, or

(B) The amount of deferred-tax assets that are dependent on future income or future events in excess of ten (10) percent of the amount of core surplus that exists before the deduction of any deferred-tax assets.

(ii) For purposes of this calculation:

(A) The amount of deferred-tax assets that can be realized from taxes paid in prior carryback years and from the reversal of existing taxable temporary differences shall not be deducted from assets and from equity capital.

(B) All existing temporary differences should be assumed to fully reverse at the calculation date.

(C) Projected future taxable income should not include net operating loss carryforwards to be used within 1 year or the amount of existing temporary differences expected to reverse within that year.

(D) Financial projections shall include the estimated effect of tax planning strategies that are expected to be implemented to minimize tax liabilities and realize tax benefits. Financial projections for the current fiscal year (adjusted for any significant changes that have occurred or are expected to occur) may be used when applying the capital limit at an interim date within the fiscal year.

(E) The deferred tax effects of any unrealized holding gains and losses on available-for-sale debt securities may be excluded from the determination of the amount of deferred-tax assets that are dependent upon future taxable income and the calculation of the maximum allowable amount of such assets. If these deferred-tax effects are excluded, this treatment must be followed consistently over time.

(f) * * *

(2) * * *

(i) *Category 1: 0 Percent.*

(A) Cash on hand and demand balances held in domestic or foreign banks.

(B) Claims on Federal Reserve Banks.

(C) Goodwill.

(D) Direct claims on and portions of claims unconditionally guaranteed by the United States Treasury, United States Government agencies, or central governments in other OECD countries. A United States Government agency is defined as an instrumentality of the United States Government whose obligations are fully and explicitly guaranteed as to the timely repayment of principal and interest by the full faith and credit of the United States Government.

(ii) *Category 2: 20 Percent.*

(A) Portions of loans and other assets collateralized by United States Government-sponsored agency securities. A United States Government-sponsored agency is defined as an agency originally chartered or established to serve public purposes specified by the United States Congress but whose obligations are not explicitly guaranteed by the full faith and credit of the United States Government.

(B) Portions of loans and other assets conditionally guaranteed by the United States Government or its agencies.

(C) Portions of loans and other assets collateralized by securities issued or guaranteed (fully or partially) by the United States Government or its agencies (but only to the extent guaranteed).

(D) Claims on domestic banks (exclusive of demand balances).

(E) Claims on, or guarantees by, OECD banks.

(F) Claims on non-OECD banks with a remaining maturity of 1 year or less.

(G) Investments in State and local government obligations backed by the ''full faith and credit of State or local government.'' Other claims (including loans) and portions of claims guaranteed by the full faith and credit of a State government (but only to the extent guaranteed).

(H) Claims on official multinational lending institutions or regional development institutions in which the United States Government is a shareholder or contributor.

(I) Loans and other obligations of and investments in Farm Credit institutions.

(J) Local currency claims on foreign central governments to the extent that the Farm Credit institution has local liabilities in that country.

(K) Cash items in the process of collection.

(iii) *Category 3: 50 Percent.*

* * * * *

(iv) *Category 4: 100 Percent.*

(A) All other claims on private obligors.

(B) Claims on non-OECD banks with a remaining maturity greater than 1 year.

(C) All other assets not specified above, including but not limited to, leases, fixed assets, and receivables.

(D) All non-local currency claims on foreign central governments, as well as local currency claims on foreign central governments that are not included in Category 2(J).

* * * * *

(3) * * *

(i) * * *

(ii) Credit conversion factors shall be applied to off-balance-sheet items as follows:

(A) *0 Percent.*

(*1*) Unused commitments with an original maturity of 14 months or less; or

(*2*) Unused commitments with an original maturity of greater than 14 months if:

* * * * *

(iii) *Credit equivalents of interest rate contracts and foreign exchange contracts.*

(A) Credit equivalents of interest rate contracts and foreign exchange contracts (except single currency floating/floating interest rate swaps) shall be determined by adding the replacement cost (mark-to-market value, if positive) to the potential future credit exposure, determined by multiplying the notional principal amount by the following credit conversion factors as appropriate.

CONVERSION FACTOR MATRIX

[In Percent]

Remaining maturity	Interest rate	Exchange rate	Commodity
One year or less	0.0	1.0	10.0

CONVERSION FACTOR MATRIX—Continued

[In Percent]

Remaining maturity	Interest rate	Exchange rate	Commodity
Over 1 to 5 years	0.5	5.0	12.0
Over 5 years	1.5	7.5	15.0

(B) For any derivative contract that does not fall within one of the categories in the above table, the potential future credit exposure shall be calculated using the commodity conversion factors. The net current exposure for multiple derivative contracts with a single counterparty and subject to a qualifying bilateral netting contract shall be the net sum of all positive and negative mark-to-market values for each derivative contract. The positive sum of the net current exposure shall be added to the adjusted potential future credit exposure for the same multiple contracts with a single counterparty. The adjusted potential future credit exposure shall be computed as $A_{net}=(0.4 \times A_{gross})+0.6\ (NGR \times A_{gross})$ where:

(*1*) A_{net} is the adjusted potential future credit exposure;

(*2*) A_{gross} is the sum of potential future credit exposures determined by multiplying the notional principal amount by the appropriate credit conversion factor; and

(*3*) NGR is the ratio of the net current credit exposure divided by the gross current credit exposure determined as the sum of only the positive mark-to-markets for each derivative contract with the single counterparty.

* * * * *

Subpart I—Issuance of Equities

9. Section 615.5220 is amended by redesignating paragraphs (a) through (h) as new paragraphs (1) through (8) consecutively; by adding the paragraph designation ''(a)'' to the introductory text; and by adding a new paragraph (b) to read as follows:

§ 615.5220 Capitalization bylaws.

* * * * *

(b) The board of directors of each service corporation (including the Leasing Corporation) shall adopt capitalization bylaws, subject to the approval of its voting shareholders, that set forth the requirements of paragraphs (a)(1), (a)(2), and (a)(3) of this section to the extent applicable. Such bylaws shall also set forth the manner in which equities will be retired and the manner in which earnings will be distributed.

10. Section 615.5230 is amended by adding a new paragraph (b)(5) to read as follows:

§ 615.5230 Implementation of cooperative principles.

* * * * *

(b) * * *

(5) Each bank shall endeavor to assure that there is a choice of at least two nominees for each elective office to be filled and that the board represent as nearly as possible all types of agriculture in the district. If fewer than two nominees for each position are named, the efforts of the bank to locate two willing nominees shall be documented in the books and records of the bank. The bank shall also maintain a list of the type or types of agriculture engaged in by each director on its board.

Subpart J—Retirement of Equities

11. Section 615.5260 is amended by revising paragraph (a)(3)(ii) to read as follows:

§ 615.5260 Retirement of eligible borrower stock.

(a) * * *

(3) * * *

(ii) In the case of participation certificates and other equities, face or equivalent value; or

* * * * *

Subpart K—Surplus and Collateral Requirements

12. Section 615.5301 is amended by revising paragraphs (a), (b)(2)(ii), (b)(3), (b)(4), and (i)(7) to read as follows:

§ 615.5301 Definitions.

* * * * *

(a) The terms *deferred-tax assets that are dependent on future income or future events, institution, permanent capital,* and *total capital* shall have the meanings set forth in § 615.5201.

* * * * *

(b) * * *

(2) * * *

(ii) The allocated equities, if subject to revolvement, are not scheduled for revolvement during the next 3 years, provided that, in the event that such allocated equities included in core surplus are retired, other than as required by section 4.14B of the Act, or in connection with a loan default or the death of an equityholder whose loan has been repaid (to the extent provided for in the institution's capital adequacy plan), any remaining such allocated equities that were allocated in the same year will be excluded from core surplus.

(3) The deductions required to be made by an institution in the computation of its permanent capital pursuant to § 615.5210(e)(6), (7), (9), and (11) shall also be made in the computation of its core surplus. Deductions required by § 615.5210(e)(1) shall also be made to the extent that they do not duplicate deductions calculated pursuant to this section and required by § 615.5330(b)(2).

(4) Equities issued by System institutions and held by other System institutions shall not be included in the core surplus of the issuing institution or of the holder, unless approved pursuant to paragraph (b)(1)(iv) of this section, except that equities held in connection with a loan participation shall not be excluded by the holder. This paragraph shall not apply to investments by an association in its affiliated bank, which are governed by § 615.5301(b)(1)(i).

* * * * *

(i) * * *

(7) Any deductions made by an institution in the computation of its permanent capital pursuant to § 615.5210(e) shall also be made in the computation of its total surplus.

13. Section 615.5330 is revised to read as follows:

§ 615.5330 Minimum surplus ratios.

(a) *Total surplus.*

(1) Each institution shall achieve and at all times maintain a ratio of at least 7 percent of total surplus to the risk-adjusted asset base.

(2) The risk-adjusted asset base is the total dollar amount of the institution's assets adjusted in accordance with § 615.5301(i)(7) and weighted on the basis of risk in accordance with § 615.5210(f).

(b) *Core surplus.*

(1) Each institution shall achieve and at all times maintain a ratio of core surplus to the risk-adjusted asset base of at least 3.5 percent, of which no more than 2 percentage points may consist of

allocated equities otherwise includible pursuant to § 615.5301(b).

(2) Each association shall compute its core surplus ratio by deducting an amount equal to the net investment in the bank from its core surplus.

(3) The risk-adjusted asset base is the total dollar amount of the institution's assets adjusted in accordance with §§ 615.5301(b)(3) and 615.5330(b)(2), and weighted on the basis of risk in accordance with § 615.5210(f).

(c) An institution shall compute its risk-adjusted asset base, total surplus, and core surplus ratios using average daily balances for the most recent 3 months.

14. Section 615.5335 is revised to read as follows:

§ 615.5335 Bank net collateral ratio.

(a) Each bank shall achieve and at all times maintain a net collateral ratio of at least 103 percent.

(b) At a minimum, a bank shall compute its net collateral ratio as of the end of each month. A bank shall have the capability to compute its net collateral ratio a day after the close of a business day using the daily balances outstanding for assets and liabilities for that date.

Subpart L—Establishment of Minimum Capital Ratios for an Individual Institution

15. Section 615.5350 is amended by adding a new paragraph (b)(7) to read as follows:

§ 615.5350 General—Applicability.

* * * * *

(b) * * *

(7) An institution with significant exposures to declines in net income or in the market value of its capital due to a change in interest rates and/or the exercising of embedded or explicit options.

Subpart M—Issuance of a Capital Directive

16. Section 615.5355 is amended by revising paragraph (a)(4) to read as follows:

§ 615.5355 Purpose and scope.

(a) * * *

(4) Take other action, such as reduction of assets or the rate of growth of assets, restrictions on the payment of dividends or patronage, or restrictions on the retirement of stock, to achieve the applicable capital ratios, or reduce levels of interest rate and other risk exposures, or strengthen management expertise, or improve management information and measurement systems; or

* * * * *

PART 620—DISCLOSURE TO SHAREHOLDERS

17. The authority citation for part 620 continues to read as follows:

Authority: Secs. 5.17, 5.19, 8.11 of the Farm Credit Act (12 U.S.C. 2252, 2254, 2279aa–11); sec. 424 of Pub. L. 100–233, 101 Stat. 1568, 1656.

Subpart A—General

§ 620.1 [Amended]

18. Section 620.1 is amended by removing the reference ''§ 615.5201(j)'' and adding in its place, the reference ''§ 615.5201(l)'' in paragraph (j).

Subpart B—Annual Report to Shareholders

§ 620.5 [Amended]

19. Section 620.5 is amended by removing the word ''permanent'' from paragraphs (d)(2), (g)(4)(v), and (g)(4)(vi); by revising paragraph (f)(3); and by adding paragraph (f)(4) to read as follows:

§ 620.5 Contents of the annual report to shareholders.

* * * * * *

(f) * * *

(3) *For all banks* (on a bank-only basis):

(i) Permanent capital ratio.

(ii) Total surplus ratio.

(iii) Core surplus ratio.

(iv) Net collateral ratio.

(4) *For all associations*:

(i) Permanent capital ratio.

(ii) Total surplus ratio.

(iii) Core surplus ratio.

* * * * *

PART 627—TITLE V CONSERVATORS AND RECEIVERS

20. The authority citation for part 627 continues to read as follows:

Authority: Secs. 4.2, 5.9, 5.10, 5.17, 5.51, 5.58 of the Farm Credit Act (12 U.S.C. 2183, 2243, 2244, 2252, 2277a, 2277a–7).

Subpart A—General

21. Section 627.2710 is amended by revising paragraphs (b)(1) and (b)(3) to read as follows:

§ 627.2710 Grounds for appointment of conservators and receivers.

* * * * *

(b) * * *

(1) The institution is insolvent, in that the assets of the institution are less that its obligations to creditors and others, including its members. For purposes of determining insolvency, ''obligations to members'' shall not include stock or allocated equities held by current or former borrowers.

* * * * *

(3) The institution is in an unsafe and unsound condition to transact business, including having insufficient capital or otherwise. For purposes of this regulation, ''unsafe or unsound condition'' shall include, but shall not be limited to, the following conditions:

(i) For banks, a net collateral ratio of 102 percent.

(ii) For associations, collateral insufficient to meet the requirements of the association's general financing agreement with its affiliated bank.

(iii) For all institutions, permanent capital of less than one-half the minimum required level for the institution.

(iv) For all institutions, a relevant total surplus ratio of less than 2 percent.

(v) For associations, stock impairment.

* * * * *

Dated: September 17, 1997.

Floyd Fithian,

Secretary, Farm Credit Administration Board.

[FR Doc. 97–25107 Filed 9–22–97; 8:45 am]

BILLING CODE 6705–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 97–NM–126–AD]

RIN 2120–AA64

Airworthiness Directives; Saab Model SAAB 2000 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes the adoption of a new airworthiness directive (AD) that is applicable to certain Saab Model SAAB 2000 series airplanes. This proposal would require inspection of the two-way check valve on the engine fire extinguishing system for discrepancies, and corrective action, if necessary. This proposal is prompted by issuance of mandatory continued airworthiness information by a foreign civil airworthiness authority. The actions specified by the proposed AD are intended to prevent discrepancies of the check valve, which could result in improper functioning of the engine fire extinguishing system.

DATES: Comments must be received by October 21, 1997.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–103, Attention: Rules Docket No. 97–NM–126–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056. Comments may be inspected at this location between 9:00 a.m. and 3:00 p.m., Monday through Friday, except Federal holidays.

The service information referenced in the proposed rule may be obtained from Saab Aircraft AB, S–581.88, Linköping, Sweden. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington.

FOR FURTHER INFORMATION CONTACT: Ruth Harder, Aerospace Engineer, Standardization Branch, ANM–113, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 227–1721; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications shall identify the rules docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this notice 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 comments submitted in response to this notice must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket Number 97–NM–126–AD.'' The postcard will be date stamped and returned to the commenter.

Availability of NPRMs

Any person may obtain a copy of this NPRM by submitting a request to the FAA, Transport Airplane Directorate, ANM–103, Attention: Rules Docket No. 97–NM–126–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056.

Discussion

The Luftfartsverket (LFV), which is the airworthiness authority for Sweden, advises that, during production testing, the ball in the two-way check valve on the engine fire extinguishing system of certain Saab Model SAAB 2000 series airplanes was stuck due to excessive pressure from the test equipment. Discrepancies of the check valve of the fire extinguishing system, if not corrected, could result in improper functioning of the engine fire extinguishing system.

Explanation of Relevant Service Information

Saab has issued Service Bulletin 2000–26–010, dated July 5, 1996, which describes procedures for inspection of the two-way check valve on the engine fire extinguishing system for discrepancies, and corrective action, if necessary. The LFV classified this service bulletin as mandatory and issued Swedish Airworthiness Directive SAD No. 1–099, dated July 8, 1996, in order to assure the continued airworthiness of these airplanes in Sweden.

FAA's Conclusions

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

Explanation of Requirements of Proposed Rule

Since an unsafe condition has been identified that is likely to exist or develop on other airplanes of the same type design registered in the United States, the proposed AD would require accomplishment of the actions specified in the service bulletin described previously.

Cost Impact

The FAA estimates that 3 airplanes of U.S. registry would be affected by this proposed AD, that it would take approximately 4 work hours per airplane to accomplish the proposed actions, and that the average labor rate is $60 per work hour. Based on these figures, the cost impact of the proposed AD on U.S. operators is estimated to be $720, or $240 per airplane.

The cost impact figure discussed above is based on assumptions that no operator has yet accomplished any of the proposed requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted.

Regulatory Impact

The regulations proposed herein would not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this proposal would not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

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

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

Saab Aircraft AB: Docket 97–NM–126–AD.

Applicability: Model SAAB 2000 series airplanes having serial numbers –002 through –043 inclusive, certificated in any category.

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

Compliance: Required as indicated, unless accomplished previously.

To prevent discrepancies of the check valve, which could result in improper functioning of the engine fire extinguishing system, accomplish the following:

(a) Within 2 months after the effective date of this AD, perform an inspection of the two-way check valve on the engine fire extinguishing system for discrepancies, in accordance with Saab Service Bulletin 2000–26–010, dated July 5, 1996. If any discrepancy is found, prior to further flight, install a new two-way check valve in accordance with the service bulletin.

(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, standardization Branch, ANM–113, FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Standardization Branch, ANM–113.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Standardization Branch, ANM–113.

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

Issued in Renton, Washington, on September 17, 1997.

James V. Devany,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 97–25168 Filed 9–22–97; 8:45 am]

BILLING CODE 4910–13–U

SOCIAL SECURITY ADMINISTRATION

20 CFR Part 404

RIN 0960–AE42

Federal Old-Age, Survivors, and Disability Insurance; Determining Disability and Blindness; Revision to Medical-Vocational Guidelines

AGENCY: Social Security Administration.

ACTION: Proposed rules.

SUMMARY: We propose to clarify § 201.00(h) of the medical-vocational guidelines in appendix 2 of subpart P of regulations part 404. This section provides guidance for evaluating disability in individuals under age 50 who have a severe impairment(s) that does not meet or equal in severity the criteria of any listed impairment in appendix 1 of subpart P, but who have a residual functional capacity for no more than the full range of sedentary work and cannot do any past relevant work. The proposed revisions are intended only to clarify the current rules; they are not intended to change any policies.

DATES: To be sure your comments are considered, we must receive them no later than November 24, 1997.

ADDRESSES: Comments should be submitted in writing to the Commissioner of Social Security, P.O. Box 1585, Baltimore, MD 21235, sent by telefax to (410) 966–2830, sent by e-mail to ''regulations@ssa.gov,'' or delivered to the Division of Regulations and Rulings, Social Security Administration, 3–B–1 Operations Building, 6401 Security Boulevard, Baltimore, MD 21235, between 8:00 a.m. and 4:30 p.m. on regular business days. Comments may be inspected during these same hours by making arrangements with the contact person shown below.

FOR FURTHER INFORMATION CONTACT: Robert Augustine, Legal Assistant, Division of Regulations and Rulings, Social Security Administration, 6401 Security Boulevard, Baltimore, MD 21235, (410) 966–5121 for information about these rules. For information on eligibility or claiming benefits, call our national toll-free number, 1–800–772–1213.

SUPPLEMENTARY INFORMATION: The Social Security Act (the Act) provides in title II for the payment of disability benefits to workers insured under the Act. Title II also provides, under certain circumstances, child's insurance benefits for persons who become disabled before age 22 and widow's and widower's insurance benefits based on disability for widows, widowers, and surviving divorced spouses of insured individuals. In addition, the Act provides in title XVI for supplemental security income (SSI) payments to persons who are disabled and have limited income and resources.

For adults under both the title II and title XVI programs and for persons claiming child's insurance benefits based on disability under title II, ''disability'' is defined in the Act as the ''inability to engage in any substantial gainful activity by reason of any medically determinable physical or mental impairment which can be expected to result in death or which has lasted or can be expected to last for a continuous period of not less than 12 months.'' Sections 223(d) and 1614(a) of the Act also state that the individual ''shall be determined to be under a disability only if his physical or mental impairment or impairments are of such severity that he is not only unable to do his previous work but cannot, considering his age, education, and work experience, engage in any other kind of substantial gainful work which exists in the national economy, regardless of whether such work exists in the immediate area in which he lives, or whether a specific job vacancy exists for him, or whether he would be hired if he applied for work.''

To implement the process for determining whether an individual is disabled based upon this statutory definition, our longstanding regulations at §§ 404.1520 and 416.920 provide for a five-step sequential evaluation process as follows:

1. Is the claimant engaging in substantial gainful activity? If the claimant is working and the work is substantial gainful activity, we find that he or she is not disabled. Otherwise, we proceed to step 2 of the sequence.

2. Does the claimant have an impairment or combination of impairments which is severe? If the claimant does not have an impairment or combination of impairments which is severe, we find that he or she is not disabled. If the claimant has an impairment or combination of impairments which is severe, we proceed to step 3 of the sequence.

3. Does the claimant's severe impairment(s) meet or equal in severity the criteria of a listed impairment in appendix 1 of subpart P of part 404? If so, and the duration requirement is met, we find that he or she is disabled. If not, we proceed to step 4 of the sequence.

4. Does the claimant's severe impairment(s) prevent him or her from doing his or her past relevant work, considering his or her residual functional capacity? If not, we find that he or she is not disabled. If so, we proceed to step 5 of the sequence.

5. Does the claimant's impairment(s) prevent him or her from performing other work that exists in the national economy, considering his or her residual functional capacity, age, education, and work experience? If so, and the duration requirement is met, we find that he or she is disabled. If not, we find that he or she is not disabled.

As discussed in § 404.1569, at step 5 of the sequential evaluation process we provide medical-vocational rules in appendix 2 of subpart P of part 404. (By reference, § 416.969 of the regulations provides that appendix 2 is also applicable to adults claiming SSI payments based on disability.) These rules take administrative notice of the existence of numerous unskilled occupations at exertional levels defined in the regulations, such as ''sedentary,'' ''light,'' and ''medium,'' and, based upon a consideration of the individual's residual functional capacity, age, education, and work experience, either direct decisions or are used as a framework for making decisions at step 5.

The revisions we are proposing would clarify one paragraph in appendix 2, section 201.00(h), which discusses the evaluation of the claims of ''younger individuals'' (i.e., individuals who have not attained age 50) who have a residual functional capacity limited to the full range of sedentary work administratively noticed by the rules in table No. 1 of appendix 2 or who can perform some sedentary work but not the full range of such work.

Summary of Proposed Changes

We propose to clarify section 201.00(h) in appendix 2. This section discusses the evaluation of disability claims of ''younger individuals'' (i.e., individuals who have not attained age 50) who have a severe impairment(s) that does not meet or equal in severity the criteria of any listing but who have a residual functional capacity for no more than the full range of sedentary work. The proposed changes are intended only as clarifications. None of these proposed revisions is intended to change the meaning of the current rules.

Specifically, we propose to clarify the second sentence of section 201.00(h) in appendix 2, which states that for workers who are age 45–49, ''age is a less positive factor'' than for individuals who are younger than age 45. The proposed clarification would more clearly explain that, for workers who are age 45–49, age is a ''less advantageous factor for making an adjustment to other work than for those who are age 18–44.'' This is consistent with our longstanding policy that, at step 5 of the sequential evaluation process, the issue is whether the individual is able to make an adjustment to work other than any past relevant work considering his or her residual functional capacity, age, education, and work experience, and would only clarify what we mean by the phrase ''a less positive factor.''

In the third sentence, clause (3), we propose to change the phrases ''relevant past work'' and ''vocationally relevant past work,'' to ''past relevant work'' to clarify our intended meaning and for consistency in our terminology. We also propose to clarify clause (4) of the same sentence to better explain that the term ''illiterate'' means that the individual is illiterate in English. This will make clearer our original intent that the fourth clause describes individuals who are either 1) unable to communicate in English (and, by definition, illiterate in English) or 2) able to speak and understand English but illiterate in English.

We propose to revise the fourth sentence to be consistent with the foregoing proposed revisions. We propose to revise the statement ''age is a more positive factor for those who are under age 45'' to ''for those who are under age 45, age is a more advantageous factor for making an adjustment to other work'' to correspond to the proposed changes in the second sentence. Likewise, we propose to clarify that ''illiterate'' means illiterate in English as in the proposed changes to the third sentence.

We propose to add four new sentences after the fifth sentence to explain the impact of a maximum sustained work capacity for no more than the full range of sedentary work on an individual's ability to do other work. The intent is twofold: 1) to make clear that such capacity reflects a very serious functional limitation and must be appropriately documented by the evidence in the record; and 2) to make clear that a finding that an individual is limited to less than the full range of sedentary work does not necessarily equate with a finding of disability. If an individual is unable to perform past relevant work and has a maximum sustained work capacity for less than the full range of sedentary work (and the medical-vocational rules would not direct a decision of disabled if the individual was limited to the full range of sedentary work), consideration must still be given to whether there is other work in the national economy that the individual is able to do.

We also propose to add language to the fifth sentence to make it explicitly clear that a finding of ''disabled'' is also not precluded for individuals age 45–49 who do not meet all of the criteria of a specific rule and who do not have the ability to perform a full range of sedentary work.

We also propose to delete without replacement the two case examples from section 201.00(h). The intent of these examples is merely to reinforce a concept already reflected in this paragraph; i.e., that, using the rules as a framework for decisionmaking, a conclusion of ''disabled'' may be, but is not necessarily, warranted for individuals under age 45 who do not satisfy all of the criteria of a specific rule and who do not have the residual functional capacity to do a full range of sedentary work.

We propose to delete the examples because they are no longer needed and our adjudicative experience has shown that they can be unclear. For example, we have received questions about whether example 2 applies only to cases involving mental impairments or whether it could apply to other types of impairments. Although our intent has always been that the case examples are applicable to all types of impairments, their removal will avoid possible confusion and help ensure consistency in decisionmaking.

In addition, over the past several years we have been following a practice of not using case examples in our disability regulations unless they serve some necessary purpose, such as when the rules present a new and complex policy where we believe that an example or examples would be helpful for understanding the new policy. We believe the examples in the current rules no longer serve such a purpose and that it is better to delete them. Again, this is not intended as a change in policy.

Finally, we are also making minor editorial changes, to improve the consistency of terminology in appendix 2.

Regulatory Procedures

Executive Order 12866

We have consulted with the Office of Management and Budget (OMB) and determined that these proposed rules meet the criteria for a significant regulatory action under Executive Order 12866. Thus, they were subject to OMB review. There are no program or administrative costs or savings associated with these proposed rules. Therefore, no assessment of costs and benefits is required.

Regulatory Flexibility Act

We certify that these proposed regulations will not have a significant economic impact on a substantial number of small entities because they affect only individuals. Therefore, a regulatory flexibility analysis, as provided in Public Law 96–354, the Regulatory Flexibility Act, is not required.

Paperwork Reduction Act

These proposed regulations will impose no new reporting or recordkeeping requirements requiring OMB clearance.

(Catalog of Federal Domestic Assistance Program Nos. 96.001, Social Security Disability Insurance; 96.006, Supplemental Security Income)

List of Subjects in 20 CFR Part 404

Administrative practice and procedure, Blind, Death benefits, Disability benefits, Old-Age, Survivors and Disability Insurance, Reporting and recordkeeping requirements, Social Security.

Dated: June 16, 1997.

John J. Callahan,

Acting Commissioner of Social Security.

For the reasons set out in the preamble, part 404, subpart P, Chapter III of Title 20, Code of Federal Regulations, is proposed to be amended as set forth below.

PART 404—FEDERAL OLD-AGE, SURVIVORS AND DISABILITY INSURANCE (1950–)

1. The authority citation for subpart P continues to read as follows:

Authority: Secs. 202, 205(a), (b), and (d)–(h), 216(i), 221(a) and (i), 222(c), 223, 225, and 702(a)(5) of the Social Security Act (42 U.S.C. 402, 405(a), (b), and (d)–(h), 416(i), 421(a) and (i), 422(c), 423, 425, and 902(a)(5)); sec. 211(b), Pub. L. 104–193, 110 Stat. 2105, 2189.

2. Section 201.00(h), appendix 2, subpart P, is revised to read as follows:

APPENDIX 2 TO SUBPART P—MEDICAL-VOCATIONAL GUIDELINES

* * * * *

201.00 Maximum sustained work capability limited to sedentary work as a result of severe medically determinable impairment(s).

* * * * *

(h) The term *younger individual* is used to denote an individual age 18 through 49. For individuals who are age 45–49, age is a less advantageous factor for making an adjustment to other work than for those who are age 18–44. Accordingly, for such individuals who: (1) are restricted to sedentary work, (2) are unskilled or have no transferable skills, (3) have no past relevant work or who can no longer perform past relevant work, and (4) are unable to communicate in English, or are able to speak and understand English but are illiterate in English, a finding of ''disabled'' is warranted. For individuals who are under age 45, age is a more advantageous factor for making an adjustment to other work and is usually not a significant factor in limiting such individuals' ability to make an adjustment to other work, even an adjustment to unskilled sedentary work, and even when the individuals are unable to communicate in English or are illiterate in English. A finding of ''disabled'' is not precluded for those individuals under age 45 (and those age 45–49 for whom rule 201.17 does not direct a decision of disabled) who do not meet all of the criteria of a specific rule and who do not have the ability to perform a full range of sedentary work. However, the inability to perform the full range of sedentary work does not necessarily equate with a finding of ''disabled.'' In deciding whether an individual who is limited to a partial range of sedentary work is able to make an adjustment to work other than any past relevant work, the adjudicator is required to make an individualized determination considering the individual's remaining occupational base, age, education, and work experience. Further, ''sedentary work'' represents a significantly restricted range of work, and individuals with a maximum sustained work capability limited to sedentary work have very serious functional limitations. Therefore, a finding that an individual is limited to less than the full range of sedentary work will be based on a careful consideration of the evidence of an individual's medical impairment(s) and the limitations and restrictions attributable thereto. Such evidence must support the finding that an individual's residual functional capacity is limited to less than the full range of sedentary work.

* * * * *

[FR Doc. 97–25125 Filed 9–22–97; 8:45 am]

BILLING CODE 4190–29–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 200

[Docket No. 96N–0048]

Sterility Requirements for Inhalation Solution Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its regulations to require that all inhalation solutions for nebulization be sterile. Inhalation solutions for nebulization, as the term is used in this document, refers to inhalation solutions administered as a fine aqueous mist created by an atomizer or nebulizer. Currently, approximately half of these products are manufactured to be sterile. Based on reports of adverse drug experiences from contaminated nonsterile inhalation solutions for nebulization and recalls of these products, FDA is taking this action to ensure the safety and effectiveness of these solutions.

DATES: Written comments by December 22, 1997. Submit written comments on the information collection requirements by October 23, 1997. FDA proposes that any final rule that may issue based on this proposal become effective March 23, 1998.

ADDRESSES: Submit written comments on this proposed rule to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Submit written comments on the information collection requirements to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Carol E. Drew, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION:

I. Background

Inhalation solutions for nebulization are used to treat a variety of breathing disorders. Currently, approximately half of the marketed products are manufactured to be sterile. Those products not manufactured to be sterile are often manufactured under assigned

microbial count limits. For the reasons stated below, FDA has determined that current manufacturing methods and purported safeguards against contamination, including the microbial limits test, have not prevented dangerous microbial contamination of nonsterile inhalation solutions for nebulization. A sterility requirement is needed to prevent such microbial contamination.

Contaminated inhalation solutions for nebulization are likely to cause lung infections because the drug product is introduced directly into the lungs in a manner which at least partially bypasses the patient's natural defense mechanisms. Many patients using inhalation solution products for nebulization have chronic obstructive airway disease or cystic fibrosis, or are immunocompromised. Microbial contamination of these products may result in serious health consequences due to opportunistic pathogens entering the lungs or to the possible inactivation of the drug product by these microorganisms. Based on the significant health risk to users, FDA is proposing to require that all aqueous-based inhalation solutions for nebulization be manufactured as sterile.

Contamination problems with several different inhalation solution products and numerous adverse experience reports have led to FDA's determination that a sterility requirement is necessary for these products. In January 1994, a marketed albuterol sulfate inhalation solution product was found to be contaminated with a bacterium best identified as belonging to the *Pseudomonas fluorescens/putida* group. The manufacturer voluntarily recalled the product (class I recall to the consumer level) and issued a press release regarding the recall.

In June 1992, a manufacturer recalled its metaproterenol sulfate inhalation solution for nebulization when the product was found to contain excessive microbial growth identified as *P. gladioli/cepacia*. A press release was also issued concerning this recall.

In 1987, an FDA investigator identified at least two potential human fungal pathogens (*Aspergillus glaucus* and *Chrysosporium*) in another albuterol sulfate inhalation solution for nebulization before market distribution.

A sterility requirement for all inhalation solutions for nebulization will provide the necessary assurance that these solutions will not be contaminated. The sterility requirement is necessary for several reasons.

First, there is a high risk of contamination of inhalation solutions. Microbial contaminants identified in two of the recalls were *Pseudomonas* species (spp.), which are ubiquitous and are commonly found in pharmaceutical water supplies and nonsterile manufacturing environments.

Second, most species of *Pseudomonas* associated with the contamination of inhalation solutions have the potential to be human pathogens. Of special concern is the fact that many of the patients using these products have compromised pulmonary defense mechanisms and are therefore at a particularly high risk of serious infection.

Third, adherence to current good manufacturing practice (CGMP) regulations without appropriate sterilization procedures does not provide an adequate level of assurance that inhalation solutions for nebulization will not be contaminated. Even if antimicrobial preservatives are used in a product, they may not be effective because many bacteria, including *Pseudomonas* spp., may develop resistance to these preservatives. The albuterol sulfate product recalled in January 1994, for example, contained benzalkonium chloride, an antimicrobial preservative, yet the preservative failed to prevent microbial contamination of the product. Resistance to preservatives is not species specific; strains of many species are resistant. Furthermore, use of a single preservative in the manufacture of a nonsterile inhalation solution for an extended period may actually select for preservative-resistant strains of *Pseudomonas* spp. or other bacteria.

Also, the microbial limits test does not ensure against contamination. End-product microbial limits tests performed prior to distribution may not be capable of detecting sufficiently low levels of contamination; a product that initially passes the microbial limits test may support the growth of contaminating organisms, which could later grow to unacceptable levels.

FDA has therefore determined that all inhalation solutions for nebulization should be manufactured as sterile products. Any failure to comply with the sterility requirement would result in a finding that the drug product is adulterated under section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 351(a)(2)(B)), and misbranded under section 502(j) of the act (21 U.S.C. 352(j)). Failure to comply with the sterility requirement would also result in the agency's refusal to approve a new or abbreviated application for the product, pursuant to section 505(d)(1), (d)(2), (d)(3), and (j)(3)(A) of the act (21 U.S.C. 355(d)(1), (d)(2), (d)(3), and (j)(3)(A)).

II. Description of the Proposed Regulation

This proposal would amend the regulations governing requirements for specific classes of drugs to include new § 200.51 for inhalation solutions for nebulization. Proposed § 200.51(a) would require that all prescription and over-the-counter (OTC) inhalation solutions for nebulization be sterile. Manufacturers may use any appropriate process to achieve sterility of their inhalation solution products, as long as the method is in compliance with current FDA regulations. In the **Federal Register** of October 11, 1991 (56 FR 51354), FDA proposed to require that manufacturers use a terminal sterilization process when preparing a sterile drug unless the process adversely affects the drug product. The October 11, 1991, proposed rule would require that manufacturers include in their applications a written justification for not using terminal sterilization if such process is not appropriate. Should that proposed rule become final, manufacturers of inhalation solution products would be subject to its requirements.

Under this proposal, all manufacturers of nonsterile inhalation solutions for nebulization have until 1 year after the date of publication of the final rule to comply with the sterility requirement. This effective date reflects the time that FDA believes applicants may need to establish the sterility of their products.

Persons holding an approved application for a nonsterile inhalation solution product should submit to FDA a supplemental application establishing the sterility of the product. If they intend to sterilize their product by terminal sterilization or make other changes listed under § 314.70(b)(2) (21 CFR 314.70(b)(2)), they must obtain FDA approval of a supplement under that section before making the change(s). If they intend to manufacture the sterile product by aseptic processing, to retain the same container and closure system, and make no changes other than those listed under § 314.70(c)(1), they may submit a supplemental application under that section.

The following information should be included in the supplements: Complete qualification data for the aseptic process, executed batch record for a production batch of the product using the approved formulation, in-process and release control data, updated release specifications that include sterility, 3 months' accelerated stability data, updated stability protocol to

include either sterility or container/closure integrity testing initially and at expiry, and commitment to place the first three commercial batches into the routine stability program and submit the data in annual reports.

Proposed § 200.51(b) states that manufacturers must comply with the recordkeeping requirements of 21 CFR 211.113(b) of FDA's CGMP regulations. This section requires that manufacturers establish and follow appropriate written procedures designed to prevent microbiological contamination of drug products purporting to be sterile. Such procedures must include validation of any sterilization process.

III. Proposed Effective Date

The agency's proposal would prohibit all manufacturers of nonsterile inhalation solution products for nebulization, including those products currently approved, from introducing or delivering for introduction into interstate commerce any such products that are nonsterile from 1 year after the date of publication in the **Federal Register** of any final rule based on this proposal.

Holders of approved new drug applications (NDA's) and abbreviated new drug applications (ANDA's) must submit data to FDA to establish sterility of these products within 1 year after the publication in the **Federal Register** of any final rule based on this proposal. This effective date reflects the time that FDA believes applicants may need to establish the sterility of their products.

Any NDA or ANDA for a nonsterile inhalation solution for nebulization under review by FDA on or after the date of publication of the final rule but before the effective date of the final rule may be approved if the application is otherwise approvable and the applicant agrees to establish the sterility of its product by the effective date. On or after the effective date of the final rule, FDA will refuse to approve an NDA or ANDA for a nonsterile inhalation solution for nebulization if the applicant has not established the sterility of the product.

IV. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(8) 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.

V. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866, under the Regulatory Flexibility Act (5 U.S.C. 601–612), and under the Unfunded Mandates Reform Act (Pub. L. 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Unless an agency certifies that a rule will not have a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires an analysis of regulatory options that would minimize any significant impact of a rule on small entities. The Unfunded Mandates Reform Act requires that agencies prepare an assessment of anticipated costs and benefits before proposing any rule that may result in an annual expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 (adjusted annually for inflation).

The expected aggregate costs of this proposed rule, and the anticipated impact of the rule on small entities, are described in the analysis below. The agency believes that the proposed rule is consistent with the regulatory philosophy and principles identified in the Executive Order. This rule is not a significant regulatory action as defined by the Executive Order, does not impose any mandates on State, local, or tribal governments, and is not a significant regulatory action under the Unfunded Mandates Reform Act. Based on the following analysis, FDA estimates that this rule will have significant adverse effects on about four to five small firms that currently manufacture nonsterile inhalation solutions for nebulization. However, since the exact number of firms manufacturing nonsterile inhalation solutions is not certain, FDA invites comments from firms that believe they would be affected by the proposed rule. The statutory basis for FDA's authority to issue the rule is presented previously in this preamble. FDA has not identified any other Federal rules that duplicate, overlap, or conflict with the proposed rule.

As described in section I of this document, the objective of the proposed rule is to ensure that all inhalation solutions for nebulization are manufactured as sterile products and are thus safe and effective for use. Nonsterile inhalation solutions have been found to result in serious health consequences to users. By ensuring sterilization, the proposed rule is expected to yield benefits from the elimination of extended patient suffering and hospitalization associated with contaminated nonsterile inhalation solution products. In addition, the industry would benefit by avoiding liability claims from persons harmed due to the contamination of nonsterile inhalation solution products.

A. Affected Entities

This proposed rule would affect only those manufacturers of inhalation solutions for nebulization that do not already manufacture the products to be sterile. Based on its compliance data base, FDA believes that all innovator prescription products are currently manufactured as sterile. Of the approximately 28 generic and OTC firms that manufacture inhalation solutions, FDA estimates that up to five firms may still use nonsterile manufacturing processes and will be affected by this proposed rule. (The remainder are believed to have either implemented sterile processes themselves or to have contracted out the manufacturing of their inhalation products to firms that use a sterile process.) All of these affected firms may be small entities as defined by the Regulatory Flexibility Act.

B. Compliance Requirements and Costs

To comply with this rule, the affected firms must implement a sterile process for manufacturing their inhalation products, either by converting their in-house manufacturing operations to ensure that the products are sterile, or by arranging to have these products manufactured under contract by a firm that can do so under sterile conditions. In addition, affected firms must: (1) Develop appropriate written procedures designed to prevent contamination of the products, including validation of the new inhalation solution processes; and (2) submit to FDA a supplemental application establishing the sterility of the product.

Firms choosing to convert in-house manufacturing operations would need to set up an in-plant sterilization process by constructing a clean room especially designated for the inhalation solution product. FDA finds that the cost of building a new clean room may amount to almost $600 per square foot. The size of pharmaceutical clean rooms is reported to vary widely, from 200 to 2,500 square feet. Thus, the estimated cost of installing a clean room in a manufacturing facility may range from $120,000 to $1,500,000 per firm. Since affected firms would presumably contract out their manufacturing process if to do so would lower their costs of

complying with this proposed rule, this figure is an upper bound.

Firms would also need to validate the new inhalation solution processes at an estimated cost of $75,000 to $100,000 per product. The firms that would need to complete these validation procedures produce an average of approximately two inhalation products each, leading to validation costs per firm of approximately $150,000 to $200,000. Each firm would also be required to incur the paperwork costs associated with filing a supplemental application for each product with FDA.

Thus, overall costs for implementing and validating a sterile manufacturing process for inhalation products would total approximately $270,000 to $1,700,000 per affected firm. Assuming that five firms are affected, the costs of complying with this rule would range from approximately $1,350,000 to $8,500,000. Amortized over 10 years at a 7 percent interest rate implies total annualized costs of $192,000 to $1,210,000. In addition, affected firms will incur any costs associated with preparing and submitting a supplemental application.

Affected firms will need to acquire some new professional skills, since this rule deals with a new manufacturing process that will require technicians to have a knowledge of sterility procedures, specifically the asceptic sterilization process. Any other skills necessary for implementation of this proposal (e.g., skills associated with preparing the application) should already exist within the firms and should not need to be newly acquired.

C. Minimizing the Impact on Small Entities

FDA initially considered requiring conversion to sterile procedures to take place within 6 months of the publication of a final rule, due to the health hazards associated with existing unsterilized inhalation products. However, the agency is concerned that this short timeframe would give affected firms an inadequate opportunity to implement aseptic manufacturing processes and might force some small firms to temporarily suspend production. Thus, this proposed rule allows 1 year for the manufacturing conversion to take place.

Exempting small businesses from the rule is not a feasible alternative, since all of the firms believed to still be using nonsterile manufacturing for these products are small. A size-based exemption would thus defeat the purpose of this proposed rule.

VI. The Paperwork Reduction Act of 1995

This proposed rule contains information collection provisions that are subject to review by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). Therefore, in accordance with 44 U.S.C. 3506(c)(2)(B) and 5 CFR part 1320, FDA is providing the following title, description, and respondent description of the information collection contained in this proposal, along with an estimate of the resulting annual collection of information burden. This estimate includes the time needed for reviewing instructions, gathering and maintaining the data needed, and completing and reviewing the collection of information.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Sterility requirements for inhalation solution products.

Description: The proposal would require that all inhalation solution products, including those currently approved, be manufactured as sterile. Applicants will have 1 year after the date of publication of the final rule to comply with the sterility requirement.

Description of Respondents: Drug manufacturers.

As indicated in the accompanying chart, the proposed one-time reporting requirement would require that most firms commit about 160 additional hours per product to report the sterility information in a supplement to a drug application (20 hours for certain manufacturers of sterile products) and about 2 additional hours per product to document sterility of their inhalation products.

The expected burden under the proposed rule is as follows:

ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
314.97	5	1	5	160	800[1]
314.70	2	1	2	20	40[2]

[1] Reporting burden for manufacturers of nonsterile products.
[2] Reporting burden for manufacturers of sterile products.

ESTIMATED ANNUAL RECORDKEEPING BURDEN

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
211.113(b)	7	1	1	2	14

There are no capital costs or operating and maintenance costs associated with this proposed rule.

The agency has submitted a copy of this proposed rule to OMB for its review and approval of this information collection. Interested persons are requested to send comments regarding this collection of information to the Office of Information and Regulatory Affairs (address above).

VII. Request for Comments

Interested persons may, on or before December 22, 1997, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 200

Drugs, Prescription drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 200 be amended as follows:

PART 200—GENERAL

1. The authority citation for 21 CFR part 200 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 505, 506, 507, 508, 515, 701, 704, 705 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 357, 358, 360e, 371, 374, 375).

2. New § 200.51 is added to subpart C to read as follows:

§ 200.51 Sterility requirements for inhalation solution drug products.

(a) All inhalation solutions for nebulization shall be manufactured to be sterile.

(b) Manufacturers shall also comply with the recordkeeping requirements in § 211.113(b) of this chapter.

Dated: September 12, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–25130 Filed 9–22–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 600 and 606

[Docket No. 97N–0242]

Biological Products; Reporting of Errors and Accidents in Manufacturing

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend the regulations requiring licensed manufacturers of biological products to report errors and accidents in manufacturing that may affect the safety, purity, or potency of a product. FDA is proposing to establish a reporting period for licensed biological products; require that error and accident reports be submitted for products that have been made available for distribution, and amend the current good manufacturing practice (CGMP) regulations for blood and blood components to require error and accident reporting by unlicensed registered blood establishments and transfusion services which are currently reporting on a voluntary basis. The proposed reporting requirements are intended to expedite reporting of errors and accidents in manufacturing of biological products; provide FDA with a more accurate surveillance of the nation's blood supply, thereby enabling FDA to monitor actions taken in response to the errors and accidents detected for all establishments involved in manufacturing of blood and blood components; and facilitate a rapid response where the public health may be at risk.

DATES: Submit written comments on the proposed rule by December 22, 1997. Submit written comments on the information collection provisions by October 23, 1997. The agency is proposing that any final rule that may issue based upon this proposed rule become effective March 23, 1998.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Submit written comments on the information collection provisions to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., Washington, DC 20503. ATTN: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Paula S. McKeever, Center for Biologics Evaluation and Research (HFM–630), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–594–3074.

SUPPLEMENTARY INFORMATION:

I. Introduction

Establishments that engage in the manufacture, preparation, propagation, compounding, or processing of drug and device products, including biological products, must register with the FDA under section 510 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360), unless specifically exempted by regulation.

Establishments propagating or manufacturing and preparing biological products for interstate commerce are subject to licensing under the Public Health Service Act (PHS Act) (42 U.S.C. 262(a)). These licenses are issued by FDA only upon a showing that the establishment and the product for which a license is desired meet applicable standards designed to ensure the continued safety, purity, and potency of such products prescribed in the regulations (42 U.S.C. 262(d)(1)).

Blood and blood products are regulated as drugs under section 201(g) of the act (21 U.S.C. 321(g)) and biologicals are regulated under 42 U.S.C. 262 of the PHS Act. Establishments manufacturing blood and blood components are required to register with FDA and to comply with the CGMP (parts 211 and 606 (21 CFR parts 211 and 606)). Transfusion services which do not routinely collect or process blood and blood components are exempted from registering as blood establishments (§ 607.65(f) (21 CFR 607.65(f))), but are required under 42 CFR 493.1273(a) to comply with parts 606 and 640 (21 CFR part 640) as they pertain to the performance of manufacturing activities, such as compatibility testing, storage, labeling, and recordkeeping, or any other process involving manufacturing.

A product is considered adulterated under the act when the methods used in its manufacture, processing, packing, or holding do not conform to the CGMP (section 501(a)(1) of the act (21 U.S.C. 351(a)(1))). By applying the CGMP, firms assure that the products meet the requirements for safety, have the identity and strength, and meet the quality and purity characteristics which they purport or are represented to possess (section 501(a)(2)(B) of the act). A product is also adulterated if its strength differs from, or purity or quality falls below what it is purported or represented to possess (section 501(c) of the act). A product is considered misbranded if its labeling is false or misleading in any particular (section 502(a) of the act (21 U.S.C. 352(a))) or if the product is dangerous to health when used as labeled under section 502(j) of the act. The introduction or delivery for introduction of adulterated and/or misbranded biological products into interstate commerce is prohibited under section 301(a) of the act (21 U.S.C. 331(a)). It is also a prohibited act to adulterate and/or misbrand biological products while held for sale after receipt of shipment in interstate commerce (section 301(k) of the act). These prohibited acts are punishable by prescribed penalties under the act.

Authority is given to the agency to issue regulations for the efficient enforcement of the act under section 701 of the act (21 U.S.C. 371) and to inspect all establishments responsible for manufacturing biological products (section 704 of the act (21 U.S.C. 374) and 42 U.S.C. 262).

FDA regards the proposal to amend the error and accident reporting regulations to be an essential tool in its directive to protect public health by establishing and maintaining surveillance programs that provide timely and useful information.

II. Background

Section 600.14 (21 CFR 600.14) requires that licensed manufacturers of biological products notify the Director, Office of Compliance, Center for Biologics Evaluation and Research (CBER), promptly of errors or accidents in manufacturing that may affect the safety, purity, or potency of any product. In addition, all blood establishments, whether licensed or unlicensed, are required by the CGMP to thoroughly investigate and make adequate corrections to their manufacturing processes concerning errors and accidents (§ 606.100(c)) and to maintain and make available to FDA appropriate records of such investigations and corrections (§§ 606.100(c) and 606.160(b)(7)(iii)). CBER has recommended to blood and blood component establishments that error and accident reports be submitted to CBER when the error or accident is associated with blood or blood components that have been made available for distribution, whether or not actual release or shipment has occurred. FDA believes this reporting standard is appropriate for ensuring the safety of the nations blood supply and proposes to codify it in the regulations.

In a memorandum to all registered blood establishments dated March 20, 1991, entitled ''Responsibilities of Blood Establishments Related to Errors and Accidents in the Manufacture of Blood and Blood Components,'' CBER recommended that unlicensed registered blood establishments and transfusion services voluntarily report to CBER errors and accidents that may affect product quality. The memorandum was issued, in part, because of an increase in the number of product recalls initiated by blood establishments due to errors and accidents in manufacturing which were not reflected in error and accident reports to CBER.

In May of 1995, the Office of Inspector General (OIG) of the Department of Health and Human Services issued a report on the ''Reporting Process for Blood Establishments to Notify the Food and Drug Administration of Errors and Accidents Affecting Blood.'' The report states that the error and accident reporting process enables the agency to evaluate and monitor blood establishments in response to detected errors and accidents, and regularly alert field staff and blood establishments with trend analysis of the types of errors and accidents reported. However, OIG placed emphasis on two existing conditions that were impeding the success of the reporting process: (1) Error and accident reports were not being submitted in a timely manner by blood establishments and (2) there was no assurance that unlicensed establishments were submitting reports. This proposed rule is intended as a step in addressing conditions identified in the OIG report.

On July 14, 1995, FDA published a notice of availability of a ''Guideline for Quality Assurance in Blood Establishments'' (60 FR 36290) initiating a blood quality assurance program aimed at ensuring the continued safety of the nation's blood supply and maintaining the operational quality of blood establishments. The goals of the quality assurance (QA) program are to significantly decrease errors, ensure the credibility of test results, implement effective manufacturing process and system controls, and ensure continued product safety, purity, and potency. The QA program includes measures to prevent, detect, investigate, assess, and correct errors. The emphasis is on preventing errors rather than detecting them retrospectively. This guidance is intended to assist manufacturers of blood and blood components, i.e., blood banks, blood centers, transfusion services, and plasmapheresis centers, in developing QA programs that are consistent with recognized principles of QA and the CGMP. One component of this guidance focuses on the blood industry's self audit, including analysis and trending of errors and accidents that may affect the safety, purity, and potency of blood and blood components.

In the **Federal Register** of January 20, 1994 (59 FR 3043), FDA announced its plan to review significant regulations under Executive Order 12866, which requires all Federal agencies to develop a program for periodically reviewing existing significant regulations. The purpose of the review is to determine whether existing significant regulations should be modified or eliminated to reduce their regulatory burden or to make the agency's regulatory program more effective. This proposed rule is considered part of the retrospective regulation review and is intended to improve the effectiveness of FDA's regulatory program.

III. Summary of the Proposed Rule

FDA is proposing to amend the regulations that require licensed manufacturers of biological products to report errors and accidents in manufacturing and to amend the CGMP regulations for blood and blood components to require error and accident reporting by all manufacturers of blood and blood components. The proposed amendments would provide definitions for the terms ''error and accident'' and ''made available for distribution'' in part 600 (21 CFR part 600) at §§ 600.3 and 606.3; require a specific timeframe for reporting at §§ 600.14 and 606.171; require reports for products that have been made available for distribution, at §§ 600.14 and 606.171; and extend the reporting requirements to unlicensed registered blood establishments and transfusion services, at § 606.171.

A. Definitions (§§ 600.3 and 606.3)

Although the terms ''error'' and ''accident'' are generally used conjunctively, FDA has listed distinguished events affecting the purported safety, purity, and potency of the product into two categories.

''Made available for distribution'' is being defined because of the numerous release and distribution patterns unique to some biological products, and to avoid the potential for misinterpretation of the term.

1. Error and Accident

In proposed §§ 600.3(ff) and 606.3(k), the first category of events is defined as an incident that represents a deviation from the CGMP, applicable standards or established specifications that may affect the safety, purity, or potency of the biological product, or otherwise cause the biological product to be in violation of the act or the PHS Act. These events are within the realm of control of the manufacturer. Examples of this category of reportable events in the manufacturing of blood and blood components which may affect product safety, purity, or potency include, but are not limited to: (1) Arm preparation not performed or performed incorrectly; (2) components prepared more than 8 hours after collection; (3) testing for ABO/Rh or infectious diseases not performed according to the package insert; (4) incorrect crossmatch label or tag; (5) shipment of a unit with a repeatedly reactive viral marker test result; and (6) shipment of a unit prior

to completion of all testing. Examples of reportable events for biological products other than blood and blood components include, but are not limited to: (1) Route of administration labeling error; (2) shipment of a product at an inappropriate temperature; (3) mold contamination of a vaccine; (4) missing product labels; (5) incorrect package insert; and (6) missing lot number.

The second category of events to be reported is defined as an unexpected or unforeseeable event that may affect the safety, purity, or potency of the biological product, or otherwise cause the biological product to be in violation of the Act or the PHS Act. These events generally are beyond the control of the manufacturer. Examples of this category of reportable events in the manufacture of blood and blood components which may affect product safety, purity, or potency include, but are not limited to: (1) Certain post donation information; (2) a collection device defect that affects the product; (3) contaminated solutions used to prepare components; (4) an autologous unit labeled with incorrect information provided by the donor; or (5) a unit of blood or blood components which becomes broken/damaged during shipment. Examples of reportable events in the manufacture of biological products other than blood and blood components which may affect product safety, purity, or potency include, but are not limited to: (1) Sterility compromised and beyond the control of the manufacturer; (2) notification from a supplier of source materials concerning a quality problem with the product shipped for use in further manufacturing; and (3) inadvertent contamination of cell lines or replication competent viruses.

2. Made Available for Distribution

In proposed §§ 600.3(ii) and 606.3(l), ''made available for distribution'' is defined as a biological product that has been determined to meet all release criteria and to be suitable for distribution, whether or not actual distribution has occurred. Thus, error and accident reports would be submitted to FDA for products that the manufacturer or blood establishment has determined are suitable for distribution.

B. Biological Product Reporting (§ 600.14)

FDA has the responsibility for protecting the public health by reviewing the safety and efficacy of biological products. FDA believes that error and accident reports help ensure that industry identifies instances where additional corrective action is needed, such as additional training and revisions of standard operating procedures (SOP's). Error and accident reports, in conjunction with inspections and other surveillance activities, give FDA a continuing overview of the biological product industry. While FDA provides guidance to help industry determine how to comply with regulations, manufacturers of biological products have the primary responsibility for ensuring the safety, purity, and potency of their products.

Section 600.14 applies to all licensed manufacturers of biological products. It requires manufacturers to report errors and accidents in manufacturing promptly to the Director, Office of Compliance, CBER. FDA agrees with the OIG's recommendations and has identified two changes that are needed to make the error and accident reporting program more meaningful and useful, i.e., timeliness in reporting for all biological products and reporting by unlicensed blood establishments and transfusion services.

1. Reporting Period

FDA is proposing to amend § 600.14(a) to replace the term ''promptly'' with a reporting period of ''as soon as possible but not to exceed 45 calendar days.''

FDA has found that licensed manufacturers of biological products were not always submitting the error and accident reports in a consistent and timely manner after detecting the error or accident. FDA has found that by not previously specifying a definitive time period for reporting errors and accidents, a liberal interpretation of the timeframe had been taken. When reports are not submitted in a timely manner, FDA is unable to adequately evaluate the public health significance of an error or accident, or assess a firm's proposed actions including activities to prevent recurrence and to address the status of the affected products. While the agency is proposing a maximum of 45 calendar days to report errors and accidents, FDA encourages manufacturers to implement SOP's to submit these reports sooner, including prior to the implementation of any corrective actions.

2. Applicability to Unlicensed Blood Establishments

FDA is proposing the addition of § § 600.14(c) and 606.171 in order to encompass all blood establishments in the reporting of errors and accidents, not just licensed manufacturers. Registered blood establishments and transfusion services are required to comply with the CGMP and additional standards for blood and blood components, set forth in parts 606 and 640, including recordkeeping requirements relating to errors and accidents. By including error and accident reporting in part 606, the regulations would make clear that all licensed blood manufacturers, unlicensed registered blood establishments, and transfusion services would submit error and accident reports as a part of their compliance with the CGMP for blood and blood components. With full reporting, the public can be further assured that expeditious and appropriate actions are being taken to protect all of the nation's blood supply.

3. Reporting for Biological Products Made Available for Distribution

FDA proposes to require manufacturers to submit error and accident reports for biological products that have been made available for distribution. FDA believes that this reporting requirement will permit it to conduct appropriate oversight of biological products manufactured for distribution to the public (including blood and blood components) and of actions taken by manufacturers to correct errors and accidents without hindering a firm's ability to expeditiously manufacture biological products. By requiring reports of errors and accidents after the manufacturer has determined that a biological product is suitable for distribution, the firm is able to investigate and correct errors and accidents during the manufacturing process and before distribution, and FDA is able to receive information necessary to adequately review and monitor the quality and safety of products released for distribution to the public, as well a firm's investigative and corrective efforts relating to the errors and accidents. FDA is also able to review and monitor a manufacturer's procedures for correcting and preventing errors and accidents during manufacture by the requirement that manufacturers investigate all such errors and accidents (§§ 211.192, 606.100(c), and 21 CFR 820.162), and maintain complete records of the investigation and promptly make them available to FDA for review during inspections (§§ 211.198(b)(2), 606.160(b)(7)(iii), and 21 CFR 820.180).

C. Error and Accident Reporting, Blood and Blood Components (§ 606.171)

FDA is proposing the addition of a new § 606.171 *Reporting errors and accidents in manufacturing* to subpart I, Records and Reports of part 606. A primary objective of this proposed rule is to make the error and accident reporting requirement applicable to all

blood establishments, i.e., licensed manufacturers, unlicensed registered manufacturers, and transfusion services. Including error and accident reporting requirements for blood and blood component manufacturing in part 606 will assure that these reporting requirements will become part of the CGMP and apply to any establishment that participates in the collection, processing, compatibility testing, storage, or distribution of blood and blood components. In order for FDA to more effectively evaluate and monitor the blood industry, it needs reports from the full spectrum of establishments engaged in manufacturing and distribution of blood and blood components. Because unlicensed registered blood establishments and transfusion services represent a large sector of the blood processing community, FDA believes these establishments must also be required to submit reports of those errors or accidents that may affect the safety, purity, or potency of distributed blood and blood components.

1. Scope

a. Establishments. FDA is proposing in the new § 606.171 to require the reporting of errors and accidents by all blood establishments including licensed manufacturers of blood and blood components, unlicensed registered blood establishments, and transfusion services. All of these establishments are required to follow the CGMP (parts 211 and 606) in their daily operation. Although certain transfusion services are exempt from registration under § 607.65(f), all transfusion services are required under 42 CFR 493.1273(a) to comply with the CGMP if performing compatibility testing, storage, labeling, and recordkeeping, or any other process involving manufacturing.

Transfusion services may receive blood or blood components from outside sources. When transfusion services discover errors and accidents made by an outside manufacturer in relation to such products they should report these errors and accidents to the manufacturer. The manufacturer, i.e., the collecting facility, would then be responsible for notifying CBER of the errors and accidents. However, errors and accidents in manufacturing which are made by the transfusion service, such as incorrect identification of samples used in compatibility testing, or incorrect tag/crossmatch label, or storing product at the incorrect temperature should be reported to CBER directly by the transfusion service if the product was made available for distribution.

b. *Blood and blood components.* FDA is proposing in new § 606.171 that all blood establishments be required, as part of their CGMP programs, to report errors and accidents for blood and blood components made available for distribution. FDA believes this reporting mechanism will help assure the quality and safety of the nation's blood supply.

2. Format for Reporting

FDA is not at this time proposing the use of a specific report form. FDA has recommended to manufacturers of blood or blood components certain essential information that should be submitted in the report. This information should include, but not be limited to: The name of the blood establishment, registration or CLIA (Clinical Laboratories Improvement Act) numbers if applicable, the unit number(s), the type of blood product(s), the nature of the error or accident, the final disposition of the blood product, and the notification of consignee(s), if any. The information submitted by manufacturers of biological products other than blood or blood components should include, but not be limited to: The name of the manufacturer, the registration/license number of the manufacturer, the location, the type of product, the lot number(s), the nature of the error or accident, the final disposition of the product, and the notification of consignee(s), if any. The report for any biological product, including blood and blood components, should also describe contributing factors causing the error or accident and the actions or proposed corrective actions taken by the manufacturer of the biological product to prevent recurrence.

At this time, the agency is requesting that any establishment or other organization submit to the docket for review any proposed format for the reporting of errors and accidents in manufacturing to be used by industry, and any comments on the issue. FDA is also soliciting comments on development of a program for electronic submission of error and accident reports.

IV. Analysis of Economic Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866, under the Regulatory Flexibility Act (5 U.S.C. 601–612), and under the Unfunded Mandates Reform Act (Pub. L. 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; and distributive impacts and equity). The Regulatory Flexibility Act requires agencies to analyze whether a rule may have a significant impact on a substantial number of small entities and, if it does, to analyze regulatory options that would minimize that impact. The Unfunded Mandates Reform Act requires that agencies prepare an assessment of anticipated costs and benefits before proposing any rule that may result in an annual expenditure by State, local and tribal governments, in the aggregate, or by the private sector, of $100,000,000 (adjusted annually for inflation). The agency has determined that the proposed rule is not an economically significant rule as described in the Executive Order, nor a significant action as defined in the Unfunded Mandates Reform Act. Aggregate impacts of the rule, and aggregate expenditures caused by the rule, will not approach $100 million for either the public or the private sector.

Available information suggests that costs to the entities most affected by this rule, including small entities, are not expected to increase by more than approximately 0.04 percent per year, as described in the analysis in section IV.C of this document. Therefore, the agency certifies that this rule will not have a significant economic impact on a substantial number of small entities.

A. Objective and Basis of the Proposed Action

As discussed previously, FDA is considering the proposed action in response to concerns regarding the accuracy, timeliness, and completeness of error and accident reporting associated with the manufacturing of blood and other biological products. The proposed reporting requirements will expedite reporting of errors and accidents in the manufacture of such products, enhance FDA's ability to identify potential quality assurance problems, and facilitate a rapid response where public health may be at risk. This action is taken under the authority of sections 351 and 361 of the PHS Act and sections 501 and 502 of the act. FDA has reviewed related Federal rules and has not identified any rules that duplicate, overlap, or conflict with the proposed rule.

B. Small Entities Affected

This proposal affects both entities that currently submit mandatory error and accident reports and those entities currently subject only to voluntary reporting. However, the magnitude of

the impact is expected to be greater for the latter group than for the former.

Entities currently subject to mandatory error and accident reporting comprise approximately 102 licensed manufacturers of biological products (excluding blood and blood components) with 280 locations, and approximately 294 licensed manufacturers of blood and plasma with 725 locations. Entities currently subject only to voluntary reporting of such incidents include approximately 2,560 unlicensed registered blood establishments and an estimated 4,500 transfusion services inspected by the Health Care Financing Administration. FDA believes many of these entities to be small entities as defined by the Regulatory Flexibility Act. For example, most of the transfusion services are located in hospitals, and nearly three-fourths of community hospitals are either not-for-profit or have fewer than 50 beds.

C. Nature of the Impact

All of the entities described in section IV.B of this document would be affected by the proposed rule. The main cost involved in implementing the rule would be the time required to review current SOP's and to ensure that the appropriate staff understand the types of errors and accidents that must be reported and the importance of timely reporting. The new time limit for reporting is expected to increase the timeliness of report submissions, but because the reporting activity itself is unchanged by this provision the costs of this increased compliance should be limited to the preparation/revision of the SOP and staff training activities. FDA has no precise estimate of this one-time cost, but the agency expects that it should require an average of 2 hours per establishment to prepare the SOP for submitting error and accident reports, and approximately 1 hour to review and update existing SOP's at the establishments that have been reporting.

The provision of the proposed rule that extends mandatory error and accident reporting to all unlicensed registered blood establishments and transfusion services will affect nearly all such entities. At present, these entities are requested to submit such reports voluntarily, but FDA estimates that only about 1 percent are doing so, and even these entities may not be submitting all the reports that would be required under this rule. Thus, this requirement would involve a new routine activity for the great majority of unlicensed blood establishments and transfusion services.

FDA has no precise estimates of the cost of submitting error and accident reports. Anecdotal evidence suggests that such reports can take an average of 30 minutes per report to complete, and that some blood establishments may be reporting up to 8 errors and accidents per 10,000 units of blood collected annually. It is not known whether these anecdotal data are representative of current practice. Nor is it known whether these figures represent unusually high (or low) levels of quality assurance, or unusually high (or low) compliance with current reporting requirements.

Nonetheless, these figures tentatively suggest that a small entity that handles 10,000 units of blood annually and that is newly subject to the requirements presented in this proposed rule might incur new costs of 6 hours per year of staff time, 2 hours for the preparation of the SOP, and 4 hours preparing and submitting error and accident reports. At an estimated $37.98 per hour value of staff time, this would lead to an annual cost of $227.88, or roughly $.028 per unit. Based on an average cost of producing a unit of blood of $65 to $75, this requirement would increase the average entity's per unit cost of producing a unit of blood by approximately 0.04 percent. Entities with above average numbers of errors and accidents would incur higher costs. (There should not be any additional costs of investigating errors and accidents or keeping records of them, since these activities are already required under other sections in 21 CFR parts 200, 600, and 800).

There are no specific educational or technical skills required to complete and submit error accident reports. These reports are generally completed by trained and qualified employees of an establishment. Updating SOP's and training staff regarding the new requirements of this proposed rule would require a person knowledgeable and experienced in medical laboratory practice.

D. Minimizing the Impact on Small Entities

A number of different possibilities for formatting and submitting the reports are possible. FDA is soliciting comments on the following topics and reporting alternatives: (1) Examples of simple, user-friendly reporting formats that would minimize the time required to submit a report but that would contain the requisite information; (2) whether a specified, uniform format is less burdensome than permitting entities to create their own formats or select from a range of possible formats; and (3) whether electronic reporting is less burdensome than paper reporting and, if so, which electronic formats are best suited to this requirement.

V. The Paperwork Reduction Act of 1995

This proposed rule contains information collection requirements which are subject to public comment and review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The title, description, and respondent description of the information collection requirements are shown below with an estimate of the annual reporting burden. Included in the estimate is the time for reviewing the instructions, gathering necessary information, and completing and reviewing the report.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Biological Product Reporting of Errors and Accidents in Manufacturing.

Description: FDA is proposing to amend the regulations that require licensed manufacturers of biological products to report errors and accidents in manufacturing that may affect the safety, purity, or potency of a product. FDA proposes to define certain terms, i.e., ''error and accident'', and ''made available for distribution;'' replace ''promptly'' with ''as soon as possible but not to exceed 45 calendar days'' with regard to the timeframe for reporting; limit the error and accident reporting requirements to biological products that have been made available for distribution; and amend the CGMP regulations to require all manufacturers of blood and blood components, including unlicensed registered blood establishments and transfusion services, to submit error and accident reports. FDA is proposing this action in response to concerns regarding the accuracy, timeliness, and completeness of error and accident reporting associated with the manufacturing of blood and other biological products, and as an essential tool in FDA's directive to

protect public health by establishing and maintaining surveillance programs that provide timely and useful information. FDA is not at this time proposing to require the use of a specific form for error and accident reports, but is requesting that establishments submit to the docket for review any proposed format for these reports. FDA is also soliciting comments on development of a program for electronic reporting of errors and accidents.

Description of Respondents: Manufacturers of blood and blood components; manufacturers of other biological products.

There are approximately 102 licensed manufacturers of biological products other than blood and blood components with 280 locations, and 294 licensed blood and plasma establishments with 725 locations. In fiscal year 1996, these manufacturers submitted a total of 10,793 error and accident reports. Of this total, 10,781 reports were submitted by licensed blood and plasma establishments. Although approximately 7,060 unlicensed registered blood establishment and transfusion service locations are currently submitting reports on a voluntary basis, FDA received only 159 error and accident reports for fiscal year 1996 from such entities. Based on the substantially larger number of reports received from licensed blood and plasma establishments, FDA believes that the number of reports currently received from unlicensed establishments is not an accurate indicator of the number of reports that will be submitted once the unlicensed establishments are required to submit error and accident reports for products made available for distribution.

The following reporting burden for proposed § 600.14 was estimated by using 1996 reporting figures for licensed manufacturers of biological products other than blood and blood components. The reporting burden for proposed § 606.171 was estimated by using the 1996 reporting frequency average for all licensed blood and plasma establishment locations of 15 reports per year; the number of respondents was estimated by adding the number of unlicensed registered blood establishment and transfusion service locations (7,060 according to FDA's records) to the number of licensed blood and plasma establishment locations that are already reporting. An average time of 0.5 hours (according to several respondents contacted by FDA) is used in the preparation of each report.

ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
600.14	280	0.04	12	0.5	6.0
606.171	7,785	15	116,775	0.5	58,387.5
Total					58,393.5

There are no capital costs or operating and maintenance costs associated with this collection of information.

In compliance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), the agency has submitted a copy of this proposed rule to OMB for review of the information collection provisions. Interested persons are requested to submit written comments regarding information collection by October 23, 1997 to the Office of Information and Regulatory Affairs, OMB (address above), ATTN: Desk Officer for FDA.

VI. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(10) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VII. Request for Comments

Interested persons may, on or before December 22, 1997, submit to the Dockets Management Branch (address above) written comments regarding this proposal, except that comments regarding information collection provisions should be submitted in accordance with the instructions in section V of this document. Two copies of any comments on issues other than information collection are to be submitted, of this document except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects

21 CFR Part 600

Biologics, Reporting and recordkeeping requirements.

21 CFR Part 606

Blood, Labeling, Laboratories, and Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR parts 600 and 606 be amended as follows:

PART 600––BIOLOGICAL PRODUCTS: GENERAL

1. The authority citation for 21 CFR part 600 continues to read as follows:

Authority: Secs. 201, 501, 502, 503, 505, 510, 519, 701, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 353, 355, 360, 360i, 371, 374); secs. 215, 351, 352, 353, 361, 2125 of the Public Health Service Act (42 U.S.C. 216, 262, 263, 263a, 264, 300aa–25).

2. Section 600.3 is amended by adding new paragraphs (hh) and (ii) to read as follows:

§ 600.3 Definitions.

* * * * *

(hh) *Error and accident* means:

(1) An event that represents a deviation from current good manufacturing practice (CGMP), applicable standards, or established specifications that may affect the safety, purity, or potency of a biological product, or otherwise cause the product to be in violation of the Federal Food, Drug, and Cosmetic Act or the Public Health Service Act, or

(2) An unexpected or unforeseeable event that may affect the safety, purity, or potency of a biological product, or otherwise cause the product to be in violation of the Federal Food, Drug, and Cosmetic Act or the Public Health Service Act.

(ii) *Made available for distribution* means that the biological product has been determined to meet all release

criteria and to be suitable for distribution.

3. Section 600.14 is amended by revising the section heading and paragraph (a) and by adding new paragraph (c) to read as follows:

§ 600.14 Reporting of errors and accidents.

(a) Except as provided in paragraph (c) of this section, the Director, Office of Compliance (HFM–650), Center for Biologics Evaluation and Research, 1401 Rockville Pike, Rockville, MD 20852–1448, shall be notified as soon as possible but not to exceed 45 calendar days, of errors or accidents in the manufacture of products that may affect the safety, purity, or potency of any biological product made available for distribution.

* * * * *

(c) In lieu of the requirements of paragraph (a) of this section, all manufacturers of blood and blood components shall submit reports to FDA in accordance with § 606.171 of this chapter.

PART 606—CURRENT GOOD MANUFACTURING PRACTICE FOR BLOOD AND BLOOD COMPONENTS

4. The authority citation for 21 CFR part 606 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 505, 510, 520, 701, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 355, 360, 360j, 371, 374); secs. 215, 351, 353, 361 of the Public Health Service Act (42 U.S.C. 216, 262, 263a, 264).

5. Section 606.3 is amended by adding new paragraphs (k) and (l) to read as follows:

§ 606.3 Definitions.

* * * * *

(k) *Error and accident* means:

(1) An event that represents a deviation from current good manufacturing practice (CGMP), applicable standards, or established specifications that may affect the safety, purity, or potency of blood or blood components, including source plasma, or otherwise cause the product to be in violation of the Federal Food, Drug, and Cosmetic Act or the Public Health Service Act, or

(2) An unexpected or unforeseeable event that may affect the safety, purity, or potency of blood or blood components, including source plasma, or otherwise cause the product to be in violation of the Federal Food, Drug, and Cosmetic Act or the Public Health Service Act.

(l) *Made available for distribution* means that the blood or blood component, including source plasma, has been determined to meet all release criteria and to be suitable for distribution.

6. Section 606.171 is added to subpart I to read as follows:

§ 606.171 Error and accident reporting, blood and blood components.

All establishments as defined in § 607.3(c) of this chapter shall notify the Director, Office of Compliance (HFM–600), Center for Biologics Evaluation and Research, 1401 Rockville Pike, Rockville, MD 20852–1448, as soon as possible but not to exceed 45 calendar days, of errors or accidents in the manufacture of blood or blood components, including source plasma, that may affect the safety, purity, or potency of any blood or blood component made available for distribution.

Dated: June 25, 1997.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 97–25129 Filed 9–22–97; 8:45 am]

BILLING CODE 4160–01–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[ME–046–6996b; A–1–FRL–5894–7]

Approval and Promulgation of Air Quality Implementation Plans; Maine; (General Conformity Rule)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve a State Implementation Plan (SIP) revision submitted by the State of Maine for the purpose of implementing General Conformity (Section 176(c)(4)(C) of the Clean Air Act (CAA) and its regulations 40 CFR part 51, Subpart W). The Maine SIP incorporates by reference the criteria and procedures set forth at 40 CFR part 51, Subpart W. This SIP revision establishes and requires federal actions to conform to all applicable implementation plans developed pursuant to Section 110 and Part D of the CAA. In the Final Rules Section of this **Federal Register**, EPA is approving the State's SIP revision as a direct final rule without prior proposal because the Agency views this as a noncontroversial revision amendment and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no adverse comments are received in response to that direct final rule, no further activity is contemplated in relation to this proposed rule. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period on this proposal. Any parties interested in commenting on this proposal should do so at this time.

DATES: Comments must be received on or before October 23, 1997.

ADDRESSES: Comments may be mailed to Susan Studlien, Deputy Director, Office of Ecosystem Protection (mail code CAA), U.S. Environmental Protection Agency, Region I, JFK Federal Bldg., Boston, MA 02203. Copies of the State submittal are available for public inspection during normal business hours, by appointment at the Office of Ecosystem Protection, U.S. Environmental Protection Agency, Region I, One Congress Street, 11th floor, Boston, MA and the Bureau of Air Quality Control, Department of Environmental Protection, 71 Hospital Street, Augusta, ME 04333.

FOR FURTHER INFORMATION CONTACT: Donald O. Cooke, (617) 565–3508, at the EPA Region I address above.

SUPPLEMENTARY INFORMATION: For additional information, see the direct final rule which is located in the Rules Section of this **Federal Register**.

Authority: 42 U.S.C. 7401—7671q.

Dated: September 9, 1997.

John P. DeVillars,

Regional Administrator, Region I.

[FR Doc. 97–25229 Filed 9–22–97; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[PA58–4039; AD–FRL–5897–2]

Approval and Promulgation of Air Quality Implementation Plans; Pennsylvania; Pennsylvania Power—New Castle NO_X RACT Proposal; Extension of Comment Period

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule; extension of the comment period.

SUMMARY: EPA is reopening the comment period for a proposed rule published on August 18, 1997 (62 FR 43959). In the August 18 document, EPA proposed to disapprove the April 19, 1995 Pennsylvania Department of

Environmental Protection proposal for nitrogen oxide reasonably available control technology (NO_X RACT) for the Pennsylvania Power—New Castle plant located in Lawrence County. At the request of Paul, Hastings, Janofsky & Walker LLP, attorneys representing Pennsylvania Power—New Castle plant, EPA is extending the comment period through November 18, 1997.

DATES: Comments must be received on or before November 18, 1997.

ADDRESSES: Comments may be mailed to David L. Arnold, Chief, Ozone/CO and Mobile Sources Section, Mailcode 3AT21, U.S. Environmental Protection Agency, Region III, 841 Chestnut Building, Philadelphia, Pennsylvania 19107.

FOR FURTHER INFORMATION CONTACT: Cynthia H. Stahl, U.S. EPA Region III, (215) 566–2180.

Dated: September 16, 1997.

W. Michael McCabe,

Regional Administrator, Region III.

[FR Doc. 97–25224 Filed 9–22–97; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[Region 2 Docket No. NY24–2–172a; FRL–5892–4]

Approval and Promulgation of Implementation Plans; Reasonably Available Control Technology for Oxides of Nitrogenfor Specific Sources in the State of New York

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The EPA proposes to approve three (3) State Implementation Plan (SIP) revisions submitted by the State of New York related to development of reasonably available control technologies for oxides of nitrogen from various sources in the State. In the Final Rules section of this **Federal Register**, EPA is approving the State's SIP revisions, as a direct final rule without prior proposal because the Agency views this as a noncontroversial revision and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no adverse comments are received in response to that direct final rule no further activity is contemplated in relation to this proposed rule. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. The EPA will not institute a secondcomment period on this rulemaking. Any parties interested in commenting on this **Federal Register** should do so at this time.

DATES: Comments must be received on or before October 23, 1997.

ADDRESSES: All comments should be addressed to: Ronald Borsellino, Chief, Air Programs Branch, Environmental Protection Agency, Region 2 Office, 290 Broadway, New York, New York 10007–1866.

Copies of the State submittal are available at the following addresses for inspection during normal business hours:

Environmental Protection Agency, Region 2 Office, 290 Broadway, 25th Floor, New York, New York 10007–1866.

New York Department of Environmental Conservation, Division of Air Resources, 50 Wolf Road, Albany, New York 12233.

FOR FURTHER INFORMATION CONTACT: Ted Gardella or Rick Ruvo, Air Programs Branch, Environmental Protection Agency, 290 Broadway, 25th Floor, New York, New York 10007–1866, (212) 637–4249.

SUPPLEMENTARY INFORMATION: For additional information see the direct final rule which is published in the rules section of this **Federal Register**.

Dated: September 2, 1997.

William J. Muszynski,

Acting Regional Administrator.

[FR Doc. 97–25231 Filed 9–22–97; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 86

[FRL–5897–5]

Control of Air Pollution From New Motor Vehicles and New Motor Vehicle Engines; Voluntary Standards for Light-Duty Vehicles; Extension of Comment Period

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule; extension of comment period.

SUMMARY: The U.S. Environmental Protection Agency is extending the comment period on the Supplemental Notice of Proposed Rulemaking (SNPRM) which takes comment on the few remaining issues necessary to finalize the regulations for the National LEV program, and which appeared in the **Federal Register** on August 22, 1997 (62 FR 44754). The public comment period was to end on September 22, 1997. The purpose of this document is to extend the comment period an additional 7 days beyond that, to end on September 29, 1997. This extension of the comment period is provided to allow commenters additional time to respond to the SNPRM.

DATES: EPA will accept public comments on the Supplemental Notice of Proposed Rulemaking until September 29, 1997.

ADDRESSES: Written comments should be submitted (in duplicate if possible) to: the EPA, Air Docket, Room M–1500 (Mail Code 6102), Waterside Mall, Attn: Docket A–95–26, 401 M Street, SW., Washington, DC 20460. Materials relevant to this rulemaking are contained in Docket No. A–95–26. The docket is located at The Air Docket, 401 M Street, SW., Washington, DC 20460, and may be viewed in room M–1500 between 8:00 a.m. and 5:30 p.m., Monday through Friday. The telephone number is (202) 260–7548 and the facsimile number is (202) 260–4400. A reasonable fee may be charged by EPA for copying docket material.

FOR FURTHER INFORMATION CONTACT: Karl Simon, Office of Mobile Sources, U.S. Environmental Protection Agency, 401 M Street SW, Washington, DC 20460. Telephone (202) 260–3623; Fax (202) 260–6011; e-mail simon.karl@epamail.epa.gov.

Dated: September 17, 1997.

Richard D. Wilson,

Acting Assistant Administrator for Air and Radiation.

[FR Doc. 97–25233 Filed 9–22–97; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Chapter IV

[OMC–029–N]

RIN 0938–AI25

Medicare Program; Solvency Standards for Provider-Sponsored Organizations; Intent To Form Negotiated Rulemaking Committee

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Intent to form negotiated rulemaking committee and notice of meetings.

SUMMARY: The Balanced Budget Act of 1997 requires the Secretary to establish a Negotiated Rulemaking Committee under the Federal Advisory Committee Act (FACA). The Committee's purpose will be to negotiate the solvency standards for provider-sponsored organizations under part C of the Medicare program. The Committee will consist of representatives of interests that are likely to be significantly affected by the solvency rule. The Committee will be assisted by a neutral facilitator.

We request public comment on whether—We have identified the key solvency issues to be negotiated by the Committee; We have identified the interests that will be affected by key issues listed below; The party we are proposing to serve as the neutral facilitator is acceptable. Additionally, comments are sought on several key definitions related to the negotiated rulemaking and the forthcoming rulemaking for Medicare+Choice organizations.

DATES: Comments will be considered if we receive them at the appropriate address provided below, no later than 5 p. m. on October 8, 1997. Comments on the definitions for the terms described in section VII of this notice will be accepted separately until October 20, 1997.

The first meeting will be held at 9:00 a.m. on October 20, 21, and 22, 1997.

ADDRESSES: Mail written comments (1 original and 3 copies) to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: PSO NOTICE, P.O. Box 7517, Baltimore, MD 21244–0517.

If you prefer, you may deliver your written comments (1 original and 3 copies) to one of the following addresses: Room 309-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW, Washington, DC 20201, or Room C5–09–26, 7500 Security Boulevard, Baltimore, MD 21244–1850.

Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code OMC–029-N. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in room 309-G of the Department's offices at 200 Independence Avenue, SW, Washington, DC, on Monday through Friday of each week from 8:30 a. m. to 5 p. m. (Phone: (202) 690–7890).

The October meeting will be held at the Sheraton National Hotel, 900 South Orme Street, Arlington, VA; (703) 521–1900.

FOR FURTHER INFORMATION CONTACT: Maureen Miller, (410) 786–1097, for general issues related to standards for provider-sponsored organizations. Philip Doerr, (410) 786–1059, for technical issues related to solvency standards. Judy Ballard, (202) 690–7419, or Celia Ford, (202) 690–8020, Conveners.

SUPPLEMENTARY INFORMATION:

I. Negotiated Rulemaking Process

The Negotiated Rulemaking Act (Pub. L. 101–648, 5 U.S.C. 561–570) establishes a framework for the conduct of negotiated rulemaking and encourages agencies to use negotiated rulemaking to enhance the informal rulemaking process. Under the Act, the head of an agency must consider whether—

- There is a need for a rule;
- There are a limited number of identifiable interests that will be significantly affected by the rule;
- There is a reasonable likelihood that a committee can be convened with a balanced representation of persons who—
- Can adequately represent the interests identified; and
- Are willing to negotiate in good faith to reach a consensus on the proposed rule;
- There is a reasonable likelihood that a committee will reach a consensus on the proposed rule within a fixed period of time;
- The negotiated rulemaking procedure will not unreasonably delay the notice of proposed rulemaking and the issuance of a final rule;
- The agency has adequate resources and is willing to commit such resources, including technical assistance, to the Committee; and
- The agency, to the maximum extent possible, consistent with the legal obligations of the agency, will use the consensus of the Committee with respect to the proposed rule as the basis for the rule proposed by the agency for notice and comment.

Negotiations are conducted by a Committee chartered under the Federal Advisory Committee Act (FACA) (5 U.S.C. App. 2). The Committee includes an agency representative and is assisted by a neutral facilitator. The goal of the Committee is to reach consensus on the language or issues involved in a rule. If consensus is reached, it is used as the basis of the agency's proposal. The process does not affect otherwise applicable procedural requirements of the FACA, the Administrative Procedure Act, and other statutes.

II. Subject and Scope of the Rule

A. Need for the Rule

The Balanced Budget Act of 1997, Pub. L. 105–33, establishes a new Medicare+Choice program under part C of title XVIII of the Social Security Act (the Act). Under this program, an eligible individual may elect to receive Medicare benefits through enrollment in a Medicare+Choice plan that has a contract with us, which may include a health plan offered by a provider-sponsored organization (PSO). We may contract only with organizations that we have certified as meeting program requirements.

A PSO is defined as a public or private entity—

- That is established or organized, and operated, by a health care provider, or group of affiliated health care providers;
- That provides a substantial proportion of the health care items and services directly through the provider or affiliated group of providers; and
- With respect to which the affiliated providers share, directly or indirectly, substantial financial risk for the provision of such items and services and have at least a majority financial interest in the entity (section 1855(d) of the Act).

Generally, a Medicare+Choice organization must be ''organized and licensed under State law as a risk-bearing entity eligible to offer health insurance or health benefits coverage in each State in which it offers a Medicare+Choice plan.'' (section 1855(a)(1) of the Act).

Section 1855(a)(2) of the Act provides, however, that the Secretary may waive the licensing requirement for a PSO that has filed a waiver application by November 1, 2002, if the Secretary determines that the State failed to complete action on a licensing application within 90 days, denied the licensing application based on discriminatory treatment, or denied the licensing application based (in whole or in part) on the organization's failure to meet applicable solvency requirements and—

- Such requirements are not the same as the solvency standards established by negotiated rulemaking as authorized under section 1856(a) of the Act; or
- The State conditioned approval on ''documentation or information requirements relating to solvency or other material requirements, procedures, or standards relating to solvency that are different from the requirements, procedures, and standards applied by the Secretary'' under section 1855(d)(2) of the Act

regarding the use of the term ''substantial proportion.''

A waiver is effective only with respect to that State, only for a nonrenewable 36-month period, supersedes any State licensing provision that would prohibit the organization from participating in a Medicare+Choice contract, and is conditioned upon the organization's compliance with State consumer protection and quality standards as provided for in section 1855(a)(2)(E) and (G) of the Act. PSOs that have a waiver application approved must meet program requirements including standards for financial solvency and capital adequacy of the organization.

B. Modified Negotiated Rulemaking Committee

Section 4001 of the BBA mandates an expedited and modified negotiated rulemaking process for establishing solvency standards for PSOs under a new Medicare Part C. The standards must be published as an interim final rule, subject to comment, by April 1, 1998. In order to meet this deadline, the BBA mandated that this notice be published within 45 days after enactment, shortened the notice's comment period to 15 days, and shortened the time period for appointment of Committee members as well as the facilitator. The Committee is required to report its proposed standards to the Secretary by March 1, 1998. Further, the Committee is required to report to the Secretary by January 1, 1998 regarding its progress and whether it is likely to achieve consensus. If the Committee reports that it has failed to make significant progress or that consensus is unlikely within the assigned time frame, the Committee will be terminated and publication of a rule will proceed using other rulemaking procedures.

C. Issues and Questions to be Resolved

The issues we anticipate include fundamental questions about solvency standards, definitions, threshold questions, overarching policy issues, and finally specific matters identified by the Congress for consideration. We invite public comment on these and on other issues, which are believed to be in the scope of the rule.

- What are solvency standards? What is the purpose of these standards? We expect the Committee to address the purpose and scope of solvency standards, particularly with regard to the operation of a fiscally sound organization and needed protections in the event of insolvency, including financial viability at application (that is, initial capitalization) and on an ongoing basis, as well as liquidity and cash flow. These discussions may extend to alternative models for approaching solvency standards, such as focusing on the nature of the health products being offered and the actual risk being assumed, in addition to the nature, assets, or other resources of the entity providing the benefits.
- Should solvency standards for PSOs be equivalent or substantially similar to those for other risk-bearing organizations? We expect to discuss the concept, or goal, of a ''level playing field'' between PSOs (which may or may not be Medicare-only health plans) and other health plans that enroll members from the general population and, possibly, Medicaid recipients; the impact of the organizational structure and nature of PSOs, and the characteristics of their enrollment, on decreasing or increasing factors that affect the financial stability of risk-bearing health plans; and the patterns and trends in State solvency requirements that are relevant to Medicare-contracting PSOs.
- How should the solvency rule take into account the delivery system assets of the PSO and its ability to provide services directly to enrollees through affiliated providers? This is a key issue, and one which the BBA directs the Committee to consider. We expect discussion of various PSO assets, such as property, plant, equipment, or other non-fiscal assets; how to value these assets, giving consideration to market forces that may affect or cause fluctuation of value; the ability to increase services to meet increased demand, and the potential, if any, of higher efficiency of an integrated network; the relevancy of Medicare enrollment size and potential use of services in comparison to PSO assets and obligations; and financial reserves.
- How should the rule take into account alternative means of protecting against insolvency? There are a number of ''tools'' or mechanisms that are used, or have been proposed for use, to assure that a health plan remains fiscally sound and to protect enrollees in the event of insolvency. The statute lists the following alternative means as included in factors to be considered: reinsurance, unrestricted surplus, letters-of-credit, guarantees (third party guarantees), organizational insurance coverage (including stop-loss and insolvency insurance), partnerships with other licensed entities, and valuation attributable to the ability of the PSO to meet its service obligations through direct delivery of care (discussed previously). Other mechanisms, or factors, will be discussed including the possibility of guarantee associations and state-held reserves where PSOs are state-licensed. The Committee will discuss the merits of these factors, their interrelatedness and will report to the Secretary on specific requirements for their use in a solvency standard.
- How should the rule take into account any standards established by the National Association of Insurance Commissioners (NAIC) for risk-based health care delivery organizations? This is the third area in which the BBA directs the Committee to work. The National Association of Insurance Commissioners invested significant time and resources to develop and improve State solvency standards for risk-bearing health care delivery organizations, specifically focusing on what is called ''risk-based capital (RBC).'' However, given that the RBC formula is in a transitional phase between development and implementation, its inclusion as part of the Medicare PSO solvency standards requires careful consideration. We believe the Committee should become knowledgeable about the RBC formula and its role relative to solvency standards. In addition, we believe the Committee should discuss the applicability of the current National Association of Insurance Commissioners' RBC formula to PSOs with Medicare-only enrollment as well as those with enrollments other than the Medicare population. We may ask the Committee to advise us on how to proceed toward utilizing a RBC formula, including further developmental work, and how to proceed with implementation given voluntary adoption by States and where PSOs may or may not be licensed by the State.
- What provisions are necessary to prevent enrollees from being held liable to any person or entity for the Medicare+Choice organization's debts in the event of the PSO's insolvency? There appears to be agreement that the provider contracts of Medicare+Choice organizations should include contractual language that prohibits providers from billing enrollees and requires continuation of care through the period for which premiums have been paid. We anticipate that the Committee may wish to discuss the period of time for which these contractual agreements are in effect, as well as difficulties in ensuring that providers continue to provide services, problems ensuring that insolvency insurance is in place, and the difficulties of getting affected patients appropriate coverage.
- What factors not specifically listed in the statute should be considered? We

believe the Committee should consider the need for more stringent solvency standards if the Secretary exercises the option to waive the minimum enrollment requirement and grants a waiver to the PSO. We believe the Committee should consider adopting certain requirements related to the fiscal soundness for health maintenance organizations, especially those requirements commonly considered good business practices, such as having insurance policies against losses stemming from fire, theft, and fraud. There may be other factors, such as actuarial opinions and cash reserves, that the Committee should consider. In addition, on the matter of cash reserves, we expect the Committee will discuss how to handle the cash reserve requirement with multi-State PSOs.

- What reporting requirements will we impose? The Committee will discuss the nature and frequency of reporting requirements. Currently, we require Medicare contracting health plans to report using the National Association of Insurance Commissioners' ''Orange Blank,'' but some modification of this requirement may be necessary to account for the organizational nature of PSOs and differences between PSOs and other Medicare+Choice plans. We anticipate that such differences will have to be limited to ensure efficient use of State and Federal monitoring resources.
- How will definitions and policies that the Secretary will develop affect the negotiations? The statute contains definitions and terms to be defined by the Secretary that are relevant to the development of solvency standards. We anticipate that the Committee will need to have guidance on the definition of the terms ''substantial proportion'' (including potential variations in the definition of this term), ''substantial financial risk,'' ''affiliated health care providers,'' ''providers,'' and ''partnerships'' as they relate to the financial stability of PSOs. We will provide preliminary definitions and use of these terms. However, because these definitions and policies will be part of a separate regulation to be published by June 1, 1998, the information provided to the Committee will not be final definitions at the time of negotiated rulemaking.

D. Issues and Questions Not Open to Negotiation

With regard to parameters outside the scope of this rule, we will not discuss or consider issues not directly related to PSO solvency standards. Thus, we will not discuss the PSO waiver process, the PSO application process, monitoring, compliance actions, or matters that will be the subject of the June 1, 1998, interim final rule. Further, issues such as who can qualify as a PSO or those that are definitional (and thereby subject of the June 1, 1998 interim final rule) will be discussed only to the extent that solvency standards may be contingent on establishing some parameters.

III. Affected Interests and Potential Participants

In addition to our participation on the committee, the Convener has proposed and we agree to accept the following as negotiation participants, some of which are coalitions of two or more groups:

American Association of Health Plans
American Association of Homes and Services for the Aging/American Health Care Association/Home Health Services and Staffing Asssociation/National Association for Home Care
American Association of Retired Persons
American Hospital Association
American Medical Association
American Medical Group Association
Blue Cross/Blue Shield Association
Catholic Health Association / Premier
Consortium on Citizens with Disabilities
Federation of American Health Systems
National Association of Insurance Commissioners
National Independent Practice Association (IPA) Coalition/The IPA Association of America
National Rural Health Association

Individuals representing the proposed organizations and health industry sectors should have ''real world'' experience, be respected in their particular community, have the ability to engage in negotiations that lead to consensus, and be able to fully represent the views of the interests they represent. We reserve the right to refuse representatives that do not possess these characteristics. Given the limited time frame for the development of this rule, it is expected that the negotiations will be time consuming and intensive. Representatives must be prepared and committed to fully participating in the negotiations. The names of the Committee members will be announced before the first meeting and Committee members will be notified. We are establishing an Internet site on our Managed Care home page, which will carry this information as well as other meeting information. We invite public comment on this list of negotiation participants.

The intent in establishing the negotiating committee is that all interests are represented, not necessarily all parties. We believe this proposed list of participants represents all interests associated with adoption of solvency standards for provider-sponsored organizations. In determining whether a party had a significant interest and was represented, we considered groups who have and will continue to actively represent the main provider groups who will form PSOs, groups that represent providers experienced in bearing risk and managed care, groups that represent entities similar in nature to PSOs, groups representing affiliated providers and the continuum of care, beneficiary groups, and state regulators. In addition, we sought to achieve balance between providers seeking to enter the Medicare market and those (including existing Medicare contractors) who advocate for strong solvency standards. We believe a complex balance has been achieved due to the diversity within the groups named or within the health systems that are their members. Lastly, while we are obligated to assure that all interests that are significantly affected are adequately represented, it is critical to the Committee's success that it be kept to a manageable size. Committee size is a consideration because of the short time frame in which the Committee must complete its task.

Groups or individuals who wish to apply for a seat on the Committee should respond to this notice, and provide detailed information as to how they would be affected by the solvency standards rule (rather than the new legislation generally) and why their interest could not be adequately represented by the proposed committee.

IV. Schedule for the Negotiations

The BBA requires that the Committee submit its final report to the Secretary by March 1, 1998. The BBA further directs that the activities of the Committee be terminated if the Committee does not report, no later than January 1, 1998, that it has made significant progress and is likely to reach consensus within the time line established by the statute. The first meeting is scheduled for October 20, 21, and 22, 1997, at a meeting facility in the Greater Washington, D.C. area beginning at 9:00 a.m. on the first day. The purpose of this meeting will be to discuss in detail how the negotiations will proceed and how the Committee will function. The Committee will agree to ground rules for committee operation, will determine how best to address the principal issues, and, if time permits, will begin hearing presentations and to address those issues.

A second meeting is scheduled for November 12, 13, and 14, 1997. We

expect that by this meeting the Committee can complete action on any procedural matters remaining from the organizational meeting and either begin or continue to address the issues. The third meeting is scheduled for December 3, 4, and 5, 1997 for continued discussion of the issues. Three subsequent meetings will be held in January and February of 1998. Times and locations of the meetings in the Greater Washington DC area will be published in the **Federal Register** and announced and placed on our Internet Managed Care Home Page.

V. Formation of the Negotiating Committee

A. Procedure for Establishing an Advisory Committee

As a general rule, an agency of the Federal government is required to comply with the requirements of FACA when it establishes or uses a group that includes non-Federal members as a source of advice. Under FACA, an advisory committee begins negotiations only after it is chartered. This process is underway.

B. Participants

The number of participants in the group is estimated to be 14 and should not exceed 16 participants. A number larger than this could make it difficult to conduct effective negotiations. One purpose of this notice is to help determine whether the proposed rule would significantly affect interests not adequately represented by the proposed participants. We do not believe that each potentially affected organization or individual must necessarily have its own representative. However, each interest must be adequately represented. Moreover, we must be satisfied that the group as a whole reflects a proper balance and mix of interests.

C. Requests for Representation

If, in response to this notice, an additional individual or representative of an interest requests membership or representation on the Committee, we will determine, in consultation with the convener, whether that individual or representative should be added to the Committee. We will make that decision based on whether the individual or interest—

- Would be significantly affected by the rule, and
- Is already adequately represented in the negotiating group.

D. Establishing the Committee

After reviewing any comments on this notice and any requests for representation, we will take the final steps to form the committee unless the comments and other relevant considerations convince us that such action is inappropriate or our charter request is disapproved.

VI. Negotiation Procedures

If a committee is formed, the following procedures and guidelines will apply, unless they are modified as a result of comments received on this notice or during the negotiating process.

A. Facilitator

We will use a neutral facilitator. The facilitator will not be involved with the substantive development or enforcement of the regulation. The facilitator's role will be to—

- Chair negotiating sessions;
- Help the negotiation process run smoothly; and
- Help participants define and reach consensus.

We propose to use the Department's Appeals Board as the facilitator.

B. Good Faith Negotiations

Participants must be willing to negotiate in good faith and be authorized to do so. We believe this may best be accomplished by selection of senior officials as participants. We believe senior officials are best suited to represent the interests and viewpoints of their organizations. This applies to us as well, and we are designating Kathleen Buto, Deputy Director of our Center for Health Plans and Providers to represent us.

C. Administrative Support

We will supply logistical, administrative, and management support. If it is deemed necessary and appropriate, we will provide technical support to the committee in gathering and analyzing additional data or information.

D. Meetings

Meetings will be held in the Baltimore/Washington area (or in another location). We will announce committee meetings and agendas in the **Federal Register**. Unless announced otherwise, meetings are open to the public.

E. Committee Procedures

Under the general guidance and direction of the facilitator, and subject to any applicable legal requirements, the members will establish the detailed procedures for committee meetings that they consider most appropriate.

F. Defining Consensus

The goal of the negotiating process is consensus. Under the Negotiated Rulemaking Act, consensus generally means that each interest concurs in the result unless the term is defined otherwise by the Committee. We expect the participants to fashion their working definition of this term.

G. Failure of Advisory Committee To Reach Consensus

If the Committee is unable to reach consensus, we will proceed to develop an interim final rule. Parties to the negotiating may withdraw at that time. If this happens, we and the remaining Committee members will evaluate whether the Committee should continue.

H. Record of Meetings

In accordance with FACA's requirements, minutes of all committee meetings will be kept. The minutes will be placed in the public rulemaking record and Internet site on our Managed Care home page.

I. Other Information

In accordance with the provisions of Executive Order 12866, this notice was reviewed by the Office of Management and Budget.

VII. Special Solicitation of Public Comment

Given the abbreviated time lines and absence of proposed rulemaking (as directed by the BBA) for this negotiated rulemaking and the forthcoming rules for Medicare Part C, we are taking this opportunity to solicit views on the definitions and use of the terms (as directed by BBA): substantial proportion, substantial financial risk, affiliated provider, provider of health services, partnerships, organized and licensed under State law as a risk-bearing entity. Because this solicitation will assist us in developing policy and providing guidance to the Committee, comments should be submitted no later than October 20, 1997, to the following addresses: Health Care Financing Administration, ATTN: Ms. Maureen Miller, Room S3–21–17, 7500 Security Boulevard, Baltimore, MD 21244–1850.

Final definitions of these terms will appear in the June 1, 1998 final rule.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance)

Dated: September 16, 1997.

Nancy-Ann Min DeParle,

Deputy Administrator, Health Care Financing Administration.

Approved: September 18, 1997.

Donna E. Shalala,

Secretary.

[FR Doc. 97–25343 Filed 9–19–97; 2:27 pm]

BILLING CODE 4120–01–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

49 CFR Part 387

[FHWA Docket No. MC–97–11]

RIN 2125–AE06

Qualifications of Motor Carriers To Self-Insure Their Operations and Fees To Support the Approval and Compliance Process

AGENCY: Federal Highway Administration (FHWA).

ACTION: Advance notice of proposed rulemaking (ANPRM); request for comments.

SUMMARY: This action is being taken pursuant to the ICC Termination Act of 1995 (ICCTA), which, among other things, directs the Secretary of DOT to adopt regulations governing the standards to approve motor carriers as self-insurers. The FHWA proposes to examine the sufficiency of the existing requirements for self-insurance authorizations, as well as the need for additional fees for functions performed in addition to the processing of the initial application. More specifically, the FHWA is considering the need for fees to cover costs associated with processing multi-carrier applications and alterations to self-insurance authorizations, and for a monitoring fee to cover costs related to compliance responsibilities. The FHWA also requests public comment on the merits of continuing the self-insurance program and whether congressional action should be proposed to terminate the authorizations.

DATES: Comments must be received on or before November 24, 1997.

ADDRESSES: Submit written, signed comments to FHWA Docket No. MC–97–11, Room 4232, HCC–10, Office of the Chief Counsel, Federal Highway Administration, 400 Seventh Street, SW., Washington, DC 20590. All comments received will be available for examination at the above address from 8:30 a.m. to 3:30 p.m., e.t., Monday through Friday, except Federal holidays. Those desiring notification of receipt of comments must include a self-addressed, stamped postcard.

FOR FURTHER INFORMATION CONTACT: John F. Grimm, Office of Motor Carriers, (202) 366–4039 or Stanley M. Braverman, Motor Carrier Law Division, Office of the Chief Counsel, (202) 358–7035; Federal Highway Administration, 400 Virginia Ave., SW, Suite 600, Washington, DC 20024. Office hours are from 7:45 a.m. to 4:15 p.m., e.t., Monday through Friday except Federal holidays.

SUPPLEMENTARY INFORMATION:

Background

The former Interstate Commerce Commission (ICC), in its earliest days of motor carrier regulation, considered applications of carriers seeking authority to self-insure their operations. The ICC took the position that self-insurance requirements should be stringent and that carriers availing themselves of that privilege should maintain adequate reserves to meet claims. *Motor Carrier Insurance Protection of the Public,* 1 M.C.C. 45, 58 (1936).

The ICC set no rules at that time governing the qualifications for self-insurers, but decided to consider for approval the application of any carrier that could establish its ability to satisfy, ''its obligations for bodily-injury liability, property-damage liability, or cargo liability without affecting the stability or permanency of its business.'' *Id.* at 59. Motor carrier requests to self-insure which were approved by the ICC required the execution of insurance endorsements which obligated the insurance company to pay final judgments regardless of any policy defenses it may have against the insured. *Id.* at 53. The self-insurance was based upon deductible levels in the insurance policies which were authorized by the ICC. Despite the size of any deductible, the insurance company remained liable to the public for the entire amount of the policy. Although the ICC considered use of deductibles to be tantamount to self-insurance, the motor carrier would be fully insured since the insurance company remained liable for the entire amount of the policy. The self-insurance authorization posed no additional risk to the public because the insurance company would be required to pay a judgement, without regard to the deductible, if the carrier refused to pay.

In response to an insurance crisis in the motor carrier industry in the mid 1980's which increased the cost of insurance coverage to extraordinary levels and affected its availability, the ICC began authorizing carriers with adequate financial resources to self-insure all, or part of, their required liability coverage backed by adequate security without the public protection provided by the traditional insurance company endorsement.[1] The ICC recognized that self-insurance plans do not necessarily afford the precise level of protection that customary insurance plans provide since insurance policies cover liability for every accident within the policy limits. Nevertheless, the ICC began issuing self-insurance authorizations subject to an extensive series of conditions designed to insure that the public would be protected from uncompensated losses. *See,* No. MC–128527, *May Trucking Company* (unpublished decision), served April 22, 1986. (*See* Appendix to this ANPRM.). Interim rules designed to establish minimum criteria that motor passenger and property carriers must meet to qualify as self-insurers were adopted by the ICC. Ex Parte No. MC–178, *Investigation into Motor Carrier Insurance Rates*, served April 12, 1986 (51 FR 15008, April 22, 1986). Final rules were adopted which included application guidelines covering the adequacy of the carrier's net worth, the existence of a sound self-insurance program, a ''satisfactory'' safety rating, and additional information the ICC might require. *Investigation into Motor Carrier Insurance Rates*, 3 I.C.C. 2d 377 (1987) (52 FR 3814, February 6, 1987).[2] The ICC expanded the list of methods carriers can use to demonstrate sound self-insurance programs to include irrevocable letters of credit and irrevocable trust funds. *Id.* at 388. In reviewing self-insurance applications, the ICC relied on its general powers to impose conditions on a case-by-case basis to insure that the public was adequately protected. *Id.* at 383. The requirement of an irrevocable trust fund or letter of credit in at least the amount of the self-insurance liability has been imposed in virtually all self-insurance authorizations.

The ICCTA, Pub. L. 104–88, 109 Stat. 803, provides that ''[T]he Secretary of Transportation shall continue to enforce the rules and regulations of the Interstate Commerce Commission, as in effect on July 1, 1995, governing the qualifications for approval of a motor carrier as a self-insurer, until such time as the Secretary finds it in the public interest to revise such rules.'' Section

[1] The minimum financial responsibility requirements for for-hire carriers, formerly regulated by the ICC and now by the FHWA, are contained in 49 CFR Part 387.

[2] These rules are now codified at 49 CFR 387.309 [former 49 CFR 1043.5].

104(h) amending 49 U.S.C. 31144. The revised rules must provide for the continuing ability of motor carriers to obtain self-insurance authorizations, and the continued qualification of all carriers conducting self-insured operations pursuant to grants issued by the ICC or the Secretary. *Id* Section 204 of the ICCTA provides that all regulations previously issued by the ICC continue in effect according to their terms until modified or terminated.

Request for Comments

The purpose of this ANPRM is to obtain comments from motor carriers, insurance companies and other interested persons to determine whether the public is adequately protected against uncompensated losses.

The self-insurance regulations require each applicant to demonstrate that it has established and will maintain an insurance program that will protect the public against all claims to the same extent as if the carrier maintained commercial coverage in the prescribed amounts. 49 CFR 387.309. In support of such a program, the carrier may make use of irrevocable letters of credit, irrevocable trust funds, reserves, sinking funds, third party financial guarantees, parent company or affiliate sureties, excess insurance coverage, or other similar arrangements. *Id.* The FHWA is concerned with the widespread use of letters of credit to support self-insurance programs and seeks public comment on whether these instruments provide the intended claims protection, especially when a carrier has terminated its self-insured operations and is no longer obligated to maintain this letter of credit as security for the claims which accrue during the self-insurance period. Generally, the ICC, as well as the FHWA, has permitted carriers to support their self-insured operations with either an irrevocable letter of credit or an irrevocable trust fund in the amount of the self-insurance liability. The FHWA requires that the carrier maintain the trust fund until all cognizable self-insurance claims are resolved. No such condition is attached to the letter of credit because of the nature of the instrument. Carriers can terminate their self-insured operations by discontinuing all operations, by relinquishing the self-insurance authorization and obtaining commercial coverage, or by violating a condition of the authorization such as losing the required ''satisfactory'' safety rating. In each situation, all cognizable self-insurance claims arising during the period of self-insured operations cannot be identified when the operations are terminated. The trust fund condition is designed to protect the potential claimants when self-insured operations are terminated. *See* No. MC–8535, *George Transfer-Application to be a Self-Insurer* (unpublished decision), served September 24, 1986. (*See* Appendix to this ANPRM.) The letter of credit cannot provide this type of protection and, by its nature, is of questionable value as a back-up security.

Accordingly, the FHWA solicits comments regarding the elimination of the use of letters of credit in support of self-insured operations and the requirement, in all cases, of the maintenance of an irrevocable trust fund which must remain in place and fully funded until all cognizable self-insurance claims have been resolved.

The FHWA seeks public comment on the need to increase the amount of back-up collateral maintained in the letters of credit or trust funds. As a general rule, these instruments are executed in the amount of the self-insurance authorization, and adjustments to reflect additional claims exposure are not requested. Should additional security be required as the level of unpaid claims increases? Should the scope of the carrier's operations be considered in determining the level of collateral or back-up security?

The FHWA also requests public comment on the sufficiency of the reporting requirements that self-insured carriers must meet with respect to bodily injury and property damage (BI&PD) claims. Generally, each carrier must submit quarterly and yearly claims handling and financial data. This information forms the basis of the FHWA's monitoring and compliance program which now is designed to insure compliance with the terms and conditions imposed by the FHWA. The compliance review, however, does not include a verification of the carrier's claims reserves, a function that can only be performed by a professional risk analyst. In the FHWA's view, the absence of this information may create a potential risk for claimants. Accordingly, the FHWA requests comments on whether a self-insured carrier should be required to submit a yearly certified BI&PD claims report. The report would indicate that the yearly claims reserves accurately represent the best estimate of the carrier's liability. This report could be prepared by the carrier's excess insurance provider or any organization qualified to conduct such an analysis. Comments are also solicited on whether the FHWA should impose such a requirement on carriers that obtained their authorization before the effective date of the ICCTA.

Section 387.309 of title 49, CFR, provides that ''any self-insurance authority granted by the Commission [now the FHWA] will automatically expire 30 days after a carrier receives a less than satisfactory rating from DOT.'' The FHWA is considering whether to extend that period to 45 days to enable safety inspectors time to evaluate the corrective measures taken by the carrier after the less than satisfactory rating was assigned. This would in no way alter the FHWA's insistence that all self-insured carriers maintain ''satisfactory'' safety ratings. *See* No. MC–176440, *Direct Transit, Inc., Authorization to Self-Insure* (unpublished decision), served February 8, 1996. (*See* Appendix to this ANPRM.).

Proposed New Fee Items

The FHWA dedicates resources to make certain that the carriers authorized to conduct self-insured operations are complying with the conditions imposed in their respective authorizations. This involves a thorough review of claims and financial data submitted generally on a quarterly and yearly basis. In some instances, the data must be submitted on a monthly basis. Detailed reports of these reviews are prepared and analyzed. In addition, where financial problems call a carrier's continuing ability to self-insure into question, considerable time is devoted to determining whether additional safeguards should be imposed or whether the authorization should be terminated. Any trends in the carrier's exposure to BI&PD claims must be scrutinized. Furthermore, review and analysis of the proposed certified claims report would add to the monitoring duties. None of the costs of these duties is recovered from the current application fees. Accordingly, the FHWA is considering a $1900 yearly monitoring fee on each carrier conducting BI&PD self-insured operations which represents only the FHWA's current estimate of the salary and overhead costs for agency employees to monitor compliance with the conditions in the self-insurance authorizations.

The FHWA solicits public comment on the need to recover costs associated with performing additional processing activities beyond the handling of a single carrier application. Considerable resources of the former ICC and the FHWA have been expended in dealing with multiple carrier applications and requests to modify outstanding authorizations by changing the self-insurance coverage, altering the type

and amount of the security coverage, or adding a carrier to the self-insured group. In many instances, these modification requests require an extensive reanalysis of the carrier's financial condition if additional self-insurance authorization is requested. The financial analysis of carrier groups and their parent corporations is often complex and time-consuming. Detailed examination of intercorporate transactions as well as the asset quality of intercorporate receivables and debt (including covenants) must be conducted. Accordingly, the FHWA solicits comments on the need to assess fees in three categories: (1) Request for an increase in coverage, change in the letter of credit or trust agreement, reporting requirements or other modifications—($2,600); (2) addition of a single carrier to an existing authorization—$3,400; and (3) multiple carrier applications or modification of applications—($400 per carrier). These costs represent only the salary and overhead expenses associated with the FHWA employees who perform these functions.

The FHWA requests comments concerning whether continuing to permit motor carriers to self-insure their operations is in the public interest or whether congressional action should be requested to repeal the statute directing the Secretary to continue the self-insurance program. In this regard the FHWA proposes the following specific questions for comments:

1. Does the self-insurance authorization jeopardize the payment of BI&PD and cargo claims by allowing carriers to conduct operations with insufficient security or collateral to guarantee payment of claims?

2. Does the ability of large carriers to conduct self-insured operations create an unfair competitive advantage over smaller carriers which must absorb the expense of the Federal insurance requirement?

3. Should the FHWA permit a motor carrier to conduct self-insured operations with less security or collateral than an insurance company would require?

4. Do the savings generated by self-insured operations justify exposing the public to the risk of uncompensated losses resulting from carrier bankruptcy or termination of operations?

5. Is it possible for the FHWA to conduct the self-insurance program in a manner that insures the potential claimants will not be placed at risk?

6. Is the administration of a self-insurance program a proper role for a Federal agency?

Executive Order 12866 (Regulatory Planning and Review) and DOT Regulatory Policies and Procedures

The FHWA has determined that a decision to seek termination of the self-insurance program would be a significant regulatory action under Executive Order 12866, and under the DOT's regulations, policies and procedures because of the substantial public interest anticipated in this action.

Currently, 56 carriers have been authorized to self-insure their operations, 9 of which have authorizations which cover only cargo liability. The gross revenues generated by carriers holding the BI&PD authorizations range from $8,396,000 to $1,207,601,000, or an average of $174,345,468. These carriers are exposed to an average claims balance of $3,412,882. The vast majority of these carriers self-insure at the $1,000,000 level which corresponds to the required level of coverage.

The potential economic impact of this rulemaking is not known at this time. Therefore, a full regulatory evaluation has not yet been prepared. The FHWA intends to use the information collected from commenters to this docket to evaluate the economic and other issues attendant to this regulatory action.

Regulatory Flexibility Act

Due to the preliminary nature of this document and lack of necessary information on costs, the FHWA is unable at this time to evaluate the effects of the potential regulatory changes on small entities. The FHWA solicits comments, information, and data on these potential impacts.

Executive Order 12612 (Federalism Assessment)

This action has been analyzed in accordance with the principles and criteria contained in Executive Order 12612, and it has been determined that this action does not have sufficient federalism implications to warrant the preparation of a federalism assessment.

Executive Order 12372 (Intergovernmental Review)

Catalog of Federal Domestic Assistance Program Number 20.217, Motor Carrier Safety. The regulations implementing Executive Order regarding intergovernmental consultation on Federal programs and activities do not apply to this program.

Paperwork Reduction Act

This action, if promulgated, would, in all likelihood, impact existing collection of information requirements for the purposes of the Paperwork Reduction Act of 1995 (49 U.S.C. 3501–3520). Because of the potential changes, existing Office of Management and Budget (OMB) approvals may require amendment or new approvals may need to be obtained. Requiring an annual BI&PD claims report should not appreciably add to the existing paperwork burden because the carriers are currently required to submit the claims information. However, a certification requirement will likely increase the costs associated with the preparation of the claims report.

National Environmental Policy Act

The agency has analyzed this action for the purpose of the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*) and has determined that this action would not have any effect on the quality of the environment.

Regulation Identification Number

A regulation identification 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 number contained in the heading of this document can be used to cross reference this action with the Unified Agenda.

List of Subjects in 49 CFR 387

Commercial motor vehicles, Hazardous materials transportation, Highways and roads, Insurance, Motor carriers, Motor vehicles safety, Penalties, Reporting and recordkeeping requirements, Surety bonds.

Issued on: September 11, 1997.

Gloria J. Jeff,

Acting Administrator.

Appendix

[The Appendix to this ANPRM should include the full text of the following three cases: (1) No. MC–128527, *May Trucking Company* (unpublished decision), served April 22, 1986; (2) No. MC–8535, *George Transfer-Application To Be A Self-Insurer* (unpublished decision), served September 24, 1986; and (3) No. MC–176440, *Direct Transit, Inc., Authorization to Self-Insure* (unpublished decision), served February 8, 1996].

Interstate Commerce Commission

[Decision No. MC–128527; Service Date: April 22, 1986]

May Trucking Company—Application To Be a Self-Insurer

Decided: April 16, 1986.

Subject to certain conditions, applicant authorized to self-insure bodily injury and property damage liability.

Summary of Decision

In this decision, the Commission is granting the application of May Trucking (May) to self-insure, under 49 U.S.C. 10927 and 49 C.F.R. 1043.5(a), its bodily injury and property damage liability subject to certain conditions.[1]

Background

In an application filed September 30, 1985, May Trucking Company (May) requested that the Commission allow it to act as a self-insurer for bodily injury and property damage (BI&PD) claims. No protest were filed. In a decision served December 9, 1985, May's application was denied by a majority of the Commission,[2] without prejudice to refiling by the carrier. On December 30, 1985, May filed a Petition to Reopen, requesting that the Commission vacate the prior decision and approve the application for self-insurance.

May's initial application and supplemental petition reveal that, as an irregular route common carrier of general commodities, it operates 275 tractors (175 of which are leased from owner-operators), and 550 trailers. It specializes in the transportation of frozen vegetables, dry grocery products, boxed meat, dairy products and paper goods and handles no highly hazardous materials. Its headquarters facility and terminal is located at Payette Idaho. It also has a terminal at Salem, Oregon, and one planned at Salt Lake City, Utah. The only direct employees of May are the Management and Administrative personnel. An unspecified number of company drivers are employees of Drivers' Employment Services, a wholly-owned subsidiary.[3] May is currently rated ''satisfactory'' by the Department of Transportation, Federal Highway Administration. As pertinent, May presently has a $3,000 deductible public liability policy and processes its own claims for collision and property damage liability under $5,000. In addition, United States National Bank of Oregon (National Bank) has established a $1 million credit line in the name of May which it indicates is dedicated to fund liability claims brought against the applicant.

As of December 31, 1984, May's financial statements reflect total assets of $9.0 million, including $5.2 million in current assets, of which $628,000 was reported as cash or cash equivalents. Its current liabilities amounted to $4.0 million and its total stockholders' equity was $3.4 million. (During 1984 it retained after-tax earnings of $700,000, bringing its retained earnings balance to $3.4 million). Its freight revenue in 1984 was $32.3 million out of its $41.2 million operating revenue, while its operating expenses amounted to $40.1 million. This yielded $1.0 million in operating earnings and net earnings of $700,000.

While not a part of the application, the quarterly financial report (QFR) filed by May for the fourth quarter 1985, shows that for 1985, the carrier generated a net operating profit of $172,000, down sharply from the operating profit it reported for the twelve months of 1984. The year to year decline in operating profit was due, in part, to a $501,000 or 50 percent increase in insurance expense. The fourth quarter 1984 and fourth quarter 1985 insurance expense increase of $291,000 accounted for the bulk of the annual increase of $501,000. May's reported net income of $419,000 for 1985 was achieved largely on the strength of a gain on the disposition of non-operating assets. May's QFR report also shows that, as of December 31, 1985, it has a balance of $8,000 in its cash account and had total stockholder equity of $3.8 million.

From September 1980 to September 1981, May had excess insurance limits extending to $15 million. From 1981 to September, 1984 the carrier had coverage to $25 million, at which time it increased its excess limits to $30 million. From 1980 through 1985, May's claims handled by insurance companies averaged $390,000 per year. In only two of those years, 1980–1 and 1983–4, did claims against it exceed $500,000.[4] Its 1984–5 claims handled by the insurance company amounted to $354,000. The average amount, in round numbers, of each claim, by year, was 1980–1, $23,000; 1981–2, $8,000; 1982–3, $10,000; 1983–4, $16,000; and 1984–5, $7,000. From the number of claims reported, it appears that few required a payout in excess of $25,000 and that none required a payment of more than $50,000. May states that none of its claims for the period September 1980–September 1985 required resort to its ''umbrella'' policies (*i.e.* coverage exceeding the $500,000 limit of its primary insurance during that time).

In its original application, May proposed to pay its liability claims from the $1 million line of credit maintained with National Bank. Despite the carrier's favorable loss history, its safety program, and its high credit rating, May's proposal was still considered inadequate to protect the public in certain key respects.

Specifically, the Commission rejected May's application for the following reasons. First, among other things, its proposed line of credit was revocable and, therefore, provided little protection for the public above May's ability to meet claims from current revenues. Also, May's proposal included no provisions for meeting obligations in the event of catastrophic occurrences. In the initial decision, the Commission set forth some guidance for any carrier seeking self-insurance authorization. The Commission indicated that any future application by May should include: a self-retention feature related to the carrier's recent claims experience; acceptable insurance to meet multiple occurrences above the self-insured retention levels; an irrevocable trust fund (also related to the carrier's claims experience), and information to allow the review of the retention levels, the carrier's loss adjustments, and loss reserves. Any future application was also to provide for periodic submission of statements of account, including profit and loss figures. May's Petition to Reopen addresses those specific concerns. In the Petition to Reopen May's offers to tie any authorization to self-insure to the carrier's maintenance of a minimum net worth. Further, May offers to convert the $1 million line of credit into an irrevocable line of credit. We believe that with May's suggested changes (and additional conditions that we will impose) May's application provides adequate protection to the public and should be granted.

Discussion

Any decision to allow self-insurance must reflect the carrier's ability to absorb both known predictable losses and unpredictable ones. Predictability is greatest at the lower claims levels. From our observations and knowledge of the claims experience of self-insured carriers the greatest frequency and predictability of losses for commercial auto BI&PD claims is in the $1–$10,000 range. May's recent claims experience fits within these limits. Each incremental step upward in claims typically has progressively fewer losses. However, to have the same degree of coverage through self-insurance as traditional insurance at a higher level of exposure to loss, the size of a motor carrier's operation must be significantly larger in scope. In this way we can to assured that adequate assets will be available to pay claims.

Self insurance is not new. See 49 C.F.R. 1043.5. However, most self-insurance programs previously approved by the Commission provide that losses that are not predictable are transferred to professional risk takers by way of insurance coverage. In the past, motor carriers that wanted to self-insure their BI&PD liability negotiated deductibles or self-retention levels in their policies of insurance. The level of self-insurance retention depended upon the size of the operation and on the carrier's financial strength. Motor carriers handled the great bulk of their ordinary claims at the lower levels of losses but insured against and passed on the unpredictable, severe losses to the insurance industry. These motor carriers met our security requirements by having insurance companies attach an endorsement to their policies of insurance and by filing our prescribed certificate of insurance (so-called ''accommodation'' filings) on behalf of carriers. The endorsement makes the insurance companies liable to the public from the first dollar of liability to the minimum limits set by law.

The current insurance crisis in the industry has resulted in a decrease in the availability

[1] The Commission's grant of this authority does not release May from its obligation to meet the financial responsibility regulations of the Department of Transportation (DOT). In this regard, we take official notice of May's recent filing with the DOT requesting a waiver of DOT's requirements to allow the carrier to self-insure.

[2] Although the prior decision is styled as also denying May's application to self-insure its cargo liability, May takes clear in the Petition to Reopen that it does not request such authority. May's Petition to Reopen, P. 7, note 3.

[3] May's 1984 Annual Report filed with the Commission fails to identify this company as an affiliate. However, we will require applicant to file information on any affiliate whose business is supportive of the operations of May trucking.

[4] Our analysis of the figures provided by May indicates that the aggregate claims against the carrier never exceeded $500,000 in any given calendar year. The figures submitted by May are based on a non-calendar year used by the carrier's insurance company.

of commercial auto BI&PD liability insurance coverage and a precipitous increase in insurance costs. Many insurance companies have withdrawn from underwriting motor carriers' insurance, while others have curtailed their underwriting. The severity of the increased costs of BI&PD coverage has been so unprecedented that some carriers have gone out of business, either unwilling or unable to increase freight rates or to pay the increased premiums. Additionally, it appears that many underwriters also are refusing to negotiate policies with higher deductibles or are not providing significantly reduced premiums for policies with high deductibles. For example, May's insurance premiums for primary BI&PD coverage increased from $398,855 for the year ending September, 1985, to $2.2 million for the year ending September 1, 1986. This increase in premium expense, however, is not based on any increase in losses paid by the insurance company. May's net profits for 1984 were only $700,000. Thus, it is faced with the real possibility of not being able to meet extraordinary insurance costs. May's history in this crisis is similar to many other motor carriers of property. As such, it presents the Commission with an example of the problem we face in meeting our responsibility to ensure that carriers have reasonable alternatives available to meet statutory security obligations, while not compromising our duty to ensure the existence of a safe motor carrier industry capable of paying all claims to the level required by law. See H.R. Rep. No. 96–1069, 96th Cong. 2d. Sess. 41 (1980) (''The purpose of [section 10927] is to create additional incentives to carriers to maintain and operate their trucks in a safe manner as well as to assure that carriers maintain an appropriate level of financial responsibility'').

Accordingly, while we must continue to ensure that motor carriers have sufficient security for the protection of the public, we will consider reasonable proposals to entirely self-insure. Such an approach is consistent with our broad authority in section 10927 to approve various types of security—and our obligation to promote a safe, efficient, and reasonably priced transportation system. 49 U.S.C § 10101. A carefully crafted proposal by a carrier to insure its own losses appears to be a reasonable method by which we can aid the industry without jeopardizing the public.

In order for the Commission to approve a motor carrier's application to self-insure its BI&PD liability, we must carefully weight the qualifications presented by the applicant against the protection to the public available in our prescribed insurance and surety programs. The prescribed insurance and surety programs give the public protection from the first dollar of liability up to our minimum requirements of $750,000, $1 million or $5 million per occurrence,[5] depending on the commodity transported.[6] There is, however, no requirement that a motor carrier like May obtain so-called ''umbrella'' coverage to cover claims exceeding its primary coverage. See 49 C.F.R. 1043.2(b)(2) and parallel DOT regulations at 49 C.F.R. 387.9.

In the initial application, May offered to establish a $1 million line of credit, dedicated to paying liability claims brought against it. In response to the Commission's objection that the letter of credit, without more, did little to enhance the protection of the public, May has amended the line of credit in two respects. First, the bank which issued the line of credit has made an irrevocable commitment to May to maintain the credit line until March 31, 1988. Second, the bank has agreed with May to notify the Commission If the credit line is drawn upon.

It is May's contention that these amendments to the line of credit significantly improve the protection being offered to the public. It further claims that the credit line is now for the full amount of financial responsibility required by the Commission.[7]

Moreover, May is willing to have its self-insurance conditioned on maintenance of at least $2 million in net worth (retained earnings and share-holders equity). The applicant intends to look to operating revenues as its first source of funds to pay liability claims. Its net worth, in excess of the $2 million, will function as its net source of funds. Finally, the $1 million irrevocable line of credit will be drawn upon as a last resort.[8] Thus, May has ensured that substantial sums of money will be available to pay claims.

We recognize that self-insurance plans will not necessarily afford the precise level of protection that customary insurance plans provide. In the normal situation, a carrier that is covered for $1 million in liability will be protected up to a million dollars for each accident. With the plan before us, however, we are convinced that the public will be adequately protected. Indeed, with the conditions that we will impose, May's plan should protect the public in a manner that is functionally equivalent to the protection provided under traditional insurance plans. We will require May to have and maintain a ''satisfactory'' safety rating as determined by the DOT, which is the highest possible rating. We will require the carrier to maintain a minimum net worth. If its net worth falls below this level, May's self-insurance authorization will automatically be terminated, unless the carrier corrects this situation within 30 days. The Commission will also monitor the carrier's financial condition and claims experience and revoke permission to self-insure should events occur that we believe could jeopardize its ability to pay future claims. See 49 C.F.R. 1043.9. We believe that, subject to these conditions designed to ensure the maintenance of assets necessary to pay all claims up to the level provided by law, May should be permitted to self-insure.

The imposition of these conditions allows the Commission to balance the needs of the public for a high level of security and the need of the public for an efficient, reasonably priced, and safe transportation system. Accordingly, we will approve the application subject to the following specific conditions.

First, May must submit to the Commission carrier quarterly and annual financial statements, as they become available, during the time the self-insurance, authorization is in effect. The financial statements (income statement, balance sheet and statement of changes in financial position) must include a certification by an appropriate May management official verifying the accuracy of the information provided in the statements. Financial disclosure is also required of affiliated companies which provide support services to the operations of May Trucking Company. These financial statements will provide up to date information on May's financial condition and thus will permit the Commission to ensure, among other things, that the net worth requirement is being maintained. In this regard, we will insist that if, at any time, the applicant's net worth balance falls below the $2 million minimum, this self-insurance authorization will automatically terminate unless within 30 days from the date of the notice, May corrects the situation or obtains other security for the protection of the public.

Second, May must file with the Commission carrier quarterly and annual claims reports, within two weeks of the close of the previous quarter, during the time the self-insurance authorization is in effect. These claims reports should detail the number, dollar amount and nature of May's claims experience. May must also provide the Commission with a quarterly report detailing pending court cases or other actions which relate to or arise from the claims experience. As with the financial statements, these claims reports must be certified as to their accuracy by an appropriate May management official.

Third, the carrier must notify the Commission *immediately* of any pending or contingent liability claim(s) which individually exceeds $50,000 or collectively exceed $250,000. If any of these reports or notices of liability claims indicate that the public is being jeopardized by May's failure to maintain an appropriate level of financial responsibility, May's self-insurance may be revoked.

Fourth, during the time the self-insurance authorization is in effect, May must have unrestricted access to the entire $1 million line of credit. In addition, drawdowns from the $1 million credit line may only be made to satisfy bodily injury and property damage claims. The Commission must be notified immediately of the specific purpose and amount of any May drawdown. Furthermore, we will require that May provide, at the time of the notice of the drawdown, a plan detailing how it proposes to respond to further liability claims. Again, should drawdowns suggest that May's financial

[5] 49 C.F.R. 1043.1 and .2. The term per occurrence means that the protection of the insurance company extends to all vehicles used in the interstate operation of the motor carrier for each accident which may occur during the life of the policy for the prescribed minimum limits. Thus, any approval to self-insure must ensure that the carrier can absorb both predictable losses and unpredictable ones.

[6] May advised that it transports commodities requiring a minimum coverage of $1 million.

[7] This is technically incorrect, as the $1 million statutory requirement is per occurrence and it has not been established that May's proposal offers identical coverage.

[8] May expects to pay BI & PD claims out of current earnings as it has in the past, thereby, obviating the need to replenish the funds available under its line of credit.

arrangements do not adequately protect the public, we will consider revocation of this authorization.

Fifth, the Commission must, at all times, be made aware of the terms and conditions under which the line of credit is being made available. In particular, the Commission must be notified no later than 90 days prior to the effective date of any change in the terms of the line of credit or its cancellation. Applicant is further required to notify the Commission of the renewal of the line of credit no later than 6 months prior to its expiration date.

Sixth, this application is granted with the express condition that the information required will be timely filed with the Commission. Any failure to timely file any of the information will subject the carrier to termination of its self-insurance authorization.

Seventh, we repeat that the Commission retains the authority to terminate May's self-insurance authorization at any time if, after notice and hearing, it appears to the Commission that applicant's financial arrangements fail to provide satisfactory protection for the public.

Eighth, the Commission retains the right to require May to submit any additional information that it deems necessary.

Finally, the Commission has reopened Ex Parte No. MC–178, *Investigation Into Motor Carrier Insurance Rates.* In that proceeding, interim rules are adopted pending completion of notice and comment on proposed final rules respecting many of the issues raised in May's application. That decision is being served today. Should any of the conditions required of May be inconsistent with any interim or final rules adopted in Ex Parte No. MC–178, May will be required to conform its financial arrangements to those rules.

Energy and Environmental Statement

This action will not significantly affect either the quality of the human environment or conservation of energy resources.

It is ordered: The application is granted subject to the conditions set forth in this decision.

(1) Applicant must submit carrier quarterly and annual financial statements to the Commission. The statements must include a certification by an appropriate May official verifying the accuracy of the information provided. Disclosure is also required of affiliated companies which provide support services for the operations of May Trucking Company;

(2) Applicant must file with the Commission quarterly claims reports detailing the number, dollar amount, and nature of its claims experience and quarterly reports detailing pending court cases which relate to or arise from the claims experience. These reports must be certified as to accuracy by an appropriate May official;

(3) Applicant must notify the Commission immediately of any pending or contingent liability claim(s) which individually exceeds $50,000 or collectively exceed $250,000;

(4) Applicant must maintain an irrevocable $1 million line of credit and must submit, within 15 days of the service date of this decision, a copy of any agreement with the bank covering the credit line; and notify the Commission immediately upon any drawdown on the line of credit; also May must have unrestricted access to the entire line of credit and drawdowns from the line of credit may only be made to satisfy BI & PD claims;

(5) At the time of any notification of any drawdown the applicant will also provide the Commission with a plan detailing how it proposes to respond to further liability claims;

(6) The applicant must notify the Commission no later than 90 days prior to the effective date of any change or cancellation of the line of credit and must notify the Commissioner of the renewal of the line of credit no later than 6 months prior to its expiration date;

(7) Applicant must maintain a new worth of at least $2 million and must notify the Commission at any time that the applicant's net worth falls below $2 million. The applicant will have 30 days to correct this situation or face termination of the authority to self-insure;

(8) The Commission retains the authority to terminate May's self-insurance authorization, at any time, if it appears to the Commission that applicant's financial arrangements fail to provide satisfactory protection for the public.

(9) This decision will be effective 30 days after service.

By the Commission, Chairman Gradison, Vice Chairman Simmons, Commissioners Sterrett, Andre, and Lamboley, Commissioner Lamboley would have granted the application subject to further clarification and conditions. Vice Chairman Simmons and Commissioner Andre commented with separate expressions.

James H. Bayne,

Secretary.

Vice Chairman Simmons, commenting:

Approval of May Trucking Company's self-insurance application in today's decision is grounded in a conclusion that the May proposal contains adequate safeguards for protection of the public. A necessary component of those safeguards is meaningful Commission monitoring of May's self-insurance program. At this time, I believe the commission possesses sufficient resources to carry out this oversight function. Depending on the number of other self-insurance applications filed and granted, however, current resources may not be adequate to maintain an appropriate level of oversight. If this situation arises, I will not hesitate to seek additional resources from Congress.

Commissioner Andre, commenting:

I am hopeful that we will be able to reduce the burden both on self-insurers and on this agency as we further develop these self-insurance procedures. It seems essential that the procedures be as simple as is consistent with maintaining protection for the public. However, I do not think it desirable to delay approval of this application any further.

Interstate Commerce Commission

[Docket No. MC–8535; Service Date: September 24, 1986.]

George Transfer, Inc.—Application To Be a Self-Insurer

Decided: September 18, 1986.

Subject to certain conditions, applicant authorized to self-insure bodily injury and property damage and cargo liability.

Summary of Decision

In this decision, the Commission is granting the application of George Transfer, Inc., (hereinafter ''George Transfer'' or ''Applicant'') to self-insure its automobile BI&PD liability for $1,000,000 and its cargo liability under 49 U.S.C. 10927 and 49 C.F.R. 1043.5(a), subject to certain conditions.

Background

George Transfer holds irregular route common and contract motor carrier authority from this Commission to transport general commodities throughout points in the United States. Approximately 90 percent of its traffic, however, involves the transportation of fabricated and processed metals and metal products. The applicant operated over 1,200 equipment units out of 29 terminals generating $34,000,000 of operating revenue in 1985. It uses owner-operators extensively in its motor carrier operations. Normally, they supply the power tractors, and the carrier supplies the trailers. The carrier's corporate headquarters is located at Parkton, Maryland. The applicant is not owned or controlled by any other corporation. It has two small subsidiaries, neither of which holds authority from this Commission.[1]

In support of its application, the carrier has submitted detailed financial statements prepared as of December 31, 1985. As of that date the carrier's balance sheet shows total assets of $12,310,290 and liabilities of $6,813,000. Current assets exceed current liabilities by $3,283,588. The carrier had a net worth of $5,497,779 as of that date. George Transfer generated total operating revenues of $34,776,494 in the calendar year ending December 31, 1985. Its net operating revenue was $761,168. It reported ordinary income before income tax of $509,649 and net income after taxes of $290,549. The operations of George Transfer were profitable in 1983 and 1984 as well as 1985.

Applicant states that it is safety conscious and expends considerable time and resources in developing safety awareness, The applicant's Safety Department is headed by a Safety Manager, who reports to its Director of Operations. This department is responsible for the overall safety program of the carrier. The program calls for a multifaceted approach to safety. Monthly safety meetings of drivers are held at each of the carriers' 29 terminals. Spot-check inspections of vehicles and of drivers' hours-of-service logs are required. Vehicles are required to be inspected every 30 days. Safe driving incentive awards are given to drivers with

[1] The two subsidiaries are George International Warehouse, Inc., which provides a warehousing service, and Marden Bros. Inc., which leases motor vehicles.

perfect driving records. Drivers are given intensive training in company and Department of Transportation safety requirements. New driver applicants are thoroughly screened by the carrier before they are hired. A complete background investigation is a part of this screening process, including contacts with past employers, reference checks, and verification of safe driving records. Applicant has a safety rating of ''satisfactory'' from the Department of Transportation. (Exhibit F to the application)

George Transfer has handled its own BI&PD and cargo liability claims in the past under self-retention insurance programs. If this application is granted, it plans to continue the same program. The only difference will be that an insurance company will not certify primary coverage with the Commission from the first dollar of liability.[2] Under the carrier's claims program, all claims are handled expeditiously. Claims reserves are established within ten days of reported accidents. Any claim with a possible liability exceeding $50,000 is reviewed monthly by its corporate attorney. The applicant is ready to supply the Commission with any reports detailing its financial condition and claims experience as a condition to the grant of self-insurance authority. The applicant offers to maintain a minimum net worth of $2 million dollars in order to ensure that funds will be available to pay liability claims. It also proposes, as an additional safeguard to the public, to establish trust funds for the payment of BI&PD and cargo liability claims. The BI&PD liability trust will be funded in the amount of $1,000,000; and the cargo fund will be funded in the amount of $250,000. Each fund will be irrevocable and used exclusively for the payment of designated claims liability. The trust funds may only be drawn upon when the carrier certifies to the trustee that it does not have sufficient operating funds to satisfy its BI&PD or cargo liability. If drawn upon, George Transfer will replenish the trust funds to the required minimum amounts within 30 days—$1,000,000 for BI&PD or $250,000 for cargo.

Applicant believes that a grant of self-insurance authority for its BI&PD and cargo liability is essential to its ability to continue profitable operations in the face of the current insurance crisis. Its insurance premiums for the present policy year, from May 1986 to May 1987, total $832,000. This represents more than a 400 percent increase over the previous policy year premiums of $201,000. This latter premium figure provided excess BI&PD and cargo liability coverage to $10,000,000. The current cost of $832,000 provides excess coverage only to $1,000,000. By the terms of the policy, the motor carrier is not permitted to handle third party liability claims, even though it has had eight years experience in this activity. It must absorb such losses up to its deductible amount and pay the insurance company a fee of 15 percent of the loss for handling the claim. The deductibles in the current policy are $250,000 per occurrence for BI&PD and $150,000 per occurrence for cargo. The applicant stresses that these increases in premiums and reductions in coverage have been made despite the fact that the carrier has paid all of its BI&PD and cargo claims over the past five years. Stated another way, the insurers of George Transfer have paid no claim under their excess policies because all losses feel within the motor carrier's self-retention level.

The applicant conducted an exhaustive search for renewal coverage before accepting the terms of its present insurance company. Ten insurance companies simply made no response to the carrier. Several would not consider primary coverage. One offered coverage up to $1,000,000 at an annual premium of $2,500,000. Another offered the same coverage but at a premium of $3,000,000. Several others told the carrier that they simply refused to consider underwriting any motor carrier risk. The carrier estimates that it will save $900,000 a year in costs if is permitted to self-insure.

The following tables provide details as to the loss experience of George Transfer over the past five years:

TABLE I.—AUTOMOBILE BODILY INJURY AND PROPERTY DAMAGE LIABILITY

Policy year	Average claim amount	Number of claims	Total claim expense
1981–1982	$4,971	110	$546,828
1982–1983	2,420	96	232,274
1983–1984	3,879	105	407,274
1984–1985	8,219	120	986,333
1985–1986	3,059	105	321,181
5 year average	4,510	107	498,778

TABLE II.—CARGO LIABILITY

Policy year	Average claim amount	Number of claims	Total claim expense
1981–1982	$3,045	64	$194,939
1982–1983	1,880	47	88,395
1983–1984	1,621	60	97,245
1984–1985	6,283	42	263,903
1985–1986	4,658	38	177,015
5 year average	3,497	50	164,300

Discussion

George Transfer, we believe, has presented a strong case for authority to self-insure its BI&PD and cargo liability. It has more than adequate financial qualifications. The company has strong cash and working capital positions. A positive working capital position is important as it indicates that the carrier can meet its current obligations from its current assets. Furthermore, its debt to debt plus equity ratio is favorable. In addition, it has handled its own BI&PD and cargo liability claims for a number of years and is capable of doing so in the future under a Commission approved self-insurance program. It also has an active and successful safety program, which it intends to maintain.

In our prior decisions, we have taken a conservative approach to the question of permitting motor carriers to self-insure their

[2] The deductible or self-retention level is a binding condition between the insurance company and its motor carrier insured, not the public. The Commission's prescribed BI&PD and cargo insurance forms override the policy terms and conditions and give the public protection from the first dollar of liability up to the required minimum limits. In the case of George Transfer, the commodities it transports requires the carrier to maintain a minimum BI&PD limit of $1,000,000 per occurrence and a cargo limit of $5,000 per vehicle, $10,000 aggregate per occurrence. 49 C.F.R. 1043.2.

BI&PD and cargo liability.[3] We are charge by the act to provide adequate security for the protection of the public. See 49 U.S.C. 10927. Because of this, the Commission has been, and will continue to be, very selective in approving carriers to exercise this privilege.

As we stated in MC–128527, *May Trucking Company, supra,* ''(A) carefully crafted proposal by a carrier to self-insure its own losses appears to be a reasonable method by which we can aid the industry without jeopardizing the public.'' We believe that the application by George Transfer meets these criteria. We will approve this application subject to certain conditions necessary to ensure that there is adequate protection for the public.

In our view, the minimum net worth requirement and the trust funds offered by applicant are such as will provide the type of protection we seek for the public. The net worth requirement will ensure protection against unpredictable claims. Moreover, the trust fund is an easily understood and easily monitored financial arrangement for establishing a means to compensate the public in the case of any accident. However, in order to ensure the protection of the public to the greatest extent possible we will require some modifications in the terms and language of the trust agreements. An explanation of these modifications and our rationale for these changes follows.

The trustees appointed by George Transfer, Inc. are Joseph Kiel and T. Bernard Williams. Mr. Kiel is apparently George Transfer's house counsel with the responsibility for reviewing personal injury and property damage claims. However, Mr. Williams is not further identified. Although we have no reason to believe the trustees are not legally competent, we believe that they should be further identified to the extent of describing their relationship to the applicant and their business addresses so the Commission will know who will have legal title to the trust money and how they may be contacted.

Similarly, we believe that the beneficiaries of the trusts should be more clearly designated. The reason for this designation is to prevent claims on the trust funds from creditors other than persons who have BI&PD and cargo claims.

Generally, creditors of a beneficiary who has an interest in a trust can subject the beneficiary's interest in the trust to satisfaction of a debt. The purpose of the trust fund created here is the payent of BI&PD claims. As established, the trustee will transfer funds to George's Transfer when applicant certifies its inability to pay the involved claims. George's Transfer will presumably pay the claims with the trust funds. The arrangement may present a problem. The settlor's (George's Transfer) continuing involvement could complicate a determination as to who is the intended beneficiary of the trust. Additionally, it creates a potential for abuse because George's Transfer will actually have possession of the funds. Applicant's possession of the funds subjects them to potential attached by George Transfer's other creditors because of the applicant's continuing interest.

To avoid any potential misconstruction and abuse we will require the applicant to revise the agreements to identify explicitly BI&PD and cargo claimants as the intended beneficiaries. Specifically, the class of beneficiaries under the cargo trust agreement should be more clearly defined, in paragraph 3 of the cargo trust agreement, ''to retire claims of persons or corporations for loss and damage to cargo arising as a result of transportation provided by George's Transfer.'' Further, both the cargo trust and liability trust agreements should be revised to provide that payment will be made to such claimants directly rather than to George's Transfer. This should be accomplished by modifying the liability trust agreement (paragraph 3, line 10) and the cargo trust agreement (paragraph 3, lines 7–8) deleting, ''Grantor funds to meet such obligations'' and inserting, ''claimants identified by the Grantor sufficient funds to meet such obligation.''

Moreover, in order to insure that the trust agreements will not be subject to attachment by George Transfer's creditors in any bankruptcy proceeding we will require the agreements be further modified (paragraph 3, line 10 in the liability trust agreement and paragraph 3, line 8 in the cargo trust agreement) in the following manner: After ''obligations'' insert: ''The payment of those funds to claimants is solely and exclusively for settlement of outstanding claims. Those claims shall be paid from the trust fund irrespective of the financial responsibility or lack thereof or insolvency or bankruptcy of the Grantor''.

Finally, we address the issue of revocation. Each trust is irrevocable ''so long as the Grantor continues to insure itself.'' However, this construction of the trust could present a problem. For example, if applicant ceased to perform operations it might no longer be insuring itself and the trust fund would be dissolved, yet there might be claims outstanding against it which it would not be able to pay. In order to ensure that trust fund assets will be applied to these outstanding claims, we require the following language added after the first sentence in paragraph 9 of both agreements: ''Notwithstanding the preceding sentence, this trust shall not be revoked until all legally cognizable claims arising prior to the date Grantor ceases to insure itself have been settled. The purpose of this provision is to insure that these funds are available to reimburse claimants who present their claims within the time allowable by the applicable statute of limitations before residual funds, if any, may be returned to the Grantor upon termination of the trust.''

Subject to these modifications, we will accept the applicant's offer to establish a trust fund in the amount of $1,000,000. We emphasize the fact that this trust fund will be utilized only for payment for liability claims. Further, we will require that applicant keep the Commission informed about the trust, its maintenance and operation, at all times. Finally, the trust fund will be replenished to the required minimum amount after each drawdown.

Applicant seeks authority to self-insure its cargo liability as well as its BI&PD liability. Our insurance rules provide for this type of self-insurance. 49 C.F.R. 1043.5. The standard for granting an application for self-insurance for cargo liability is the same as that for BI&PD liability. Namely, that the carrier ''will furnish a true and accurate statement of its financial condition and other evidence which will establish to the satisfaction of the Commission the ability of such carrier to satisfy its obligation for * * * cargo liability without affecting the stability or permanency of the business of such motor carrier.''

As demonstrated above, applicant has the ability to self-insure its cargo liability claims as well as its BI&PD claims. The present minimum security requirements for cargo is $5,000 or $10,000 for aggregate losses. 47 C.F.R. 1043.2(c). George Transfer's current self-insurance retention program has required it to pay all claims under $250,000 for the last five years. The claims chart reproduced above also shows that there have been no claims in excess of that amount during that period. In fact, in the last five years, George Transfer has not had a cargo claim exceed $40,000. Thus, in reality George Transfer has been self-insured for its cargo liability for several years. In granting its application for self-insurance with respect to cargo liability, we are doing nothing more than allowing the carrier to continue its present practice, albeit without an insurance company intermediary between the public and the applicant. The record before use shows that George Transfer has the qualifications necessary to self-insure its cargo liability, and we approve its application subject to the conditions set forth below.

As in the case of its BI&PD liability, applicant has offered to establish a separate trust fund of $250,000 for the sole purpose of the payment of claims attributable to cargo loss or damage. This trust fund will be utilized in the event that George Transfer is unable to pay claims from operating revenues. Notably, the amount of this fund will equal the present coverage of George Transfer's existing policy. We will accept the applicant's offer to establish a trust fund for the payment of cargo claims subject to the conditions set forth above in the discussion of the liability trust fund.

Findings

Given the carrier's financial position, its claims history and experience and its safety record we find that the establishment of these trust funds with the conditions discussed above will provide protection for the public. Therefore, we accept George Transfer's offer to establish these trust funds. We emphasize that these funds will be utilized only for payment of BI&PD and cargo liability claims. Further, we will require that applicant keep the Commission informed about the trusts, and their maintenance and operation, at all times. Finally, the trust funds will be replenished to the required minimum amount after each drawdown. In addition, we will impose the following conditions on this grant of self-insurance authority.

Applicant must submit to the Commission a carrier quarterly and annual financial

[3] Ex Parte No. MC–5, *Motor Carrier Insurance for the Protecting of the Public,* 1 MCC 45, 58 (1936); MC–128527, *May Trucking Company—Application to be a Self-Insurer (not printed);* and *Ex Parte No. MC–178, Investigation Into Motor Carrier Insurance.*

statements, as they become available, during the time the self-insurance authorization is in effect. The financial statements (income statement, balance sheet and statement of changes in financial position) must include a certification by an appropriate management official verifying the accuracy of the information provided in the statements. These financial statements will provide up to date information on the carrier's financial condition.

Further, applicant must file with the Commission carrier quarterly and annual claims reports, within two weeks of the close of the previous quarter, during the time the self-insurance authorization is in effect. These claims reports should detail the number, dollar amount and nature of George Transfer's claims experience. As with the financial statements, these claims reports must be certified as to their accuracy by an appropriate management official.

Additionally, the carrier must notify the Commission immediately of any pending or contingent liability claim(s) which individually exceeds $50,000 or collectively exceed $250,000. If any of these reports or notices of liability claims indicate that the public is being jeopardized by the carrier's failure to maintain an appropriate level of financial responsibility, George Transfer's, self-insurance may be revoked.

Moreover, the Commission must, at all times, be made aware of the terms and conditions under which the trust agreements are operating. In particular, the Commission must be notified no later than 90 days prior to the effective date of any change in any of the terms of the trust or its cancellation.

The application is granted with the express condition that the information required will be timely filed with the Commission. Any failure to timely file any of the information will subject the carrier to notice of termination of self-insurance authorization.

Finally, the Commission retains the authority to terminate applicant's self-insurance authorization at any time if, after notice and hearing, it appears to the Commission that applicant's financial arrangements fail to provide continued satisfactory protection for the public.

It is ordered: The application is granted subject to the conditions set forth in this decision.

(1) Applicant must submit carrier quarterly and annual financial statements to the Commission. The statements must include a certification by an appropriate applicant official verifying the accuracy of the information provided. Financial disclosure is also required of affiliated companies which provide support services for the operations of the motor carrier.

(2) Applicant must file with the Commission quarterly claims reports detailing the number, dollar amount, and nature of its claims experience and quarterly reports detailing pending court cases which relate to or arise from the claims experience. These reports must be certified as to accuracy by an appropriate carrier official;

(3) Applicant must maintain a net worth of at least $2 million dollars and must notify the Commission at any time that the applicant's net worth falls below $2 million dollars.

(4) Applicant must establish a trust fund in the amount of $1,000,000 for the payment of BI&PD liability claims and one in the amount of $250,000 for the payment of cargo liability claims as set forth in Exhibits ''G'' & ''H'' attached to its application and as modified in this decision. The trust funds must be irrevocable and used only for the payment of its BI&PD or cargo liability. If drawn upon, applicant must contribute to the trust fund, within a period of 30 days after the date on which the trust funds are used to retire claims, sufficient cash to increase the BI&PD trust fund to the $1,000,000 minimum. or the cargo trust fund to the $250,000 minimum. The executed trust fund agreements, must be submitted within 15 days of the service date of this decision. Any changes in their terms must be given prior approval by the Commission. Furthermore, any draw down on these funds and failure to replenish within 30 days must be reported immediately to the Commission, along with an explanation as to how it proposes to respond to further BI&PD or cargo claims.

(5) Applicant must notify the Commission immediately of any pending or contingent BI–PD liability claim(s) which individually exceeds $50,000 or collectively exceed $250,000; and any pending or contingent cargo liability claims which exceed $50,000 individually or $100,000 collectively.

(6) The Commission retains the authority to terminate George Transfer's self-insurance authorization, at any time, if it appears to the Commission that applicant's financial arrangements fail to provide satisfactory protection for the public.

(7) This decision will be effective 30 days after service.

Energy and Environment Statement

This action will not significantly affect either the quality of the human environment or the conservation of energy resources.

By the Commission, Chairman Gradison, Vice Chairman Simmons, Commissioners Sterrett, Andre and Lamboley.

Noreta R. McGee,

Secretary.

Federal Highway Administration

[Docket No. MC–176440; Service Date: February 8, 1996]

Decision; Direct Transit, Inc. (North Sioux City, SD); Authorization To Self-Insure

Decided: February 8, 1996.

By decision of the former Interstate Commerce Commission (Commission) served May 25, 1995, Direct Transit Inc. (Direct) was authorized to self-insure its bodily injury and property damage (BI&PD) liability subject to certain conditions. The self-insurance authorization was activated on August 1, 1995. As a result of a safety audit conducted by the Federal Highway Administration (FHWA), Direct was notified that it was assigned an ''Unsatisfactory'' safety rating effective January 12, 1996.

Section 1043.5(a)(3) of Title 49 of the Code of Federal Regulations governing qualifications for a self-insurer, provides in part:

Any self-insurance authority granted by the Commission will automatically expire 30 days after a carrier receives a less than satisfactory rating form the U.S. Department of Transportation (DOT).

Direct's self-insurance authorization will expire automatically on February 11, 1996.

By virtue of the ICC Termination Act of 1995, P.L. 104–88, the responsibility for making determinations regarding the self-insurance program and all authorizations pursuant thereto was vested in the Secretary of Transportation, and subsequently by delegation, in FHWA.

By a petition filed February 6, 1996 with FHWA, Direct seeks a waiver of the automatic termination provision and an emergency extension of its self-insurance authorization for a period of 30 days or until it is issued a ''Satisfactory'' safety rating, whichever occurs first.

In support of its petition, Direct contends that the automatic termination provision is inappropriate and will simply penalize the carrier by increasing its insurance premiums. While acknowledging that the ''Satisfactory'' safety rating requirement is justifiable in most circumstances, the carrier claims nonetheless that the public is protected and that it is not in the public interest to invoke the automatic termination rule in this instance. Direct maintains that automatic termination should apply only to a ''withering and desperate carrier''. (Petition at 7).

Direct's arguments are groundless and disturbing. In developing the self-insurance requirements, the Commission recognized the possibility that ''Unsatisfactory'' or ''Conditional'' ratings militate against allowing an applicant to self-insure because such ratings indicate operations that might result in a higher than average claims experience or the potential for substantial liability, both of which could adversely affect a carrier's ability to indemnify claimants. *Investigation Into Motor Car. Insurance Rates,* 3 I.C.C. 2nd 377,379 (1987). The Commission further noted, ''It is also consistent with our intent that safe operations serve as the touchstone for any self-insurance authorization.''*Id.* at 384. The 30-day expiration provision was implemented because ''a diminution in a carrier's safety status would warrant immediate reexamination of self-insurance authority.'' *Id.* at 385.

Direct, having begun self-insured operations only several months ago, has too short a track record to trumpet the success of its program and can hardly profess that the public will be protected based on that meager record. The Commission's self-insurance requirements were imposed ''to guarantee that a carrier can meet its financial responsibility to the public''. *Id.* at 380. Carriers that conduct unsafe operations cannot make such guarantees. The issue before me concerns the relationship between unsafe operations and self-insurance. I reject Direct's contention that the payment of premiums for additional commercial insurance coverage is a relevant factor. I also note that the circumstances surrounding this matter do not appear to justify the eleventh-hour filing of Direct's petition.

It should come as no surprise that FHWA, the agency charged with ensuring safe

operation of commercial vehicles on our Nation's highways, will continue to insist that all carriers operating with self-insurance authority maintain ''Satisfactory'' safety ratings. Nevertheless, I will authorize an extension of the self-insurance authorization to March 7, 1996 for the sole purpose of conducting another compliance review of the carrier's operations.

Direct should understand that failure to obtain a ''Satisfactory'' safety rating during the extension period will not provide support for a further extension. Accordingly, the carrier should begin the process of securing commercial insurance coverage in the event its self-insurance authorization terminates.

It is ordered: 1. A waiver of the automatic 30-day period for expiration of petitioner's self-insurance authority and an extension of the self-insurance authorization until March 7, 1996, is hereby granted.

2. The terms and conditions of the self-insurance authorization activated August 1, 1995, will remain in effect throughout the extension period.

3. As of 12:01 A.M. on March 8, 1996, in the absence of the issuance of a ''Satisfactory'' safety rating, Petitioner's self-insurance authorization will terminate without further order of the FHWA.

4. A copy of this decision is to be filed in Docket No. MC–176440 and all sub numbers thereunder.

5. This decision is effective when served.

By the Federal Highway Administration.

John F. Grimm,

Director, Office of Motor Carrier Information Analysis.

[FR Doc. 97–24714 Filed 9–22–97; 8:45 am]

BILLING CODE 4910–22–P–M

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

49 CFR Part 571

Denial of Petition for Rulemaking; Federal Motor Vehicle Safety Standards

AGENCY: National Highway Traffic Safety Administration (NHTSA); Department of Transportation.

ACTION: Denial of petition for rulemaking.

SUMMARY: This notice denies the petition by John Chevedden for the issuance of a mandatory Federal regulation that would require all new cars to be manufactured with windshield edge coating in the space between the center rear view mirror and the lowered sun visors. The petitioner stated that this will prevent blinding glare from the sun in the early morning and late afternoon. According to the petitioner the targeted windshield coating is currently standard on the Hyundai Accent. Based upon the information provided by the petitioner and other information available to NHTSA, the agency has concluded that there is insufficient evidence to support a mandatory Federal requirement that all new cars be manufactured with a windshield shade band that is identical to the shade band currently installed on the Hyundai Accent.

FOR FURTHER INFORMATION CONTACT: Kenneth O. Hardie, Safety Performance Standards, NHTSA, 400 Seventh Street, SW, Washington, DC 20590. Mr. Hardie's telephone number is (202) 366–6987.

SUPPLEMENTARY INFORMATION: By letter dated May 21, 1997, John Chevedden of Redondo Beach, California, petitioned NHTSA to issue a new rule that would require that all new cars be manufactured with windshield edge coating in the space between the center rear view mirror and the lowered sun visors. Mr. Chevedden's petition stated that the targeted windshield coating is currently standard on the Hyundai Accent. Mr Chevedden stated that this will prevent blinding sun glare and enhance safety by reducing collisions in the early morning and late afternoon sun.

The specific area of the windshield that Mr. Chevedden's petition addresses is called the ''glazing shade band,'' *i.e.*, the area immediately adjacent to and below the top edge of the vehicle glazing, through which light transmission is less than that required for glazing that are requisite for driving visibility, as defined in ANSI Z26.1. ANSI Z26.1 is the *American National Standard for Safety Glazing Materials for Glazing Motor Vehicles Operating on Land Highways; Safety Code.* Examples of shade bands are:

a. Laminated Safety Glass—A color band in the laminated product formed by the application of a dye or pigment to the interlayer material prior to lamination.

b. Tempered Safety Glass—A pattern comprised of lines and spaces, or dots and voids, printed into the glass surface from a durable opaque or translucent material.

Mr. Chevedden asked that all new cars be required to be manufactured with a windshield edge coating (windshield shade band) identical to that which is installed on the Hyundai Accent. Federal law requires that the area of window requisite for driving visibility have light transmittance of not less than 70%. Motor vehicle manufacturers place a mark on the windshield designating the AS1 line. The windshield below that line is ''requisite for driving visibility'' and must comply with the 70% light transmittance requirement. Federal law does not specify any minimum light transmittance for the windshield above the AS1 line. Thus, manufacturers are free to install any shade band design they choose above that line.

In addition to the Federal limit that windshield shade bands can only extend down to the AS1 mark, there are some States that have motor vehicle regulations that prohibit the windshield shade band from extending downward from the top edge of the vehicle by more than six inches. Further, there is a voluntary standard for windshield shade bands promulgated by the Society of Automotive Engineers (SAE). This SAE standard is SAE J100, *Vehicle Glazing Shade Bands.* Although the use of the SAE Standards by anyone in the automotive industry is entirely voluntary, SAE standards are widely used by the automotive industry. All SAE Standards are submitted to the American National Standards Institute for recognition as American National Standards.

Mr. Chevedden petitioned to change the status quo and make the Hyundai Accent shade band design mandatory for all new cars, light trucks and sport utility vehicles. While NHTSA has carried out many suggestions from concerned citizens regarding motor vehicle safety, to change or impose a new Federal motor vehicle safety standard, NHTSA must present information to the public demonstrating that there is a safety problem with the current situation and that the proposed solution will address the problem and improve safety in a cost effective way. The petitioner provided no information to support his contention that there is a safety problem with the current situation or that his proposed solution will improve safety in a cost effective manner. NHTSA has no information indicating that the Hyundai Accent windshield shade band design is more effective than any other vehicle that is equipped with a windshield shade band, nor does the agency possess information regarding the efficacy of any shade band in reducing motor vehicle-related deaths and injuries. Absent such information, NHTSA has no basis for initiating a rulemaking proceeding.

After carefully considering the petition, NHTSA concludes that there is not a reasonable possibility that the order requested by the petitioner would be issued at the conclusion of a rulemaking proceeding. Accordingly, the petition is denied.

Authority: 49 U.S.C. 30103, 30111, 30162; delegations of authority at 49 CFR 1.50 and 501.8.

Issued on: September 17, 1997.

L. Robert Shelton,

Associate Administrator for Safety Performance Standards.

[FR Doc. 97–25209 Filed 9–22–97; 8:45 am]

BILLING CODE 4910–59–P

Notices

Federal Register

Vol. 62, No. 184

Tuesday, September 23, 1997

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

Forest Service

Notice of Intent To Prepare a Revised Environmental Impact Statement, Port Houghton/Cape Fanshaw Timber Sale(s), Tongass National Forest, Stikine Area and Chatham Area, Petersburg and Sitka, Alaska

AGENCY: Forest Service, USDA.

ACTION: Notice of intent.

SUMMARY: The Department of Agriculture, Forest Service will prepare a Revised Draft Environmental Impact Statement for the Port Houghton/Cape Fanshaw Timber Sale(s) located on the Stikine Area and the Chatham Area of the Tongass National Forest. This notice of intent revises the notice of intent published September 12, 1994, (page 48619) and the Notice of Intent published August 14, 1995, (page 41872) by describing changes to the purpose and need, proposed action and the schedule for the decision. A Revised Draft Environmental Impact Statement is being prepared to respond to the new land use designations, management direction, and standards and guidelines of the Tongass National Forest Land and Resource Management Plan (Forest Plan) released in May 1997.

DATES: Comments concerning the scope of the analysis or significant issues regarding the proposal to build roads and harvest timber in the Port Houghton/Cape Fanshaw Project Area should be received in writing by October 17, 1997.

ADDRESSES: Send written comments to Michael J. Weber, USDA Forest Service, 204 Siginaka Way, Sitka, AK 99835.

FOR FURTHER INFORMATION: Questions concerning the proposed action and Environmental Impact Statement should be directed to Michael J. Weber, Interdisciplinary Team Leader, phone: (907) 747–6671, fax: (907) 747–4331.

SUPPLEMENTARY INFORMATION: The Port Houghton/Cape Fanshaw Project Area includes Value Comparison Units 79 through 89 on the mainland in Southeast Alaska approximately 30 miles north of Petersburg, Alaska, and 80 miles south of Juneau, Alaska.

The Tongass National Forest Land and Resource Management Plan of May 1997 provides the overall guidance (land use designations, goals, objectives, management prescriptions, standards and guidelines) to achieve the desired future condition for the area in which this project is proposed. This revised Forest Plan allocates portions of the project area to six management prescriptions (Timber Production, Modified Landscape, Scenic Viewshed, Old-growth Habitat, Semi-remote Recreation, and Research Natural Area). Furthermore, the new standards and guidelines in the revised Forest Plan provide increased protection for riparian areas, wolves, and wetlands which conflict with activities proposed and analyzed in the Draft Environmental Impact Statement published in December 1995. The Revised Draft Environmental Impact Statement for the Port Houghton/Cape Fanshaw Timber Sale(s) will now tier to the Final Environmental Impact Statement for Tongass Land Management Plan Revision of May 1997 and be consistent with the revised Forest Plan.

The purpose and need for the project is to respond to the goals and objectives identified by the Forest Plan for the timber resource and to move the Port Houghton/Cape Fanshaw Project Area toward the desired future condition. The Forest Plan identified the following goals and objectives: (1) Manage the timber resource for production of saw timber and other wood product from suitable timber lands made available for timber harvest, on an even-flow, long-term sustained yield basis and in an economically efficient manner (Forest Plan page 2–4); (2) seek to provide a timber supply sufficient to meet the annual market demand for Tongass National Forest timber, and the demand for the planning cycle (page 2–4); and (3) maintain and promote industrial wood production from suitable timber lands, providing a continuous supply of wood to meet society's needs (page 3–144). The Port Houghton/Cape Fanshaw Project will be designed to produce desired resource values, products, and conditions in ways that also sustain the diversity and productivity of ecosystems (page 2–1).

The Port Houghton/Cape Fanshaw Project is now expected to provide a range of volume to the timber industry in three or more timber sales. The actual range of alternatives considered in the Environmental Impact Statement will be determined during analysis and will reflect issues raised during scoping.

The Proposed Action provides for: (1) Construction of approximately 80 miles of road; (2) harvest of approximately 6,000 acres of timber in several timber sales; and, (3) construction of a long transfer facility in Little Lagoon and use of the existing log transfer facility in Hobart Bay. This level of development would result in the harvest of approximately 120 million board feet of sawlog and utility timber volume.

A number of public comments have been received on this project. Based on comments from the public and other agencies during the original scoping effort and the public comment period on the original Draft Environmental Impact Statement, the following significant issues have been identified:

(1) What changes may be anticipated in the character of the timber resource?

(2) To what extent are alternative silvicultural treatments proposed, and what are the benefits?

(3) What will be the effect of log transfer facility development on marine resource values?

(4) What change in wildlife habitat capability would occur with implementation of the project?

(5) What changes will occur in habitat and plant and animal diversity?

(6) What will be the effect of timber harvest and transportation system development on the fish habitat?

(7) What effect will timber harvest have on soil stability?

(8) How will timber harvest affect subsistence fishing, hunting and gathering opportunities?

(9) What visual and recreational changes will affect both local and tourist use and enjoyment?

(10) What are the basic economic values that can be expected with the project?

These issues are being used to design alternatives to the proposed action and to identify the potential environmental effects of the proposed action and

alternatives. The Revised Draft Environmental Impact Statement is scheduled for publication in March 1998 and the Final Environmental Impact Statement and Record of Decision is schedule for publication in August 1998.

The Forest Service believes, at this early stage, it is important to alert reviewers about several court rulings related to public participation in the environmental review process. First, reviewers of Draft Environmental Impact Statements must structure their participation in the environmental review of the proposal so that it is meaningful and alerts an agency to the reviewer's position and contentions. *Vermont Yankee Nuclear Power Corp.* v. *NRDC,* 435 U.S. 519, 553 (1978). Also, environmental objections that could be raised at the Draft Environmental Impact Statement may be waived or dismissed by the courts. *City of Angoon* v. *Hodel,* 803 F.2d 1016, 1022 (9th Cir. 1986) and *Wisconsin Heritages, Inc.* v. *Harris,* 490 F. Supp. 1334, 1338 (E.D. Wis. 1980). Because of these court rulings, it is important that those interested in this proposed action participate by the close of the Draft Environmental Impact Statement 45 day comment period so that substantive comments and objections are made available to the Forest Service at a time when it can meaningfully consider them and respond to them in the Final Environmental Impact Statement.

Dated: September 11, 1997.

Particia A. Grantham,

Acting Forest Supervisor, Stikine Area.

Dated: September 12, 1997.

Gary A. Morrison,

Forest Supervisor, Chatham Area.

[FR Doc. 97–25176 Filed 9–22–97; 8:45 am]

BILLING CODE 3410–11–M

DEPARTMENT OF AGRICULTURE

Forest Service

Olympic Provincial Interagency Executive Committee (PIEC), Advisory Committee

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Olympic PIEC Advisory Committee will meet on October 17, 1997 at the Olympic Forest Headquarters Building located at 1835 Black Lake Blvd., SW., Olympia, Washington. The meeting will begin at 9:30 a.m. and continue until 3:00 p.m. Agenda items to be covered include: (1) Review and discussion of revised Olympic Adaptive Management Area Guide; (2) Province Restoration Effectiveness Monitoring Update from Committee; (3) Potential timber harvest from non-regulated areas; (4) Review and Validation of Implementation Monitoring Report; (5) Open Forum and (6) future agenda topics. Interested citizens are encouraged to attend.

FOR FURTHER INFORMATION CONTACT:

Direct questions regarding this meeting to Kathy Snow, Province Liaison, USDA, Quilcene Ranger District, P.O. Box 280, Quilcene, WA 98376, (360) 765–2211, or Ronald R. Humphrey, Forest Supervisor, at (360) 956–2300.

Dated: September 17, 1997.

Ronald R. Humphrey,

Forest Supervisor.

[FR Doc. 97–25172 Filed 9–22–97; 8:45 am]

BILLING CODE 3410–11–M

DEPARTMENT OF AGRICULTURE

Forest Service

Southwest Oregon Provincial Interagency Executive Committee (PIEC), Advisory Committee

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Southwest Oregon PIEC Advisory Committee will meet on October 7 at the Oregon State Extension Office, on Hanley Road, Central Point Oregon. The meeting will begin at 9:00 a.m. and continue until 5:00 p.m. Agenda items to be covered include: (1) Marbled Murrelet habitat; (2) Monitoring (3) Regional Ecosystem Office presentation; (4) Forest Service and Bureau of Land Management local issues; and (5) Mining/riparian issues. All Province Advisory Committee meetings are open to the public.

FOR FURTHER INFORMATION CONTACT:

Direct questions regarding this meeting to Chuck Anderson, Province Advisory Committee staff, USDA, Forest Service, Rogue River National Forest, 333 W. 8th Street, Medford, Oregon 97501, phone 541–858–2322.

Dated: September 16, 1997.

James T. Gladen,

Forest Supervisor, Designated Federal Official.

[FR Doc. 97–25205 Filed 9–22–97; 8:45 am]

BILLING CODE 3410–11–M

DEPARTMENT OF COMMERCE

Bureau of the Census

National Employers Survey—4 (NES–4)

ACTION: Proposed collection; comment request.

SUMMARY: The Department of Commerce, 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, Pub. L. 104–13 (44 U.S.C. 3506(c)(2)(A)).

DATES: Written comments must be submitted on or before November 24, 1997.

ADDRESSES: Direct all written comments to Linda Engelmeier, Departmental Forms Clearance Officer, Department of Commerce, Room 5327, 14th and Constitution Avenue, NW., Washington, DC 20230.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument(s) and instructions should be directed to Michael Hartz, U. S. Bureau of the Census, Room 2538–3—EPCD, Washington, DC 20233–6100; (301–457–2633).

SUPPLEMENTARY INFORMATION:

I. Abstract

The Census Bureau conducted three earlier National Employers Surveys (1994, 1995 and 1997) for the National Center on the Educational Quality of the Workforce (EQW), a nonprofit research group. This group's focus is discovering relationships among employment, hiring, training, education, and business success. This information collection seeks to build upon the results of the previous surveys.

This information collection seeks to gather information on employees' histories and to identify employees' perceptions regarding employer-provided training and job-related educational requirements. The collection will relate these employees' responses to similar information collected previously from employers in the 1997 National Employers Survey (NES–3). The purpose is to identify those areas where employee and employer views are similar and where they are different. This information then would be used to suggest areas where additional emphasis regarding employer job requirements are needed to enable potential employees to qualify for employment.

This new survey will be a mail questionnaire, to be sent to approximately 6,000 employees of a sample of companies that responded to the NES–3. The questionnaire will include about 40 questions that solicit employees' views regarding employment qualifications and training opportunities available to them that relate to their employment. These survey questions are constructed to eliminate the need for respondents to review any records relating to the subject of this collection. We expect that each respondent completing the questionnaire will spend about 20 minutes.

II. Method of Collection

The Bureau of the Census will conduct the NES–4 survey using a mail questionnaire. This questionnaire will be sent to approximately 6,000 employees (at random) of companies that provided information for the NES–3 survey. The questionnaire will consist of approximately 40 questions. Most questions will be constructed using a ''check-box'' format. The check boxes primarily will be questions requiring a ''yes/no'' or ''on a range of 1 to 5'' response.

The surveys will be mailed to approximately 500 companies, chosen through a stratified, random-sampling method. The companies will be asked to distribute the questionnaires to a randomly selected set of employees, using an appropriate criteria for randomization—which we will provide. Employees completing the questionnaires will send them directly to the Bureau of the Census, using pre-addressed, postage-paid return envelopes. We will provide the employer with a second complete set of questionnaires to be forwarded to all of the selected employees approximately three weeks after the initial mailing. Employees will be instructed to ignore this request if they have already responded. By using a complete follow up, the employer will have no indication of the employees' response status. Employers will not be allowed access to the questionnaires completed by the employees or the information reported on the questionnaires. Confidentiality is guaranteed by Title 13, United States Code. After the Census Bureau performs data keying and consistency editing, the data set will be provided to sworn Census agents representing the survey sponsor.

As a high participation rate for employers is crucial for statistically reliable data in the NES–4, Census has discussed this issue with selected respondents from the NES–3. Nearly all of the business establishments we contacted stated that they would strongly consider participating in the survey. The businesses indicated that their decision to participate in a survey was primarily based on their perception of the usefulness of the requested information. The businesses are very interested in the issues of the survey. One business respondent said, ''After all, these are our concerns, too.'' Also, more respondents (employers) than in the previous two surveys told the interviewers that they wanted the results of the survey. Based on these factors (and especially the employers concerns about these workplace issues), we expect a high rate of the employers from the NES–3 to participate in the NES–4.

Some businesses expressed concern about the expenses (postage, programming, labeling, etc.) of performing the operations for the survey. They said it would be most important for us to provide the postage and stationery. Labeling and programming were much less of a concern to them as the businesses already have programs and procedures in place that could accommodate this type of operation without much cost or inconvenience to them. Based on these initial discussions (and using information from future discussions) with potential employers, we will include these features in the final design. We will provide the participants with postage-paid envelopes and all necessary stationery for the survey as these were the primary concerns. This is more direct than reimbursing the employers and eliminates extra bookkeeping for the employers to account for such payments. We plan to rely on the employers to supply the labeling and employee selection services. We will be talking to a few more respondents to help design an effective and comfortable operational design for selecting employees and distributing the materials.

A major concern Census had was the ability of the businesses to draw a reliable, random sample. This did not present much of a problem to the potential participants because the payroll was computerized and the payroll record contained the Social Security number (which we proposed to use as the selection criteria).

The EQW had two designs they wanted to evaluate. One was to measure only newly hired employees and address a set of issues that relate to that segment of the work force. Another is to survey across the board. When we asked about limiting the selection to ''new hires,'' several of the businesses thought that would pose a problem and recommended that we survey all their employees. Based on our initial conversations, the employers do understand our needs. At this point we believe that the employers can effect a proper sample, however, some uncertainties remain, and we will do further consultation with potential respondents. We will be working with a few of the potential respondents to determine how to impart our statistical requirements in written instructions. We also will work with the employers to determine methods of validating the sampling processes.

Another concern we discussed was anonymity. Those businesses we consulted feel that employees are more likely to return the questionnaires with accurate responses if we can assure them that the employer would not see any of the responses and would not know if the employee had responded or not. Employees are very sensitive to access of their personal information, and we feel that good response will require that we provide assurance of confidentiality.

We will do further investigation concerning anonymity, sampling of employees, and operational considerations during the 60-day comment period and we would particularly welcome any ideas or concerns on these issues.

III. Data

OMB Number: 0607–0787.
Form Number: NES–4.
Type of Review: Regular.
Affected Public: Employees of business establishments with 20 or more employees.
Estimated Number of Respondents: 6,000.
Estimated Time Per Response: 20 minutes.
Estimated Total Annual Burden Hours: 2,000.
Estimated Total Annual Cost: No cost to the respondent other than the time required to complete the questionnaire. There would be a small cost to the employer in distributing the questionnaires, and, if required, to select the sample of employees.
Respondent's Obligation: Voluntary.
Legal Authority: United States Code, Title 13, sections 8 and 9.

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden

(including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: September 16, 1997.

Linda Engelmeier,

Departmental Forms Clearance Officer, Office of Management and Organization.

[FR Doc. 97–25192 Filed 9–22–97; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 091697B]

Gulf of Mexico Fishery Management Council; Public Meeting

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

ACTION: Notice of public meeting.

SUMMARY: The Gulf of Mexico Fishery Management Council will convene a public meeting of the Reef Fish Stock Assessment Panel.

DATES: This meeting will begin at 8:30 a.m. on Monday, October 6 and conclude by 12:00 noon on Thursday, October 9, 1997.

ADDRESSES: The meeting will be held at NMFS Southeast Fisheries Science Center, 75 Virginia Beach Drive, Miami, FL.

Council address: Gulf of Mexico Fishery Management Council, 3018 U.S. Highway 301 North, Suite 1000, Tampa, FL 33619.

FOR FURTHER INFORMATION CONTACT: Steven Atran, Population Dynamics Statistician; telephone: 813–228–2815.

SUPPLEMENTARY INFORMATION: The Reef Fish Stock Assessment Panel members will meet to review new stock assessments prepared by NMFS for red snapper and gag in the Gulf of Mexico, and to review available biological information and landings data for gray triggerfish. In addition, the Panel is tentatively scheduled to review an independent red snapper stock assessment prepared by Dr. Brian Rothschild of the University of Massachusetts. All scheduled presentations will be given during the first two days of the meeting.

Although other issues not contained in this agenda may come before the Panel for discussion, in accordance with the Magnuson-Stevens Fishery Conservation Act, those issues may not be the subject of formal Panel action during this meeting. Panel action will be restricted to those issues specifically identified in the agenda listed 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 Anne Alford at the Council (see **ADDRESSES**) by September 29, 1997.

Dated: September 17, 1997.

Bruce C. Morehead,

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

[FR Doc. 97–25245 Filed 9–22–97; 8:45 am]

BILLING CODE 3510–22–F

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 091697A]

Gulf of Mexico Fishery Management Council; Public Meetings

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

ACTION: Notice of public meeting.

SUMMARY: The Gulf of Mexico Fishery Management Council will convene a public meeting of the Socioeconomic Assessment Panel (SEP).

DATES: A joint meeting of the SEP Reef Fish Subgroup and the Reef Fish Stock Assessment Panel will be held beginning at 8:30 a.m. on Wednesday, October 8 and will conclude by 5:00 p.m. on Thursday, October 9, 1997. On Friday, October 10, the entire SEP will hold their meeting.

ADDRESSES: The meeting will be held at NMFS Southeast Fisheries Science Center, 75 Virginia Beach Drive, Miami, FL.

Council address: Gulf of Mexico Fishery Management Council, 3018 U.S. Highway 301 North, Suite 1000, Tampa, FL 33619.

FOR FURTHER INFORMATION CONTACT: Antonio B. Lamberte, Economist; telephone: 813–228–2815.

SUPPLEMENTARY INFORMATION: The SEP members will meet to review available social and economic data on red snapper and gag and to determine the social and economic implications of the levels of acceptable biological catches (ABC) recommended by the Council's Reef Fish Stock Assessment Panel (RFSAP). The SEP may recommend to the Council total allowable catches (TAC) for the 1998 fishing year. Specific TAC recommendations for gag will depend on whether an ABC range is recommended by the RFSAP.

Although other issues not contained in this agenda may come before the Panel for discussion, in accordance with the Magnuson-Stevens Fishery Conservation Act, those issues may not be the subject of formal Panel action during this meeting. Panel action will be restricted to those issues specifically identified in the agenda listed in this notice.

A copy of the agenda can be obtained by contacting the Gulf Council (see **ADDRESSES**).

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Anne Alford at the Council (see **ADDRESSES**) by October 1, 1997.

Dated: September 17, 1997.

Bruce C. Morehead,

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

[FR Doc. 97–25246 Filed 9–22–97; 8:45 am]

BILLING CODE 3510–22–F

COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE AGREEMENTS

Cancellation of an Import Limit, Guaranteed Access Level and Visa Requirements for Certain Wool Produced or Manufactured in Honduras

September 17, 1997.

AGENCY: Committee for the Implementation of Textile Agreements (CITA).

ACTION: Issuing a directive to the Commissioner of Customs cancelling a limit, guaranteed access level and visa requirements.

EFFECTIVE DATE: September 30, 1997.

FOR FURTHER INFORMATION CONTACT: Roy Unger, International Trade Specialist, Office of Textiles and Apparel, U.S. Department of Commerce, (202) 482–4212.

SUPPLEMENTARY INFORMATION:

Authority: Executive Order 11651 of March 3, 1972, as amended; section 204 of the Agricultural Act of 1956, as amended (7 U.S.C. 1854); Uruguay Round Agreements Act.

The United States Government has decided to cancel the limit and guaranteed access level (GAL) on imports of wool textile products in Category 435 from Honduras established for the period beginning on January 1, 1997 and extending through December 31, 1997. A visa will no longer be required for textile products in Category 435, regardless of the date of export.

In the letter published below, the Chairman of CITA directs the Commissioner of Customs, effective on September 30, 1997, to cancel the 1997 limit and GAL for Category 435. Also, U.S. Customs Service is directed not to sign the form ITA–370P for export of U.S. formed and cut parts in Category 435.

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 61 FR 66263, published on December 17, 1996). Also see 61 FR 38236, published on July 23, 1996; and 61 FR 59865, published on November 25, 1996.

The letter to the Commissioner of Customs and the actions taken pursuant to it are not designed to implement all of the provisions of the Uruguay Round Agreements Act and the Uruguay Round Agreement on Textiles and Clothing, but are designed to assist only in the implementation of certain of their provisions.

Troy H. Cribb,

Chairman, Committee for the Implementation of Textile Agreements.

Committee for the Implementation of Textile Agreements

September 17, 1997.

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 19, 1996, by the Chairman, Committee for the Implementation of Textile Agreements. That directive concerns imports of certain cotton, wool and man-made fiber textile products, produced or manufactured in Honduras and exported during the twelve-month period which began on January 1, 1997 and extends through December 31, 1997.

Effective on September 30, 1997, you are directed to cancel the current limit and guaranteed access level for Category 435. A visa will no longer be required for shipments of goods in Category 435 which are produced or manufactured in Honduras, regardless of the date of export.

Also effective on September 30, 1997, U.S. Customs Service is directed to no longer sign the form ITA–370P for export of U.S. formed and cut parts in Category 435.

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,

Troy H. Cribb,

Chairman, Committee for the Implementation of Textile Agreements.

[FR Doc. 97–25206 Filed 9–22–97; 8:45 am]

BILLING CODE 3510–DR–F

COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE AGREEMENTS

Adjustment of Import Limits for Certain Cotton, Wool and Man-Made Fiber Textiles and Textile Products and Silk Blend and Other Vegetable Fiber Apparel Produced or Manufactured in the Philippines

September 19, 1997.

AGENCY: Committee for the Implementation of Textile Agreements (CITA).

ACTION: Issuing a directive to the Commissioner of Customs adjusting import limits.

EFFECTIVE DATE: September 23, 1997.

FOR FURTHER INFORMATION CONTACT: Janet Heinzen, 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 or call (202) 927–5850. For information on embargoes and quota re-openings, call (202) 482–3715.

SUPPLEMENTARY INFORMATION:

Authority: Executive Order 11651 of March 3, 1972, as amended; section 204 of the Agricultural Act of 1956, as amended (7 U.S.C. 1854); Uruguay Round Agreements Act.

The current limits for certain categories are being adjusted, variously, for swing, special shift and carryforward.

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 61 FR 66263, published on December 17, 1996). Also see 61 FR 64507, published on December 5, 1996.

The letter to the Commissioner of Customs and the actions taken pursuant to it are not designed to implement all of the provisions of the Uruguay Round Agreements Act and the Uruguay Round Agreement on Textiles, but are designed to assist only in the implementation of certain of their provisions.

Troy H. Cribb,

Chairman, Committee for the Implementation of Textile Agreements.

Committee for the Implementation of Textile Agreements

September 19, 1997.

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 29, 1996, by the Chairman, Committee for the Implementation of Textile Agreements. That directive concerns imports of certain cotton, wool and man-made fiber textiles and textile products and silk blend and other vegetable fiber apparel, produced or manufactured in the Philippines and exported during the twelve-month period beginning on January 1, 1997 and extending through December 31, 1997.

Effective on September 23, 1997, you are directed to adjust the current limits for the following categories, pursuant to the Uruguay Round Agreements Act and the Uruguay Round Agreement on Textiles and Clothing:

Category	Adjusted twelve-month limit [1]
Levels in Group I	
237	1,358,802 dozen.
331/631	5,654,141 dozen pairs.
333/334	242,549 dozen of which not more than 40,848 dozen shall be in Category 333.
335	77,287 dozen.
338/339	2,380,268 dozen.
345	191,417 dozen.
359–C/659–C [2]	1,454,874 kilograms.
433	3,712 dozen.
445/446	33,634 dozen.
447	8,971 dozen.
633	37,332 dozen.
634	621,397 dozen.
635	415,492 dozen.
636	1,745,780 dozen.
638/639	2,364,122 dozen.
645/646	769,333 dozen.
649	7,425,078 dozen.
847	235,498 dozen.

Category	Adjusted twelve-month limit [1]
Group II	
200–229, 300–326, 330, 332, 349, 353, 354, 359–O [3], 360, 362, 363, 369–O [4], 400–414, 432, 434–442, 444, 448, 459, 464–469, 600–607, 613–629, 630, 632, 644, 653, 654, 659–O [5], 665, 666, 669–O [6], 670–O [7], 831–846 and 850–859, as a group.	158,991,713 square meters equivalent.

[1] The limits have not been adjusted to account for any imports exported after December 31, 1996.

[2] Category 359–C: only HTS numbers 6103.42.2025, 6103.49.8034, 6104.62.1020, 6104.69.8010, 6114.20.0048, 6114.20.0052, 6203.42.2010, 6203.42.2090, 6204.62.2010, 6211.32.0010, 6211.32.0025 and 6211.42.0010; Category 659–C: only HTS numbers 6103.23.0055, 6103.43.2020, 6103.43.2025, 6103.49.2000, 6103.49.8038, 6104.63.1020, 6104.63.1030, 6104.69.1000, 6104.69.8014, 6114.30.3044, 6114.30.3054, 6203.43.2010, 6203.43.2090, 6203.49.1010, 6203.49.1090, 6204.63.1510, 6204.69.1010, 6210.10.9010, 6211.33.0010, 6211.33.0017 and 6211.43.0010.

[3] Category 359–O: all HTS numbers except 6103.42.2025, 6103.49.8034, 6104.62.1020, 6104.69.8010, 6114.20.0048, 6114.20.0052, 6203.42.2010, 6203.42.2090, 6204.62.2010, 6211.32.0010, 6211.32.0025 and 6211.42.0010 (Category 359–C).

[4] Category 369–O: all HTS numbers except 6307.10.2005 (Category 369–S).

[5] Category 659–O: all HTS numbers except 6103.23.0055, 6103.43.2020, 6103.43.2025, 6103.49.2000, 6103.49.8038, 6104.63.1020, 6104.63.1030, 6104.69.1000, 6104.69.8014, 6114.30.3044, 6114.30.3054, 6203.43.2010, 6203.43.2090, 6203.49.1010, 6203.49.1090, 6204.63.1510, 6204.69.1010, 6210.10.9010, 6211.33.0010, 6211.33.0017, 6211.43.0010 (Category 659–C); 6502.00.9030, 6504.00.9015, 6504.00.9060, 6505.90.5090, 6505.90.6090, 6505.90.7090 and 6505.90.8090 (Category 659–H).

[6] Category 669–O: all HTS numbers except 6305.32.0010, 6305.32.0020, 6305.33.0010, 6305.33.0020 and 6305.39.0000 (Category 669–P).

[7] Category 670–O: all HTS numbers except 4202.12.8030, 4202.12.8070, 4202.92.3020, 4202.92.3030 and 4202.92.9025 (Category 670–L).

The Committee for the Implementation of Textile Agreements has determined that these actions fall within the foreign affairs exception of the rulemaking provisions of 5 U.S.C. 553(a)(1).

Sincerely,

Troy H. Cribb,

Chairman, Committee for the Implementation of Textile Agreements.

[FR Doc. 97–25363 Filed 9–22–97; 8:45 am]

BILLING CODE 3510–DR–F

COMMODITY FUTURES TRADING COMMISSION

Chicago Board of Trade Proposed Futures and Option Contracts on the Dow Jones Utility Average Index and the Dow Jones Transportation Average Index

AGENCY: Commodity Futures Trading Commission.

ACTION: Notice of availability of the terms and conditions of proposed commodity futures and option contracts.

SUMMARY: The Chicago Board of Trade (CBOT or Exchange) has applied for designation as a contract market in futures and futures options on the Dow Jones Utility Average Index and the Dow Jones Transportation Average Index. The Acting Director of the Division of Economic Analysis (Division) of the Commission, acting pursuant to the authority delegated by Commission Regulation 140.96, has determined that publication of the proposal for comment is in the public interest, will assist the Commission in considering the views of interested persons, and is consistent with the purposes of the Commodity Exchange Act.

DATE: Comments must be received on or before October 23, 1997.

ADDRESSES: Interested persons should submit their views and comments to Jean A. Webb, Secretary, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st St., NW, Washington, DC 20581. In addition, comments may be sent by facsimile transmission to (202) 418–5521 or by electronic mail to secretary@cftc.gov. Reference should be made to the Chicago Board of Trade Dow Jones Utility Average Index and the Dow Jones Transportation Average Index.

FOR FURTHER INFORMATION CONTACT: Please contact Thomas Leahy of the Division of Economic Analysis, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st St., NW, Washington, DC 20581, telephone 202–418–5278. Facsimile number (202) 418–5527. Electronic mail tleahy@cftc.gov.

SUPPLEMENTARY INFORMATION: Copies of the terms and conditions will be available for inspection at the Office of the Secretariat, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st St., NW, Washington, DC 20581. Copies of the terms and conditions can be obtained through the Office of the Secretariat by mail at the above address, by phone at (202) 418–5100, or via the internet on the CFTC website at www.cftc.gov under ''What's Pending.''

Other materials submitted by the CBOT in support of the application for contract market designation may be available upon request pursuant to the Freedom of Information Act (5 U.S.C. 552) and the Commission's regulations thereunder (17 CFR part 145 (1987)), except to the extent they are entitled to confidential treatment as set forth in 17 CFR 145.5 and 145.9. Requests for copies of such materials should be made to the FOI, Privacy and Sunshine Act Compliance Staff of the Office of the Secretariat at the Commission's headquarters in accordance with 17 CFR 145.7 and 145.8.

Any person interested in submitting written data, views, or arguments on the proposed terms and conditions, or with respect to other materials submitted by the CBOT, should send such comments to Jean A. Webb, Secretary, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st St., NW, Washington, DC 20581 by the specified date.

Issued in Washington, DC, on September 17, 1997.

John R. Mielke,

Acting Director.

[FR Doc. 97–25203 Filed 9–22–97; 8:45 am]

BILLING CODE 6351–01–P–M

DEPARTMENT OF DEFENSE

Office of the Secretary

Group of Advisors to the National Security Education Board Meeting

AGENCY: Office of the Assistant Secretary of Defense, Strategy and Requirements.

ACTION: Notice of meeting.

SUMMARY: Pursuant to Pub. L. 92–463, notice is hereby given of a forthcoming meeting of the Group of Advisors to the National Security Education Board. The purpose of the meeting is to review and make recommendations to the Board concerning requirements established by the David L. Boren National Security Education Act, Title VIII of Pub. L. 102–183, as amended.

DATES: October 26, 1997.

ADDRESSES: 1101 Wilson Boulevard, Suite 1210, Arlington, Virginia 22209–2248.

FOR FURTHER INFORMATION CONTACT: Dr. Edmond J. Collier, Deputy Director, National Security Education Program, 1101 Wilson Boulevard, Suite 1210, Rosslyn P.O. Box 20010, Arlington, Virginia 22209–2248; (703) 696–1991. Electronic mail address: collier@osd.pentagon.mil

SUPPLEMENTARY INFORMATION: The Group of Advisors meeting is open to the public.

Dated: September 18, 1997.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 97–25189 Filed 9–22–97; 8:45 am]

BILLING CODE 5000–04–M

DEPARTMENT OF DEFENSE

Office of the Secretary

National Security Education Board Meeting

AGENCY: Office of the Assistant Secretary of Defense, Strategy and Requirements.

ACTION: Notice of meeting.

SUMMARY: Pursuant to Pub. L. 92–463, notice is hereby given of a forthcoming meeting of the National Security Education Board. The purpose of the meeting is to review and make recommendations to the Secretary of Defense concerning requirements established by the David L. Boren National Security Education Act, Title VIII of Pub. L. 102–183, as amended.

DATES: October 27, 1997.

ADDRESSES: The Crystal City Marriott Hotel, 1999 Jefferson Davis Highway, Arlington, Virginia 22202.

FOR FURTHER INFORMATION CONTACT:

Dr. Edmond J. Collier, Deputy Director, National Security Education Program, 1101 Wilson Boulevard, Suite 1210, Rosslyn, Virginia 22209–2248; (703) 696–1991. Electronic mail address: collier@osd.pentagon.mil

SUPPLEMENTARY INFORMATION: The Board meeting is open to the public.

Dated: September 18, 1997.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 97–25190 Filed 9–22–97; 8:45 am]

BILLING CODE 5000–04–M

DEPARTMENT OF DEFENSE

Office of the Secretary

Defense Science Board Task Force on Satellite Reconnaissance

ACTION: Notice of advisory committee meetings.

SUMMARY: The Defense Science Board Task Force on Satellite Reconnaissance will meet in closed session on October 8–9, October 24, and December 8, 1997 at Headquarters NRO, Chantilly, Virginia.

The mission of the Defense Science Board is to advise the Secretary of Defense through the Under Secretary of Defense for Acquisition and Technology on scientific and technical matters as they affect the perceived needs of the Department of Defense. At these meetings the Task Force will review the operational, technical, industrial, and financial aspects of the following and recommend a course of action for the Department: the National Reconnaissance Office's (NRO) is creating a Future Imager Architecture as a basis for acquiring the next generation of imaging satellite systems and their associated ground control and processing; and in parallel, DARPA is advocating the development and demonstration of a Surveillance and Targeting Light Satellite (Starlite) System with attributes that may not be included in NRO's architecture.

In accordance with Section 10(d) of the Federal Advisory Committee Act, Pub. L. No. 92–463, as amended (5 U.S.C. App. II, (1994)), it has been determined that these DSB Task Force meetings concern matters listed in 5 U.S.C. § 552b(c)(1) (1994), and that accordingly these meetings will be closed to the public.

Dated: September 18, 1997.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 97–25186 Filed 9–22–97; 8:45 am]

BILLING CODE 5000–04–M

DEPARTMENT OF DEFENSE

Office of the Secretary

Defense Science Board Task Force on Control of Military Excess/Surplus Materiel

ACTION: Notice of advisory committee meetings.

SUMMARY: The Defense Science Board Task Force on Control of Military Excess/Surplus will meet in closed session on October 7–8, 1997 at Strategic Analysis, Inc., 4001 N. Fairfax Drive, Arlington, Virginia.

The mission of the Defense Science Board is to advise the Secretary of Defense through the Under Secretary of Defense for Acquisition and Technology on scientific and technical matters as they affect the perceived needs of the Department of Defense. At this meeting the Task Force will examine existing regulatory and statutory guidance in support of controls, DoD Demilitarization policy, and private sector possession of DoD surplus materiel. Investigate the framework which defines MLI/SLI and SME and evaluate the capabilities and shortfalls for identifying and controlling them. Investigate concepts for analysis and execution of the control of DoD surplus materiel in a post cold-war environment focusing on trade-off analysis of different levels of control.

In accordance with Section 10(d) of the Federal Advisory Committee Act, Pub. L. No. 92–463, as amended (5 U.S.C. App. II, (1994)), it has been determined that this DSB Task Force meeting concerns matters listed in 5 U.S.C. § 552b© (1) (1994), and that accordingly this meeting will be closed to the public.

Dated: September 18, 1997.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 97–25187 Filed 9–22–97; 8:45 am]

BILLING CODE 5000–04–M

DEPARTMENT OF DEFENSE

Office of the Secretary

Defense Science Board Task Force on Defense Acquisition Reform, Phase IV

ACTION: Notice of advisory committee meeting.

SUMMARY: The Defense Science Board Task Force on Defense Acquisition Reform, Phase IV will meet in open session on October 3, 1997 at the Pentagon, Room 1E801#4, Arlington, Virginia.

The mission of the Defense Science Board is to advise the Secretary of Defense and the Under Secretary of Defense for Acquisition and Technology on scientific and technical matters as they affect the perceived needs of the Department of Defense.

Persons interested in further information should call Mr. Rick Sylvester at (703) 697–6398.

Dated: September 18, 1997.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 97–25188 Filed 9–22–97; 8:45 am]

BILLING CODE 5000–04–M

DEPARTMENT OF EDUCATION

Notice of Proposed Information Collection Requests

AGENCY: Department of Education.

ACTION: Notice of Proposed Information Collection Requests.

SUMMARY: The Acting Deputy Chief Information Officer, Office of the Chief Information Officer, invites comments on the proposed information collection requests as required by the Paperwork Reduction Act of 1995.

DATES: An emergency review has been requested in accordance with the Act (44 U.S.C. Chapter 3507 (j)), since public harm is reasonably likely to result if normal clearance procedures are followed. Approval by the Office of Management and Budget (OMB) has been requested by October 21, 1997. A regular clearance process is also beginning. Interested persons are invited to submit comments on or before [insert the 60th day after publication of this notice].

ADDRESSES: Written comments regarding the emergency review should be addressed to the Office of Information and Regulatory Affairs, Attention: Dan Chenok, Desk Officer: Department of Education, Office of Management and Budget, 725 17th Street, NW., Room 10235, New Executive Office Building, Washington, D.C. 20503. Requests for copies of the proposed information collection request should be addressed to Patrick J. Sherrill, Department of Education, 7th & D Streets, S.W., Room 5624, Regional Office Building 3, Washington, D.C. 20202–4651.

Written comments regarding the regular clearance and requests for copies of the proposed information collection requests should be addressed to Patrick J. Sherrill, Department of Education, 600 Independence Avenue, S.W., Room 5624, Regional Office Building 3, Washington, DC 20202–4651, or should be electronic mailed to the internet address #FIRB@ed.gov, or should be faxed to 202–708-9346.

FOR FURTHER INFORMATION CONTACT: Patrick J. Sherrill (202) 708–8196. Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. and 8 p.m., Eastern time, Monday through Friday.

SUPPLEMENTARY INFORMATION: Section 3506 (c)(2)(A) of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 3506 (c)(2)(A) requires that the Director of OMB provide interested Federal agencies and the public an early opportunity to comment on information collection requests. The Office of Management and Budget (OMB) may amend or waive the requirement for public consultation to the extent that public participation in the approval process would defeat the purpose of the information collection, violate State or Federal law, or substantially interfere with any agency's ability to perform its statutory obligations. The Acting Deputy Chief Information Officer, Office of the Chief Information Officer, publishes this notice containing proposed information collection requests at the beginning of the Departmental review of the information collection. 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. ED invites public comment at the address specified above. Copies of the requests are available from Patrick J. Sherrill at the address specified above.

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: September 17, 1997.

Charles E. Hansen,

Acting Deputy Chief Information Officer, Office of the Chief Information Officer.

Office of Educational Research and Improvement

Type of Review: New.

Title: Voluntary National Tests in Reading and Mathematics.

Abstract: The American Institutes for Research, under contract with the Office of Educational Research and Improvement, is coordinating the development of the Voluntary National Tests in Reading and Mathematics. Each Fall from 1997 to 2001, a pilot study of developed test items will help detect procedural problems and aid item selection for field tests conducted the following Spring.

Additional Information: The Department is requesting an emergency clearance for the Pilot Test of the Voluntary National Tests in Reading and Mathematics by October 21, 1997. If normal clearance procedures were followed, it would prevent the pilot tests from occurring this Fall which, in turn, would prevent the final tests being ready in the Spring, 1999, as called for by the President.

Frequency: Annually.

Affected Public: Individuals or households; State, local or Tribal Gov't, SEAs or LEAs.

Reporting Burden and Recordkeeping:
Responses: 46,000.
Burden Hours: 53,800.

[FR Doc. 97–25158 Filed 9–22–97; 8:45 am]
BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Notice of Proposed Information Collection Requests

AGENCY: Department of Education.

ACTION: Proposed collection; comment request.

SUMMARY: The Acting Deputy Chief Information Officer, 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 November 24, 1997.

ADDRESSES: Written comments and requests for copies of the proposed information collection requests should be addressed to Patrick J. Sherrill, Department of Education, 600 Independence Avenue, S.W., Room 5624, Regional Office Building 3, Washington, DC 20202–4651.

FOR FURTHER INFORMATION CONTACT: Patrick J. Sherrill (202) 708–8196. Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. and 8 p.m., Eastern time, Monday through Friday.

SUPPLEMENTARY INFORMATION: Section 3506 of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35) requires that the Office of Management and Budget (OMB) provide interested Federal agencies and the public an early opportunity to comment on information collection requests. OMB may amend or waive the requirement for public consultation to the extent that public participation in the approval process would defeat the purpose of the information collection, violate State or Federal law, or substantially interfere with any agency's ability to perform its statutory obligations. The Acting Deputy Chief Information Officer, Office of the Chief Information Officer, publishes this 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 at the address specified above. Copies of the requests are available from Patrick J. Sherrill at the address specified above.

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: September 17, 1997.

Charles E. Hansen,

Acting Deputy Chief Information Officer, Office of the Chief Information Officer.

Office of Educational Research and Improvement

Type of Review: Reinstatement.

Title: 1999 National Study of Postsecondary Faculty (NSOPF—99): Faculty Questionnaire.

Frequency: One Time.

Affected Public: Individuals or households.

Reporting Burden and Recordkeeping:
Responses: 25,000.
Burden Hours: 19,550.

Abstract: The third cycle of the NSOPF is being conducted in response to a continuing need for data on faculty and instructors. The study will provide information about faculty in postsecondary institutions which is key to learning about the quality of education and research in these institutions. This study will expand the information about faculty and instructional staff in two ways—allowing comparisons to be made over time and examining critical issues surrounding faculty that have developed since the first two studies. This clearance request covers field test and full scale activities for the second phase of the study—collection of information from a nationally representative sample of faculty and instructional staff at postsecondary institutions. This information, together with information collected in the first phase of the study (1850–0665) on the institutions themselves, will provide a source of descriptive, analytical, trend and policy relevant research on the way postsecondary education functions.

Office of Special Education and Rehabilitative Services

Type of Review: New.

Title: Uniform Data System for Assistive Technology Devices and Services.

Frequency: On occasion.

Affected Public: Individuals or households; State, local or Tribal Gov't, SEAs or LEAs.

Annual Reporting and Recordkeeping Hour Burden:
Responses: 1,346.
Burden Hours: 271.

Abstract: Assistive technology (AT) devices and the services can increase opportunities for education, employment, independence, and integration for persons with disabilities.

However, many of these individuals have not gained access to AT, despite several federal initiatives to address their AT needs. This data collection will allow the Department of Education to assemble information on the types of AT currently used by this nation's disabled and the funding sources for these devices and services, as specified in the Technology-Related Assistance for Individuals with Disabilities Act, as amended. Subjects will represent two groups: AT service providers (e.g., district special education coordinators, vocational rehabilitation counselors, and state AT project personnel) and (B) consumers of AT devices and services.

[FR Doc. 97–25159 Filed 9–22–97; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Environmental Management Site-Specific Advisory Board, Monticello Site

AGENCY: Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: Pursuant to the provisions of the Federal Advisory Committee Act (Public Law 92–463, 86 Stat. 770) notice is hereby given of the following Advisory Board Committee Meeting: Environmental Management Site-Specific Advisory Board, Monticello Site.

Date and Time: Tuesday, October 21, 1997—6:00 p.m.–8:00 p.m.

Address: San Juan County Courthouse, 2nd Floor Conference Room, 117 South Main, Monticello, Utah 84535.

FOR FURTHER INFORMATION CONTACT: Audrey Berry, Public Affairs Specialist, Department of Energy Grand Junction Projects Office, P.O. Box 2567, Grand Junction, CO, 81502 (970) 248–7727.

SUPPLEMENTARY INFORMATION:

Purpose of the Board

The purpose of the Board is to advise DOE and its regulators in the areas of environmental restoration, waste management, and related activities.

Tentative Agenda

Update on Operable Unit I project; reports from subcommittees on local training and hiring, health and safety, and future land use.

Public Participation

The meeting is open to the public. Written statements may be filed with the Committee either before or after the meeting. Individuals who wish to make oral statements pertaining to agenda items should contact Audrey Berry's office at the address or telephone number listed above. Requests must be received 5 days prior to the meeting and reasonable provision will be made to include the presentation in the agenda. The Designated Federal Official is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. Each individual wishing to make public comment will be provided a maximum of 5 minutes to present their comments.

Minutes

The minutes of this meeting will be available for public review and copying at the Freedom of Information Public Reading Room, 1E–190, Forrestal Building, 1000 Independence Avenue, SW, Washington, DC 20585 between 9:00 a.m. and 4 p.m., Monday-Friday, except Federal holidays. Minutes will also be available by writing to Audrey Berry, Department of Energy Grand Junction Projects Office, P.O. Box 2567, Grand Junction, CO 81502, or by calling her at (303) 248–7727.

Issued at Washington, DC on September 18, 1997.

Rachel M. Samuel,

Deputy Advisory Committee Management Officer.

[FR Doc. 97–25249 Filed 9–22–97; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Office of Energy Research

Basic Energy Sciences Advisory Committee

AGENCY: Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: Pursuant to the provisions of the Federal Advisory Committee Act (Public Law 92–463, 86 Stat. 770), notice is given of a meeting of the Basic Energy Sciences Advisory Committee.

DATES: Wednesday, October 8, 1997—8:30 a.m.–5:00 p.m.; Thursday, October 9, 1997—8:30 a.m.–3:00 p.m.

ADDRESSES: Gaithersburg Holiday Inn, #2 Montgomery Village Avenue, Gaithersburg, MD 20879.

FOR FURTHER INFORMATION CONTACT:

Dr. Patricia M. Dehmer, Basic Energy Sciences Advisory Committee, U.S. Department of Energy, ER–10, GTN, 19901 Germantown Road, Germantown, MD 20874–1290, Telephone: (301) 903–3081.

SUPPLEMENTARY INFORMATION:

Purpose of the Meeting

The Committee will provide advice and guidance with respect to the basic energy sciences research program.

Tentative Agenda

The meeting will be devoted to the report of the Synchrotron Radiation Light Source Panel. Presentations and discussion will cover synchrotron radiation light sources. After an overview of synchrotron radiation light sources, each facility will make a brief presentation. Members of the Synchrotron Radiation Light Source Panel then will make presentations summarizing their findings followed by the Chair of the Panel, Professor Robert Birgeneau, presenting the Panel's recommendations.

A detailed agenda will be available two weeks before the meeting from the Office of Basic Energy Sciences.

Public Participation

The meeting is open to the public. The Chairperson of the Committee is empowered to conduct the meeting in a fashion that will, in his judgment, facilitate the orderly conduct of business. Any member of the public who wishes to make oral statements pertaining to agenda items should contact Patricia Dehmer at the address or telephone number listed above. Requests must be received at least five days prior to the meeting and reasonable provision will be made to include the presentation on the agenda. Public comment will follow the 10 minute rule.

Minutes

The minutes of this meeting will be available for public review and copying at the Freedom of Information Public Reading Room, 1E–190, Forrestal Building, 1000 Independence Avenue, S.W., Washington, D.C. 20585, between 9:00 a.m. and 4:00 p.m., Monday through Friday, except holidays.

Issued in Washington, D.C. on September 18, 1997.

Rachel M. Samuel,

Deputy Advisory Committee Management Officer.

[FR Doc. 97–25250 Filed 9–22–97; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Office of Energy Research

Fusion Energy Sciences Advisory Committee

AGENCY: Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: Pursuant to the provisions of the Federal Advisory Committee Act (Public Law No. 92–463, 86 Stat. 770), notice is given of a meeting of the Fusion Energy Sciences Advisory Committee.

DATES: Monday, October 20, 1997, 9:00 a.m. to 6:00 p.m., and Tuesday, October 21, 1997, 9:00 a.m. to 4:00 p.m.

ADDRESSES: U.S. Department of Energy, 19901 Germantown Road, Auditorium, Germantown, Maryland 20874.

FOR FURTHER INFORMATION CONTACT: Albert L. Opdenaker, III, Executive Assistant, Office of Fusion Energy Sciences, U.S. Department of Energy, Germantown, MD 20874, Telephone: 301–903–4941.

SUPPLEMENTARY INFORMATION:

Purpose of the Meeting

To receive the report of the subpanel on possible U.S. participation in International Thermonuclear Experimental Reactor (ITER), and to receive informational updates on other fusion program activities.

Monday, October 20, 1997

DOE Perspective
Report of the subpanel on U.S. Participation in ITER
Public Comments on Subpanel Report
Review of Theory and Computing Program
Report from the Working Group on International Collaborations
Public Comments

Tuesday, October 21, 1997

Complete Report to DOE
Report to Director, Energy Research

Public Participation

The meeting is open to the public. Written statements may be filed with the Committee either before or after the meeting. Members of the public who wish to make oral statements pertaining to agenda items should contact Albert L. Opdenaker at 301–903–8584 (fax) or albert.opdenaker@mailgw.er.doe.gov (e-mail). Requests to make oral statements must be received 5 days prior to the meeting; reasonable provision will be made to include the statement in the agenda. The Chairperson of the Committee is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business.

Minutes

The minutes of this meeting will be available for public review and copying within 30 days at the Freedom of Information Public Reading Room, I–190, Forrestal Building, 1000 Independence Avenue, S.W., Washington, D.C., between 9:00 a.m. and 4:00 p.m., Monday through Friday, except Federal holidays.

Issued at Washington, D.C. on September 18, 1997.

Rachel M. Samuel,

Deputy Advisory Committee Management Officer.

[FR Doc. 97–25248 Filed 9–22–97; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. TM98–1–118–000]

Arkansas Western Pipeline Company; Notice of Proposed Changes in FERC Gas Tariff

September 17, 1997.

Take notice that on September 12, 1997, Arkansas Western Pipeline Company (AWP) tendered for filing as part of its FERC Gas Tariff, Fourth Revised Sheet No. 4 to become effective October 1, 1997.

AWP states that the filing establishes the revised Annual Charge Adjustment (ACA) rate effective October 1, 1997, for AWP's transportation rates. The ACA rate is designed to recover the charge assessed by the Commission pursuant to Part 382 of the Commission's Regulations.

Any person desiring to be heard or protest this filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, DC 20426, in accordance with Sections 385.211 and 385.214 of the Commission's Rules and Regulations. All such petitions or protests must be filed in accordance with Section 154.210 of the Commission's Regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 97–25146 Filed 9–22–97; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP97–742–000]

Columbia Gas Transmission Corporation; Notice of Request Under Blanket Authorization

September 17, 1997.

Take notice that on September 10, 1997, Columbia Gas Transmission Corporation (Columbia), Post Office Box 1273, Charleston, West Virginia 25325-1273, filed in Docket No. CP97–742–000 a request pursuant to Sections 157.205 and 157.211 of the Commission's Regulations under the Natural Gas Act (18 CFR 157.205, 157.211) for authorization to construct and operate an additional point of delivery to Columbia Gas of Pennsylvania, Inc. (CPA), located in Franklin County, Pennsylvania, under Columbia's certificate issued in Docket No. CP83–76–000, pursuant to Section 7(c) of the Natural Gas Act, all as more fully set forth in the request that is on file with the Commission and open to public inspection.

Columbia proposes to construct and operate a new point of delivery to CPA, consisting of interconnecting and appurtenant facilities to be constructed and operated by Columbia, located in Franklin County, Pennsylvania. Columbia states the estimated quantities of natural gas to be delivered at the new point of delivery are 80 Dth per day and 1,600 Dth annually. Columbia declares the point of delivery has been requested by CPA to serve Deerwood Mountain Estates.

Columbia states the estimated cost to construct this new point of delivery is $29,100, of which CPA will reimburse Columbia 100% of the total actual cost.

Any person or the Commission's staff may, within 45 days after issuance of the instant notice by the Commission, file pursuant to Rule 214 of the Commission's Procedural Rules (18 CFR 385.214) a motion to intervene or notice of intervention and pursuant to Section 157.205 of the Regulations under the Natural Gas Act (18 CFR 157.205) a protest to the request. If no protest is filed within the time allowed therefor, the proposed activity shall be deemed to be authorized effective the day after the time allowed for filing a protest. If a protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request shall be treated as an application for

authorization pursuant to Section 7 of the Natural Gas Act.

Lois D. Cashell,

Secretary.

[FR Doc. 97–25138 Filed 9–22–97; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP97–731–000]

Kern River Gas Transmission Company; Notice of Request Under Blanket Authorization

September 17, 1997.

Take notice that on September 8, 1997, Kern River Gas Transmission Company (Kern River), 295 Chipeta Way, Salt Lake City, Utah 84108, filed in Docket No. CP97–731–000 a request pursuant to Sections 157.205, 157.211, and 157,216, of the Commission's Regulations under the Natural Gas Act (18 CFR 157.205, 157,211, 157.216) for authorization to remove and abandon facilities at an existing meter station and to install and operate upgraded metering facilities at the same site in Washington County, Utah under Kern River's blanket certificate issued in Docket No. CP89–2048–000 pursuant to Section 7 of the Natural Gas Act, all as more fully set forth in the request that is on file with the Commission and open to public inspection.

Kern River states that it proposes to upgrade the Central Meter Station by removing the one existing two-inch roots meter and the dual-run, two-inch regulator setting and replace them with one four-inch turbine meter and one two-inch flow control valve. The station upgrade will result in a maximum station design capacity of 22,000 Mcf per day at a contract delivery pressure of 650 psig.

Any person or the Commission's staff may, within 45 days after issuance of the instant notice by the Commission, file pursuant to Rule 214 of the Commission's Procedural Rules (18 CFR 385.214) a motion to intervene or notice of intervention and pursuant to Section 157.205 of the Regulations under the Natural Gas Act (18 CFR 157.205) a protest to the request. If no protest is filed within the time allowed therefor, the proposed activity shall be deemed to be authorized effective the day after the time allowed for filing a protest. If a protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request shall be treated as an application for authorization pursuant to Section 7 of the Natural Gas Act.

Lois D. Cashell,

Secretary.

[FR Doc. 97–25135 Filed 9–22–97; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP97–526–000]

Mississippi River Transmission Corporation; Notice of Proposed Changes in FERC Gas Tariff

September 17, 1997.

Take notice that on September 12, 1997, Mississippi River Transmission Corporation (MRT) tendered for filing as part of its FERC Gas Tariff, Third Revised Volume No. 1, Third Revised Sheet No. 9, with an effective date of October 12, 1997.

MRT states that the purpose of the instant filing is to provide for recovery of additional prior period adjustments to MRT's Account No. 191 balance, representing amounts paid by MRT to partially resolve litigation involving pre-Order No. 636 gas purchase contracts, pursuant to Sections 16.2(b) and (c) of the General Terms and Conditions of MRT's Tariff.

Any person desiring to be heard or protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, in accordance with Rules 214 and 211 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). All such motions and protests should be filed as provided in Section 154.210 of the Commission's Regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 97–25144 Filed 9–22–97; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP97–431–001]

Natural Gas Pipeline Company of America; Notice of Compliance Filing

September 17, 1997.

Take notice that on September 12, 1997, Natural Gas Pipeline Company of America (Natural) tendered for filing as part of its FERC Gas Tariff, Sixth Revised Volume No. 1, Substitute Third Revised Sheet No. 324, to be effective September 1, 1997.

Natural states that the purpose of this filing is to comply with the Commission's order issued August 29, 1997 in Docket No. RP97–431–000, which required Natural to reflect a contract term cap of five years, but to delete other of the proposed changes in the present docket.

Natural requests waiver of the Commission's Regulations to the extent necessary to permit the tendered tariff sheet to become effective on September 1, 1997.

Natural states that copies of the filing have been mailed to Natural's customers, interested state regulatory agencies and all parties on the official service list in Docket No. RP97–431–000.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, in accordance with Section 385.211 of the Commission's Rules and Regulations. All such protests must be filed as provided in Section 154.210 of the Commission's Regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room.

Lois D. Cashell,

Secretary.

[FR Doc. 97–25142 Filed 9–22–97; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP97–733–000]

Northern Natural Gas Company; Notice of Request Under Blanket Authorization

September 17, 1997.

Take notice that on September 8, 1997, Northern Natural Gas Company (Northern), 1111 South 103rd Street, Omaha, Nebraska 68124–1000, filed in Docket No. CP97–733–000 a request pursuant to Sections 157.205, and 157.212, of the Commission's Regulations under the Natural Gas Act (18 CFR 157.205, 157.212) for authorization to install and operate a new delivery point, located in Irion County, Texas under Northern's blanket certificate issued in Docket No. CP82–401–000 pursuant to Section 7 of the Natural Gas Act, all as more fully set forth in the request that is on file with the Commission and open to public inspection.

Northern states that is requests authority to install and operate the proposed delivery point to accommodate interruptible natural gas deliveries to West Texas Gas, Inc. (WTG). The proposed volumes to be delivered are 500 MMBtu on a peak day and 135,284 MMBtu on an annual basis. Northern asserts that WTG has requested the proposed delivery point to provide compressor fuel.

Any person or the Commission's staff may, within 45 days after issuance of the instant notice by the Commission, file pursuant to Rule 214 of the Commission's Procedural Rules (18 CFR 385.214) a motion to intervene or notice of intervention and pursuant to Section 157.205 of the Regulations under the National Gas Act (18 CFR 157.205) a protest to the request. If no protest is filed within the time allowed therefor, the proposed activity shall be deemed to be authorized effective the day after the time allowed for filing a protest. If a protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request shall be treated as an application for authorization pursuant to Section 7 of the National Gas Act.

Lois D. Cashell,

Secretary.

[FR Doc. 97–25136 Filed 9–22–97; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP97–751–000]

Northwest Pipeline Corporation; Notice of Request Under Blanket Authorization

September 17, 1997.

Take notice that on September 12, 1997, Northwest Pipeline Corporation (Northwest), 295 Chipeta Way, Salt Lake City, Utah 84158, filed in Docket No. CP97–751–000 a request pursuant to §§ 157.205 and 157.216 of the Commission's Regulations under the Natural Gas Act (18 CFR 157.205, 157.216) for authorization to abandon by removal certain obsolete facilities at the Warden Meter Station located in Grant County, Washington, under Northwest's blanket certificate issued in Docket No. CP82–443–000 pursuant to Section 7 of the Natural Gas Act, all as more fully set forth in the request that is on file with the Commission and open to public inspection.

Northwest proposes to remove the obsolete 2-inch positive displacement meter at the Warden Meter Station, which has been shut-in since 1992, in order to allow easier access to perform routine maintenance on the remaining facilities since there is limited space in the existing meter building. Northwest states that appurtenant piping will be installed as auxiliary facilities under 18 CFR Section 2.55(a) so the former meter run can be used as a meter by-pass line when necessary.

Northwest states that removing the 2-inch positive displacement meter will not change the design capacity of the Warden Meter Station since it originally was installed only to measure lower flows than the remaining 3-inch turbine meter could accurately measure and the capacity of the meter station still will be limited by the existing regulators.

Northwest further states that the cost of removing the 2-inch positive displacement meter at the Warden Meter Station is estimated to be approximately $2,000.

Any person or the Commission's staff may, within 45 days after issuance of the instant notice by the Commission, file pursuant to Rule 214 of the Commission's Procedural Rules (18 CFR 385.214) a motion to intervene or notice of intervention and pursuant to § 157.250 of the Regulations under the Natural Gas Act (18 CFR 157.205) a protest to the request. If no protest is filed within the time allowed therefor, the proposed activity shall be deemed to be authorized effective the day after the time allowed for filing a protest. If a protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request shall be treated as an application for authorization pursuant to Section 7 of the Natural Gas Act.

Lois D. Cashell,

Secretary.

[FR Doc. 97–25140 Filed 9–22–97; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ES97–44–001]

Orange and Rockland Utilities, Inc.; Notice of Filing

September 19, 1997.

Take notice that on September 18, 1997, Orange and Rockland Utilities, Inc. (O&R) filed an amendment to its application for authorization to issue securities in the above-captioned docket. The only change to the previously-approved application is a request by O&R that the authorization become effective October 1, 1997.

Any person desiring to be heard or to protest said filing 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 18 CFR 385.214). All such motions or protests must be filed on or before September 25, 1997. 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. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 97–25331 Filed 9–22–97; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP97–735–000]

Southern Natural Gas Company; Notice of Request Under Blanket Authorization

September 17, 1997.

Take notice that on September 8, 1997, Southern Natural Gas Company (Southern), Post Office Box 2563, Birmingham, Alabama 35202–2563, filed in Docket No. CP97–735–000 a request pursuant to Sections 157.205 and 157.216 of the Commission's Regulations under the Natural Gas Act (18 CFR 157.205, 157.216) for authorization to abandon measurement and pipeline facilities at certain delivery point locations, under Southern's blanket certificate issued in Docket No. CP82–406–000, pursuant to Section 7 of the Natural Gas Act, all as more fully set forth in the request that is on file with the Commission and open to public inspection.

Specifically, Southern proposes to abandon the following meter stations: (1) The Crown/Zellerbach Meter Station (Point Code 712500) and the Crown/Zellerbach 4-inch Pipeline which are located at or near milepost 1.4 on Southern's 10-inch Hub Field Line in Marion County, Mississippi; (2) the Brookhaven Meter Station (Point Code 743100) which is located at or near milepost 39.1 on Southern's 18-inch Cranfield-Gwinville Line in Lincoln County, Mississippi; (3) the Borden Chemical Meter Station (Point Code 801200) which is located at or near milepost 130.2 on Southern's 18-inch South Main Line in Marengo County, Alabama; (4) the Corps of Engineers Meter Station (Point Code 731700) which is located at or near milepost 2.6 on Southern's 6-inch Oliver Electric Line in Warren County, Mississippi; (5) the McGraw Edison Meter Station and associated tap line (Point Code 731800) which are located at or near milepost 2.3 on Southern's 6-inch Oliver Electric Line in Warren County, Mississippi; (6) the Valley Cement Industries Meter Station (Point Code 731500) which is located at or near milepost 18.4 on Southern's Vicksburg Line & Loop Line in Warren County, Mississippi; (7) the TCI Concord Mines Meter Station (Point Code 828500) which is located at or near milepost 6.4 on Southern's 12-inch Bessemer/Calera Line in Jefferson County, Alabama; (8) the Vulcan Materials Meter Station (Point Code 837700) which is located at or near milepost 4.9 on Southern's 12-inch TCI Line in Jefferson County, Alabama; (9) the TCI Coke Works Meter Station (Point Code 838900) and associated tap line which are located at or near milepost 6.8 on Southern's 10-inch TCI Line in Jefferson County, Alabama; (10) the TCI Wenonah-Ishkooda Meter Station (Point Code 839400) and associated tap line which are located at or near milepost 7.5 on Southern's 10-inch TCI Line in Jefferson County, Alabama; (11) the Continental Group, Inc. Meter Station (Point Code 839900) which is located at or near milepost 8.0 on Southern's 10-inch TCI Line in Jefferson, Alabama; (12) the Shades Valley Meter Station (Point Code 824200) which is located at or near milepost 327.8 on Southern's North Main Line & Loop Line in Jefferson County, Alabama; (13) the Walker County Brick Meter Station (Point Code 836500) which is located at or near milepost 18.9 on Southern's 6-inch Cordova Line in Walker County, Alabama; (14) the Certain Teed Meter Station (Point Code 935700) which is located at or near milepost 0.7 on Southern's 4-inch Certain Teed Line in Chatham County, Georgia; and (15) the Southland Oil Meter Station (Point Code 732500) which is located at or near milepost 2.6 on Southern's 6-inch Tinsley Field Line in Yazoo County, Mississippi.

Southern states that the plant operations of many of these locations have ceased and that it has not provided natural gas service at these meter stations for at least three years. Southern also states that the abandonment of facilities will not result in any termination or interruption of existing service.

Any person or the Commission's staff may, within 45 days after issuance of the instant notice by the Commission, file pursuant to Rule 214 of the Commission's Procedural Rules (18 CFR 385.214) a motion to intervene or notice of intervention and pursuant to Section 157.205 of the Regulations under the Natural Gas Act (18 CFR 157.205) a protest to the request. If no protest is filed within the time allowed therefor, the proposed activity shall be deemed to be authorized effective the day after the time allowed for filing a protest. If a protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request shall be treated as an application for authorization pursuant to Section 7 of the Natural Gas Act.

Lois D. Cashell,

Secretary.

[FR Doc. 97–25137 Filed 9–22–97; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP97–748–000]

Tennessee Gas Pipeline Company; Notice of Request Under Blanket Authorization

September 17, 1997.

Take notice that on September 11, 1997, Tennessee Gas Pipeline Company (Tennessee), P.O. Box 2511, Houston, Texas 77252, filed in Docket No. CP97–748–000 a request pursuant to Sections 157.205 and 157.212 of the Commission's Regulations under the Natural Gas Act (18 CFR 157.205 and 157.212) for approval to convert an existing receipt point for SONAT Intrastate-Alabama (SONAT), an intrastate pipeline company, under Tennessee's blanket certificate issued in Docket No. CP82–413–000, pursuant to Section 7(c) of the Natural Gas Act (NGA), all as more fully set forth in the request which is on file with the Commission and open to public inspection.

Tennessee proposes to convert existing receipt point No. 1–2038 located in Lamar County, Alabama, by removing an eight-inch check-valve, installing a spool piece, and modifying the existing electronic measuring equipment to function as a delivery meter. Tennessee asserts that SONAT will reimburse Tennessee for the cost of this project, which Tennessee estimates to be $20,800.

Tennessee states that the volumes of natural gas to be delivered to SONAT at the proposed delivery point will be on an interruptible basis. Tennessee asserts that the total volumes delivered to SONAT before the conversion of the receipt point do not exceed the total volumes to be delivered to SONAT after the conversion and that this change is not prohibited by an existing tariff. Tennessee further asserts that it has sufficient capacity to accomplish the deliveries specified herein without detriment or disadvantage to Tennessee's other customers.

Any person or the Commission's Staff may, within 45 days of the issuance of the instant notice by the Commission, file pursuant to Rule 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.214), a motion to intervene and pursuant to Section 157.205 of the regulations under the Natural Gas Act (18 CFR 157.205), a protest to the request. If no protest is filed within the time allowed therefor, the proposed activities shall be deemed to be authorized effective the day after

the time allowed for filing a protest. If a protest is filed and not withdrawn 30 days after the time allowed for filing a protest, the instant request shall be treated as an application for authorization pursuant to Section 7 of the Natural Gas Act.

Lois D. Cashell,

Secretary.

[FR Doc. 97–25139 Filed 9–22–97; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP97–527–000]

Texas Eastern Transmission Corporation; Notice of Proposed Changes in FERC Gas Tariff

September 17, 1997.

Take notice that on September 12, 1997, Texas Eastern Transmission Corporation (Texas Eastern) tendered for filing as part of its FERC Gas Tariff, Original Volume No. 2, the revised tariff sheets listed on Appendix A of the filing to become effective October 6, 1997.

Texas Eastern states that the purpose of this filing is to reflect changes in Texas Eastern's Rate Schedule X–28 which were authorized in Texas Eastern's Order No. 636 restructuring proceeding in Docket Nos. RS92–11–000, et al.

Texas Eastern states that copies of the filing were served on all affected parties.

Any person desiring to be heard or to protest this filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Sections 385.214 and 385.211 of the Commission's Rules and Regulations. All such motions or protests must be filed as provided in Section 154.210 of the Commission's Regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room.

Lois D. Cashell,

Secretary.

[FR Doc. 97–25145 Filed 9–22–97; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP97–437–000]

Williams Natural Gas Company and Missouri Gas Energy, a Division of Southern Union Company; Data Request and Notice of Staff Technical Conference

September 17, 1997.

On August 1, 1997, Williams Natural Gas Company (Williams) and Missouri Gas Energy, a Division of Southern Union Company (MGE) filed a request for a declaratory order requesting that the Commission resolve certain issues concerning the operation of the right of first refusal (ROFR) mechanism on William's system. A number of parties have filed interventions and protests or comments on the filing. Some of those filing comments and the Commission staff are not clear about some aspects of the request for a declaratory order. In order to clarify these issues, Williams and MGE are required to respond to the following questions by October 3, 1997. A technical conference to discuss these issues will be held on October 21, 1997.

1. For each example posited in the August 1, 1997 Declaratory Order request, Williams and MGE must provide a complete description of the expiring contract and the bids received on the capacity, including, the capacity for each component of TSS service under the expiring contract, whether the bids submitted are for TSS service, the capacities of each TSS component contained in each bid for the expiring capacity, the duration of the bids, and the rate bid and maximum rate for each component.

2. Parts A and C of the August 1, 1997 Declaratory Order request appear to pose the same question, and Williams and MGE must explain any intended difference in the questions posed.

3. Williams and MGE must explain how the examples in their request for a Declaratory Order differ from the issue addressed by the Commission in William's restructuring proceeding, Williams Natural Gas Company, 66 FERC ¶ 61,315, at 61,946 (1994).

The response to these questions should be filed in accordance with the provisions of the Commission's Rules of Practice and Procedure, in particular, 18 CFR 385.2001 and 385.2010 (Rules 2001 and 2010), which require that documents be filed with the Secretary of the Commission and served on all parties in the docket.

The conference to address these issues will be held on October 21, 1997, beginning at 10 a.m., in a room to be designated at the offices of the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, DC 20426.

All interested persons are invited to attend.

Lois D. Cashell,

Secretary.

[FR Doc. 97–25143 Filed 9–22–97; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Surrender of License

September 17, 1997.

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. Type of Application: Surrender of License.

b. Project No.: 8924–030.

c. Date filed: August 5, 1997.

d. Applicant: Northeast Hydrodevelopment Corporation.

e. Name of Project: McLane Dam.

f. Location: Souhegan River, in Hillsboro County, New Hampshire.

g. Filed Pursuant to: Federal Power Act, 16 U.S.C. 791(a)–825(r).

h. Applicant Contact: Mr. Jason M. Hines, 1114 East Victor Street, Bellingham, WA 98225, (360) 752–9502.

i. FERC Contact: James Hunter, (202) 219–2839.

j. Comment Date: October 30, 1997.

k. Description of Project: The project would have consisted of: (1) The existing 230-foot-long, 18-foot-high, concrete McLane Dam and 6-acre reservoir; (2) a 32-foot-long, 16-foot-wide powerhouse containing a 300-kilowatt generating unit; and (3) a 225-foot-long, buried transmission line.

The Licensee requests surrender of the license, stating that restoration of the dam's spillway and west abutment, and site preparation have been the only on-site construction activities. This work was completed prior to July 1, 1993, when construction was suspended due to a lack of funds.

l. This notice also consists of the following standard paragraphs: B, C1, and D2.

B. 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.

C1. 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. 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. A copy of any motion to intervene must also be served upon each representative of the Applicant specified in the particular application.

D2. 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.

Lois D. Cashell,

Secretary.

[FR Doc. 97–25141 Filed 9–22–97; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice; Sunshine Act Meeting

September 17, 1997.

THE FOLLOWING NOTICE OF MEETING IS PUBLISHED PURSUANT TO SECTION 3(A) OF THE GOVERNMENT IN THE SUNSHINE ACT (PUB. L. NO. 94–409), 5 U.S.C. 552B:

AGENCY HOLDING MEETING: Federal Energy Regulatory Commission.

DATE AND TIME: September 24, 1997, 10:00 a.m.

PLACE: Room 2C, 888 First Street, N.E., Washington, D.C. 20426.

STATUS: Open.

MATTERS TO BE CONSIDERED: Agenda.

*Note—Items Listed on the agenda may be deleted without further notice.

CONTACT PERSON FOR MORE INFORMATION: Lois D. Cashell, Secretary; Telephone (202) 208–0400. For a recording listing items stricken from or added to the meeting, call (202) 208–1627.

THIS IS A LIST OF MATTERS TO BE CONSIDERED BY THE COMMISSION. IT DOES NOT INCLUDE A LISTING OF ALL PAPERS RELEVANT TO THE ITEMS ON THE AGENDA; HOWEVER, ALL PUBLIC DOCUMENTS MAY BE EXAMINED IN THE REFERENCE AND INFORMATION CENTER.

CONSENT AGENDA—HYDRO

682ND MEETING—SEPTEMBER 24, 1997

REGULAR MEETING (10:00 A.M.)

CAH–1.
PROJECT NO. 2442–028, CITY OF WATERTOWN, NEW YORK

CAH–2.
PROJECT NO. 8185–032, BLUESTONE ENERGY DESIGN, INC.

CAH–3.
PROJECT NO. 4632–020, CLIFTON POWER CORPORATION

CAH–4.
PROJECT NO. 10078–014, CARL AND ELAINE HITCHCOCK

CAH–5.
PROJECT NO. 2322–023, CENTRAL MAINE POWER COMPANY
PROJECT NO. 2325–021, CENTRAL MAINE POWER COMPANY
PROJECT NO. 2552–022, CENTRAL MAINE POWER COMPANY
PROJECT NO. 2574–021, MERIMIL LIMITED PARTNERSHIP
PROJECT NO. 5073–051, BENTON FALLS ASSOCIATES
PROJECT NO. 2611–030, KIMBERLY-CLARK TISSUE COMPANY/UAH HYDRO-KENNEBEC LIMITED PARTNERSHIP
PROJECT NO. 11472–002, CONSOLIDATED HYDRO MAINE INC.

CAH–6.
PROJECT NO. 2833–055, PUBLIC UTILITY DISTRICT NO. 1 OF LEWIS COUNTY, WASHINGTON

CAE–7.
OMITTED

CONSENT ELECTRIC—AGENDA

CAE–1.
DOCKET NO. ER97–3955–000, COMMONWEALTH EDISON COMPANY AND COMMONWEALTH EDISON COMPANY OF INDIANA, INC.

CAE–2.
DOCKET NO. ER97–4116–000, INVENTORY MANAGEMENT AND DISTRIBUTION COMPANY, INC.

CAE–3.
DOCKET NO. ER97–2460–000, UNITIL POWER CORPORATION
DOCKET NO. ER97–2462–000, UNITIL RESOURCES, INC.
DOCKET NO. ER97–2463–000, FITCHBURG GAS AND ELECTRIC LIGHT COMPANY

CAE–4.
DOCKET NO. ER97–3832–000, DETROIT EDISON COMPANY
DOCKET NO. ER97–3834–000, DTE ENERGY TRADING, INC.
DOCKET NO. ER97–3835–000, DTE COENERGY, L.L.C.

CAE–5.
DOCKET NOS. ER96–1794–000 AND 001, SOUTHERN COMPANY SERVICES, INC.

CAE–6.
DOCKET NO. ER96–2850–001, SIERRA PACIFIC POWER COMPANY

CAE–7.
OMITTED

CAE–8.
OMITTED

CAE–9.
OMITTED

CAE–10.
DOCKET NOS. ER96–2381–000 AND OA96–39–000, FLORIDA POWER & LIGHT COMPANY

CAE–11.
DOCKET NO. TX96–2–000, CITY OF COLLEGE STATION, TEXAS

CAE–12.
DOCKET NO. EC93–6–004, CINCINNATI GAS & ELECTRIC COMPANY AND PSI ENERGY, INC.

CAE–13.
DOCKET NO. ER97–3663–000, UNION ELECTRIC DEVELOPMENT CORPORATION
DOCKET NO. ER97–3664–000, UNION ELECTRIC COMPANY

CAE–14.
DOCKET NO. EL97–40–001, INDEPENDENT POWER PRODUCERS OF NEW YORK, INC.

CAE–15.
OMITTED

CAE–16.
OMITTED

CAE–17.
DOCKET NO. ER95–59–001, SOUTHERN COMPANY SERVICES, INC.
DOCKET NO. ER95–138–001, MISSISSIPPI POWER COMPANY
DOCKET NO. ER95–149–001, ALABAMA POWER COMPANY

CAE–18.
DOCKET NO. ER96–3146–001, WEST PENN POWER COMPANY

CAE–19.
DOCKET NO. EL97–25–001, NORAM ENERGY SERVICES, INC.

CAE–20.
DOCKET NO. ER97–1510–001, CONSUMERS ENERGY COMPANY
CAE–21.
OMITTED
CAE–22.
DOCKET NO. ER86–645–008, BOSTON EDISON COMPANY
CAE–23.
OMITTED
CAE–24.
OMITTED
CAE–25.
DOCKET NO. EL96–37–000, PACIFIC GAS & ELECTRIC COMPANY
CAE–26.
DOCKET NO. RM95–7–000, SERVICE COMPARABILITY IN THE ELECTRIC UTILITY INDUSTRY
DOCKET NO. RM95–10–000, ELECTRIC TRANSMISSION SERVICE COMPARABILITY TARIFFS
DOCKET NO. RM95–13–000, REPORTING REQUIREMENTS AND FEES APPLICABLE TO POWER MARKETERS

CONSENT AGENDA—OIL AND GAS

CAG–1.
DOCKET NOS. RP96–268–002 AND 003, TENNESSEE GAS PIPELINE COMPANY
DOCKET NOS. RP96–308–001, 002 AND 003, TENNESSEE GAS PIPELINE COMPANY
DOCKET NO. RP96–269–003, EAST TENNESSEE NATURAL GAS COMPANY
CAG–2.
DOCKET NO. RP97–446–000, NAUTILUS PIPELINE COMPANY, LLC
CAG–3.
DOCKET NO. RP97–487–000, GARDEN BANKS GAS PIPELINE, LLC
CAG–4.
DOCKET NO. RP97–494–000, ANR PIPELINE COMPANY
CAG–5.
OMITTED
CAG–6.
OMITTED
CAG–7.
DOCKET NO. RP97–469–000, NATURAL GAS PIPELINE COMPANY OF AMERICA
CAG–8.
DOCKET NO. RP97–484–000, WILLIAMS NATURAL GAS COMPANY
CAG–9.
DOCKET NO. RP97–488–000, COLORADO INTERSTATE GAS COMPANY
CAG–10.
DOCKET NO. RP97–490–000, TRAILBLAZER PIPELINE COMPANY
CAG–11.
DOCKET NO. RP97–496–000, NORTHERN NATURAL GAS COMPANY
CAG–12.
DOCKET NO. RP97–497–000, KOCH GATEWAY PIPELINE COMPANY
CAG–13.
OMITTED
CAG–14.
DOCKET NO. RP97–503–000, WYOMING INTERSTATE COMPANY, LTD.
CAG–15.
DOCKET NOS. PR96–7–000 AND 001, TRANSOK, INC.
CAG–16.
DOCKET NOS. PR97–3–000 AND 001, OLYMPIC PIPELINE COMPANY
CAG–17.
DOCKET NO. RP96–345–001, TENNESSEE GAS PIPELINE COMPANY
CAG–18.
DOCKET NOS. RP96–366–005 AND FA94–15–002, FLORIDA GAS TRANSMISSION COMPANY
CAG–19.
DOCKET NOS. RP97–411–000 AND 001, SEA ROBIN PIPELINE COMPANY
CAG–20.
DOCKET NO. RP91–26–017, EL PASO NATURAL GAS COMPANY
CAG–21.
OMITTED
CAG–22.
DOCKET NOS. RP97–248–000 AND 001, NORTHERN NATURAL GAS COMPANY
CAG–23.
DOCKET NOS. RP97–315–000 AND 004, NORTHWEST PIPELINE CORPORATION
CAG–24.
DOCKET NOS. TM97–3–25–001, 002 AND RP97–233–000, MISSISSIPPI RIVER TRANSMISSION CORPORATION
CAG–25.
OMITTED
CAG–26.
DOCKET NOS. RP87–33–011, 012 AND TA88–1–43–005, WILLIAMS NATURAL GAS COMPANY
CAG–27.
DOCKET NOS. RP93–206–018 AND RP96–347–009, NORTHERN NATURAL GAS COMPANY
CAG–28.
DOCKET NO. RP97–397–001, EL PASO NATURAL GAS COMPANY
CAG–29.
DOCKET NO. RP97–284–001, SOUTHERN CALIFORNIA EDISON COMPANY V. SOUTHERN CALIFORNIA GAS COMPANY
CAG–30.
DOCKET NO. RP97–1–009, NATIONAL FUEL GAS SUPPLY CORPORATION
CAG–31.
OMITTED
CAG–32.
DOCKET NO. RM87–3–028, ANNUAL CHARGES UNDER THE OMNIBUS BUDGET RECONCILIATION ACT OF 1966 (EXPLORER PIPELINE COMPANY)
CAG–33.
OMITTED
CAG–34.
DOCKET NOS. RP91–203–065, RP92–132–053 AND RS92–23-030, TENNESSEE GAS PIPELINE COMPANY
CAG–35.
DOCKET NO. RP96–383–002, CNG TRANSMISSION CORPORATION
CAG–36.
DOCKET NO. RM97–8–000, INFORMATION AND REQUESTS
CAG–37.
DOCKET NO. CP96–544–003, PACIFIC INTERSTATE TRANSMISSION COMPANY
CAG–38.
DOCKET NO. CP96–572–001, KOCH GATEWAY PIPELINE COMPANY
CAG–39.
DOCKET NO. CP96–727–002, KERN RIVER GAS TRANSMISSION COMPANY
CAG–40.
DOCKET NO. CP91–1794–002, TRUNKLINE GAS COMPANY AND KOCH GATEWAY PIPELINE COMPANY
CAG–41.
DOCKET NO. CP97–331–000, TRANSCONTINENTAL GAS PIPE LINE CORPORATION
CAG–42.
DOCKET NO. CP96–178–004, MARITIMES & NORTHEAST PIPELINE, L.L.C.
DOCKET NO. CP97–238–001, MARITIMES & NORTHEAST PIPELINE, L.L.C. AND PORTLAND NATURAL GAS TRANSMISSION SYSTEM
CAG–43.
DOCKET NO. CP97–521–000, TEXAS GAS TRANSMISSION CORPORATION

HYDRO AGENDA

H–1.
PROJECT NO. 5090–005, CITY OF IDAHO FALLS, IDAHO. ORDER ON APPLICATION FOR LICENSE.

ELECTRIC AGENDA

E–1.
DOCKET NOS. ER97–4024–000 AND EL95–62–000, BRITISH COLUMBIA POWER EXCHANGE

CORPORATION.
ORDER ON MARKET BASED RATES, BLANKET AUTHORIZATIONS, AND WAIVERS, AND ON WITHDRAWAL OF PETITION FOR DECLARATORY ORDER.
E–2.
DOCKET NO. NJ97–1–000, SOUTHERN ILLINOIS POWER COOPERATIVE.
ORDER ON RECIPROCITY TARIFF FILED BY NON-JURISDICTIONAL UTILITY.

OIL AND GAS AGENDA

I. PIPELINE RATE MATTERS

PR–1.
DOCKET NO. RP94–365–000, WILLIAMS NATURAL GAS COMPANY
ORDER ON INITIAL DECISION.

II. PIPELINE CERTIFICATE MATTES

PC–1.
DOCKET NOS. CP96–152–000 AND 001, KANSAS PIPELINE COMPANY AND RIVERSIDE PIPELINE COMPANY, L.P.
DOCKET NO. CP97–738–000, TRANSOK, INC.
DOCKET NO. PR94–3–002, KANSOK PARTNERSHIP
DOCKET NO. RP95–212–002, KANSOK PARTNERSHIP, KANSAS PIPELINE PARTNERSHIP AND RIVERSIDE PIPELINE COMPANY, L.P.
DOCKET NO. RP95–395–002, WILLIAMS NATURAL GAS COMPANY V. KANSAS PIPELINE OPERATING COMPANY, KANSAS PIPELINE PARTNERSHIP, KANSOK PARTNERSHIP AND RIVERSIDE PIPELINE COMPANY, L.P.
APPLICATION FOR CERTIFICATE TO OPERATE EXISTING FACILITIES AS JURISDICTIONAL INTERSTATE PIPELINE COMPANY.
PC–2.
DOCKET NO. CP96–610–000, GRANITE STATE GAS TRANSMISSION, INC.
APPLICATION TO CONSTRUCT AND OPERATE LNG FACILITY IN WELLS, MAINE.
PC–3.
DOCKET NOS. CP96–248–000, 001, 002, 003 AND OO4, PORTLAND NATURAL GAS TRANSMISSION SYSTEM
DOCKET NOS. CP96–249–000, 001, 002, 003, 004, 005 AND 006, PORTLAND NATURAL GAS TRANSMISSION SYSTEM
DOCKET NO. CP97–238–000, MARITIMES AND NORTHEAST PIPELINE, L.L.C. AND PORTLAND NATURAL GAS TRANSMISSION SYSTEM
APPLICATION TO CONSTRUCT AND OPERATE NEW 242 MILE PIPELINE.
PC–4.
DOCKET NOS. CP96–809–000, 001, 002, 003 AND CP96–810–000, MARITIMES & NORTHEAST PIPELINE, L.L.C.
DOCKET NO. CP96–178–004, MARITIMES & NORTHEAST PIPELINE, L.L.C.
DOCKET NO. CP97–238–000, MARITIMES & NORTHEAST PIPELINE, L.L.C. AND PORTLAND NATURAL GAS TRANSMISSION SYSTEM.
APPLICATION TO CONSTRUCT AND OPERATE 230 MILE PIPELINE.
PC–5.
OMITTED

Lois D. Cashell,

Secretary.

[FR Doc. 97–25280 Filed 9–18–97; 4:17 pm]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–5896–6]

Agency Information Collection Activities Under OMB Review; Standards of Performance for New Stationary Sources Ammonium Sulfate Manufacturing Plants

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (44 U.S.C. 3507(a)(1)(D)), this notice announces that the following Information Collection Request (ICR) has been forwarded to the Office of Management and Budget (OMB) for review and approval: Standards of Performance for New Stationary Sources —Ammonium Sulfate Manufacturing Plants— NSPS Subpart PP (OMB# 2060–0032). The ICR describes the nature of the information collection and its expected burden and cost; where appropriate, it includes the actual data collection instrument.

DATES: Comments must be submitted on or before October 23, 1997.

FOR FURTHER INFORMATION OR A COPY CALL: Sandy Farmer at EPA, (202) 260–2740, and refer to EPA ICR No.1066.02

SUPPLEMENTARY INFORMATION:

Title: Standards of Performance for Ammonium Sulfate Manufacturing Plants (OMB Control No. 2060–0032; EPA ICR No 1066.02). This is a request for reinstatement without change of a previously approved collection for which approval has expired.

Abstract: The Administrator has judged that PM emissions from ammonium sulfate manufacturing plants cause or contribute to air pollution that may reasonably be anticipated to endanger public health or welfare. Owners/operators of ammonium sulfate manufacturing plants must make the following one-time-only reports: notification of the date of construction or reconstruction; notification of the anticipated and actual dates of startup; notification of any physical or operational change to an existing facility which may increase the regulated pollutant emission rate; and the notification of the date of the initial performance test. The recordkeeping requirements for ammonium sulfate plants consist of the occurrence and duration of all start-ups and malfunctions, the initial performance tests results, amount of ammonium sulfate feed material, and the pressure drop across the emission control system. Records of startups, shutdowns and malfunctions shall be noted as they occur. Records of the performance test should include information necessary to determine the conditions of the performance test, and performance test measurements (including pressure drop across the emission control system) and results. The continuous monitoring system (CMS) shall record pressure drop across the scrubbers continuously and automatically.

In order to ensure compliance with the standards promulgated to protect public health, adequate reporting and recordkeeping is necessary. In the absence of such information enforcement personnel would be unable to determine whether the standards are being met on a continuous basis, as required by the Clean Air Act.

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 listed in 40 CFR Part 9 and 48 CFR Chapter 15. The Federal Register Notice required under 5 CFR 1320.8(d), soliciting comments on this collection of information was published on March 5, 1997. No comments were received.

Burden Statement: The annual public reporting and recordkeeping burden for this collection of information is estimated to average 91.2 hours per response. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain,

or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

Respondents/Affected Entities: Ammonium sulfate manufacturing facilities.

Estimated Number of Respondents: 2.

Frequency of Response: 1.

Estimated Number of Responses: 2.

Estimated Total Annual Hour Burden: 182 hours.

Estimated Total Annualized Cost Burden: 0.

Send comments 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 to the following addresses. Please refer to EPA ICR No. 1066.02 and OMB Control No. 2060–0032 in any correspondence.

Ms. Sandy Farmer, U.S. Environmental Protection Agency, OPPE Regulatory Information Division (2137), 401 M Street, SW, Washington, DC 20460.

and

Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for EPA 725 17th Street, NW, Washington, DC 20503.

Dated: September 17, 1997.

Joseph Retzer,

Director, Regulatory Information Division.

[FR Doc. 97–25131 Filed 9–22–97; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FR–5897–4]

Industrial Non-Hazardous Waste Policy Dialogue Committee; Notice of Charter Renewal

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of charter renewal.

The Charter for the Environmental Protection Agency's (EPA) Industrial Non-Hazardous Waste Policy Dialogue Committee will be renewed for an additional two-year period, as a necessary committee which is in the public interest, in accordance with the provisions of the Federal Advisory Committee Act of (FACA), 5 U.S.C. appl.2 section 9(c). The purpose of INHWPDC is to provide advice and counsel to the EPA on issues associated with management and disposal guidelines for industrial, non-hazardous waste under the Resource Conservation and Recovery Act. It is determined that INHWPDC is in the public interest in connection with the performance of duties imposed on the Agency by law.

Inquiries may be directed to Deborah Dalton, Designated Federal Officer, NACEPT, U.S. EPA, Deputy Director, Consensus and Dispute Resolution Program (mail code 2136), 401 M Street, SW, Washington, DC 20460.

Dated: September 17, 1997.

Deborah Dalton,

Designated Federal Officer.

[FR Doc. 97–25222 Filed 9–22–97; 8:45 am]

BILLING CODE 6560–50–M

ENVIRONMENTAL PROTECTION AGENCY

[FRL–5896–8]

San Gabriel Valley Superfund Sites Notice of Proposed Administrative Settlement

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice; request for public comment.

SUMMARY: In accordance with the Comprehensive Environmental Response, Compensation and Liability Act of 1980, as amended by the Superfund Amendments and Reauthorization Act of 1986 (''CERCLA''), 42 U.S.C. 9600 *et seq.*, notice is hereby given that on August 16, 1997 the United States Environmental Protection Agency (''EPA'') and the United States Department of Justice (''DOJ'') executed a proposed Prospective Purchaser Agreement pertaining to a property transaction within the San Gabriel Valley Superfund Sites. The proposed Prospective Purchaser Agreement would resolve certain potential claims of the United States under sections 106 and 107 of CERCLA, 42 U.S.C. 9606 and 9607, and section 7003 of the Solid Waste Disposal Act, as amended, 42 U.S.C. 6973, against Ekstrom Properties and Cardinal Industrial Finishes (the ''Purchasers''). The Purchasers plan to acquire an eleven acre parcel located within the Puente Valley Operable Unit of the San Gabriel Valley Superfund Sites near Los Angeles, California for the purposes of developing and operating a powder coating manufacturing facility. The proposed settlement would require the Purchasers to make a one-time payment of $150,000, which would be placed into a special account for response actions in the Puente Valley Operable Unit.

For thirty (30) calendar days following the date of publication of this document, EPA will receive written comments relating to this proposed settlement. If requested prior to the expiration of this public comment period, EPA will provide an opportunity for a public meeting in the affected area. EPA's response to any comments received will be available for public inspection at the U.S. Environmental Protection Agency, 75 Hawthorne Street, San Francisco, CA 94105.

DATES: Comments must be submitted on or before October 23, 1997.

AVAILABILITY: The proposed Prospective Purchaser Agreement and additional background documentation relating to the settlement are available for public inspection at the U.S. Environmental Protection Agency, 75 Hawthorne Street, San Francisco, CA, 94105. A copy of the proposed settlement may also be obtained from Brett Moffatt, Assistant Regional Counsel (ORC–3), Office of Regional Counsel, U.S. EPA Region IX, 75 Hawthorne Street, San Francisco, CA, 94105. Comments should reference ''Cardinal Industrial Finishes—Puente Valley Operable Unit, San Gabriel Valley Superfund Sites'' and ''Docket No. 97–12'' and should be addressed to Brett Moffatt at the above address.

FOR FURTHER INFORMATION CONTACT: Brett Moffatt, Assistant Regional Counsel (ORC–3), Office of Regional Counsel, U.S. EPA Region IX, 75 Hawthorne Street, San Francisco, CA, 94105; E-mail: moffatt.brett@epamail.epa.gov; Phone: (415) 744–1374.

Keith Takata,

Director, Superfund Division, U.S. EPA, Region IX.

[FR Doc. 97–25227 Filed 9–22–97; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–5897–1]

Proposed CERCLA Administrative Cost Recovery Settlement; Fourth And Carey Site

AGENCY: Environmental Protection Agency.

ACTION: Notice; request for public comment.

SUMMARY: In accordance with section 122(i) of the Comprehensive Environmental Response, Compensation, and Liability Act, as amended (''CERCLA''), 42 U.S.C. 9622(i), notice is hereby given of a proposed administrative cost recovery settlement concerning the Fourth and Carey Site in Hutchinson, Kansas, with the following settling parties: 4th & Carey PRP Group and the Lowen Corporation. The settlement requires the settling parties to pay $180,382.66 to the Hazardous Substances Superfund. The settlement includes a covenant not to sue the settling parties pursuant to Section 107(a) of CERCLA, 42 U.S.C. 9607(a). For thirty (30) days following the date of publication of this document, the Agency will receive written comments relating to the settlement. The Agency will consider all comments received and may modify or withdraw its consent to the settlement if comments received disclose facts or considerations which indicate that the settlement is inappropriate, improper, or inadequate. The Agency's response to any comments received will be available for public inspection at the Hutchinson Public Library, 901 N. Main Street, Hutchinson, Kansas 67501–4401, and at the EPA RegionVII Office, located at 726 Minnesota Avenue in Kansas City, Kansas 66101.

DATES: Comments must be submitted on or before October 23, 1997.

ADDRESSES: The proposed settlement and additional background information relating to the settlement are available for public inspection at the Hutchinson Public Library, located at 901 N. Main Street, Hutchinson, Kansas 67501–4401, and during weekday business hours at the EPA Region VII Office at 726 Minnesota Avenue in Kansas City, Kansas 66101. A copy of the proposed settlement may be obtained from Vanessa Cobbs, Regional Docket Clerk, EPA Region VII, 726 Minnesota Avenue, Kansas City, Kansas 66101, telephone: (913) 551–7630. Comments should reference the Fourth and Carey Site in Hutchinson, Kansas, and EPA Docket No. VII–97-F–0013 and should be addressed to Ms. Cobbs at the address above.

FOR FURTHER INFORMATION CONTACT: Mr. Gerhardt Braeckel, Assistant Regional Counsel, EPA Region VII, Office of Regional Counsel, 726 Minnesota Avenue, Kansas City, Kansas 66101, telephone: (913) 551–7471.

Dated: September 2, 1997.

Michael J. Sanderson,

Director, Superfund Division, U.S. EPA Region VII.

[FR Doc. 97–25225 Filed 9–22–97; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–5896–9]

Proposed CERCLA Administrative Cost Recovery Settlement; Fourth And Carey Site

AGENCY: Environmental Protection Agency.

ACTION: Notice; request for public comment.

SUMMARY: In accordance with section 122(i) of the Comprehensive Environmental Response, Compensation, and Liability Act, as amended (''CERCLA''), 42 U.S.C. 9622(i), notice is hereby given of a proposed administrative cost recovery settlement concerning the Fourth and Carey Site in Hutchinson, Kansas, with the following settling parties: Groendyke Transport Inc., and V & M Transport, Inc. The settlement requires the settling parties to pay $25,496.00 to the Hazardous Substances Superfund. The settlement includes a covenant not to sue the settling parties pursuant to Section 107(a) of CERCLA, 42 U.S.C. 9607(a). For thirty (30) days following the date of publication of this document, the Agency will receive written comments relating to the settlement. The Agency will consider all comments received and may modify or withdraw its consent to the settlement if comments received disclose facts or considerations which indicate that the settlement is inappropriate, improper, or inadequate. The Agency's response to any comments received will be available for public inspection at the Hutchinson Public Library, 901 N. Main Street, Hutchinson, Kansas 67501–4401, and at the EPA RegionVII Office, located at 726 Minnesota Avenue in Kansas City, Kansas 66101.

DATES: Comments must be submitted on or before October 23, 1997.

ADDRESSES: The proposed settlement and additional background information relating to the settlement are available for public inspection at the Hutchinson Public Library, located at 901 N. Main Street, Hutchinson, Kansas 67501–4401, and during weekday business hours at the EPA Region VII Office at 726 Minnesota Avenue in Kansas City, Kansas 66101. A copy of the proposed settlement may be obtained from Vanessa Cobbs, Regional Docket Clerk, EPA Region VII, 726 Minnesota Avenue, Kansas City, Kansas 66101, telephone: (913) 551–7630. Comments should reference the Fourth and Carey Site in Hutchinson, Kansas, and EPA Docket No. VII–97–F–0014 and should be addressed to Ms. Cobbs at the address above.

FOR FURTHER INFORMATION CONTACT: Mr. Gerhardt Braeckel, Assistant Regional Counsel, EPA Region VII, Office of Regional Counsel, 726 Minnesota Avenue, Kansas City, Kansas 66101, telephone: (913) 551–7471.

Dated: September 2, 1997.

Michael J. Sanderson,

Director, Superfund Division, U.S. EPA Region VII.

[FR Doc. 97–25226 Filed 9–22–97; 8:45 am]

BILLING CODE 6560–50–P

EXECUTIVE OFFICE OF THE PRESIDENT

Office of National Drug Control Policy

Designation of High Intensity Drug Trafficking Areas

AGENCY: Office of National Drug Control Policy, Executive Office of the President.

ACTION: Notice.

SUMMARY: This notice lists two (2) new High Intensity Drug Trafficking Areas designated by the Director of the Office of National Drug Control Policy. HIDTAs are domestic regions identified as having the most critical drug trafficking problems that adversely affect the United States. These new HIDTAs are designated pursuant to 21 U.S.C. 1504(c), as amended, to promote more effective coordination of drug control efforts. The additional resources provided by Congress enable task forces of local, State and Federal officials to assess regional drug threats, design strategies to combat the threats, develop initiatives to implement the strategies, and evaluate the effectiveness of these coordinated efforts.

FOR FURTHER INFORMATION CONTACT: Comments and questions regarding this notice should be directed to Mr. Richard Y. Yamamoto, Director, HIDTA, Office

of National Drug Control Policy, Executive Office of the President, Washington, D.C. 20503; 202–395–6755.

SUPPLEMENTARY INFORMATION: In 1990, the Director of ONDCP designated the first five HIDTAs. These original HIDTAs, areas through which most illegal drugs enter the United States, are the Southwest Border, Houston, Los Angeles, New York/New Jersey, and South Florida. In 1994, the Director designated the Washington/Baltimore HIDTA to address the extensive drug distribution networks serving hardcore drug users. Also in 1994, the Director designated Puerto Rico/U.S. Virgin Islands as a HIDTA based on the significant amount of drugs entering the United States through this region. In 1995, the Director designated three more HIDTAs in Atlanta, Chicago, and Philadelphia/Camden to target drug abuse and drug trafficking in those areas.

Five additional HIDTAs were designated on December 20, 1996. These are: the Gulf Coast HIDTA (includes parts of Alabama, Louisiana, and Mississippi); the Lake County, Indiana HIDTA, the Midwest HIDTA (includes parts of Iowa, Kansas, Missouri, Nebraska, and South Dakota, with focus on methamphetamine); the Northwest HIDTA (includes seven counties of Washington State); and the Rocky Mountain HIDTA (includes parts of Colorado, Utah, and Wyoming).

The program supports more than 160 collocated officer/agent task forces; strengthens mutually supporting local, State, and Federal drug trafficking and money laundering task forces; bolsters information analysis and sharing networks; and, improves integration of law enforcement, drug treatment and drug abuse prevention programs. The states and counties included in the two new HIDTAs are:

(1) *Southeastern Michigan*—The following Michigan counties: Wayne, Oakland, Macomb, and Washtenaw.

(2) *San Francisco Bay Area*—The following California counties: Alameda, Contra Costa, Lake, Marin, Monterey, San Francisco, San Mateo, Santa Clara, Santa Cruz, and Sonoma.

Signed at Washington, D.C. this 10th day of September, 1997.

Barry R. McCaffrey,

Director.

[FR Doc. 97–25162 Filed 9–22–97; 8:45 am]

BILLING CODE 3180–02–P

FEDERAL COMMUNICATIONS COMMISSION

Notice of Public Information Collection(s) Being Reviewed by the Federal Communications Commission

September 15, 1997.

SUMMARY: The Federal Communications Commission, as part of its continuing effort to reduce paperwork burden invites the general public and other Federal agencies to take this opportunity to comment on the following information collection(s), as required by the Paperwork Reduction Act of 1995, Public Law 104–13. An agency may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act (PRA) that does not display a valid control number. Comments are requested concerning (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimate; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology.

DATES: Written comments should be submitted on or before November 24, 1997. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all comments to Judy Boley, Federal Communications Commissions, Room 234, 1919 M St., NW., Washington, DC 20554 or via internet to jboley@fcc.gov.

FOR FURTHER INFORMATION CONTACT: Judy Boley at 202–418–0214 or via internet at jboley@fcc.gov.

OMB Approval No.: 3060–0192.

Title: Section 87.103, Posting station license.

Form No.: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities; individuals or households; state, local or tribal government, not-for-profit institutions.

Number of Respondents: 47,800.

Estimated Hour Per Response: .250 hours per response.

Frequency of Response: Recordkeeping requirement.

Cost to Respondents: N/A.

Estimated Total Annual Burden: 11,950 hours.

Needs and Uses: The recordkeeping requirement contained in Section 87.103 is necessary to demonstrate that all transmitters in the Aviation Service are properly licensed in accordance with the requirements of Section 201 of the Communications Act of 1934, as amended, 47 U.S.C. 301, No. 2020 of the International Radio Regulations, and Article 30 of the Convention on International Civil Aviation. This requirement is necessary so that quick resolution of any harmful interference problems can be achieved and to ensure that the station is operating in accordance with the appropriate rules, statutes, and treaties.

Federal Communications Commission.

Shirley Suggs,

Chief, Publications Branch.

[FR Doc. 97–25123 Filed 9–22–97; 8:45 am]

BILLING CODE 6712–01–F

FEDERAL COMMUNICATIONS COMMISSION

Notice of Public Information Collection(s) Being Reviewed by the Federal Communications Commission for Extension Under Delegated Authority 5 CFR 1320 Authority, Comments Requested

September 17, 1997.

SUMMARY: The Federal Communications Commission, as part of its continuing effort to reduce paperwork burden invites the general public and other Federal agencies to take this opportunity to comment on the following information collection(s), as required by the Paperwork Reduction Act of 1995, Public Law 104–13. An agency may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act (PRA) that does not display a valid control number. Comments are requested concerning (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimate; (c) ways to enhance

the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology.

DATES: Persons wishing to comment on this information collection should submit comments November 24, 1997.

ADDRESSES: Direct all comments to Judy Boley, Federal Communications Commissions, Room 234, 1919 M St., NW., Washington, DC 20554 or via internet to jboley@fcc.gov.

FOR FURTHER INFORMATION CONTACT: Judy Boley at 202–418–0214 or via internet at jboley@fcc.gov.

OMB Approval Number: 3060–0202.

Title: Section 87.37 Developmental license.

Form No.: N/A.

Type of Review: Extension of existing collection.

Respondents: Businesses or other for-profit, individuals or households, state, local or tribal government, not-for-profit institutions.

Number of Respondents: 12.

Estimated Time Per Response: 8 hour per response.

Total Annual Burden: 96 hours.

Frequency of Response: On occasion.

Needs and Uses: The information collection requirement contained in Section 87.37 is needed to gather data on developmental programs for which a developmental authorization was granted to determine whether the developmental authorization should be renewed or whether to initiate proceedings to include such operations with in the normal scope of the Aviation Services. If the information was not collected the value of developmental programs in the Aviation Service would be severely limited.

OMB Approval Number: 3060–0222.

Title: Section 97.213 Remote control of a station.

Form No.: N/A.

Type of Review: Extension of existing collection.

Respondents: Individuals or households.

Number of Respondents: 500.

Estimated Time Per Response: .2 hour per response

Total Annual Burden: 100 hours.

Frequency of Response: Recordkeeping requirement.

Needs and Uses: The recordkeeping requirement in Section 97.213 consist of posting a photocopy of the station license, a label with the name, address and telephone number of the station licensee, and the name of at least one authorized control operator. The requirement is necessary so that quick resolution of any harmful interference problems can be achieved and to ensure that the station is operating in accordance with the Communications Act of 1934, as amended.

OMB Approval Number: 3060–0259.

Title: Section 90.263 Substitution of frequencies below 25 MHz.

Form No.: N/A.

Type of Review: Extension of existing collection.

Respondents: Businesses or other for-profit, state, local or tribal government.

Number of Respondents: 60.

Estimated Time Per Response: .5 hour per response.

Total Annual Burden: 30 hours.

Frequency of Response: On occasion.

Needs and Uses: The information collection requirement contained in Section 90.263 is needed to require applicants to provide a supplemental information showing that the proposed use of frequencies below 25 MHz are needed from a safety standpoint and that frequencies above 25 MHz will not meet the operational needs of the applicant. The information is used to evaluate the applicant's need for such frequencies and the interference potential to other stations operating on the proposed frequencies.

OMB Approval Number: 3060–0264.

Title: Section 80.413 On-board station equipment records.

Form No.: N/A.

Type of Review: Extension of existing collection.

Respondents: Businesses or other for-profit, individuals or households, state, local or tribal government, not-for-profit institutions.

Number of Respondents: 1,000.

Estimated Time Per Response: 2 hour per response.

Total Annual Burden: 2,000 hours.

Frequency of Response: Recordkeeping requirement.

Needs and Uses: The recordkeeping requirement contained in Section 80.413 is needed to demonstrate that all on-board repeaters and transmitters are properly operating pursuant to a station authorization issued by the FCC. The information is used by FCC Compliance and Information Bureau personnel during inspections and investigations to determine what mobile units and repeaters are associated with on-board stations aboard a particular vessel.

OMB Approval Number: 3060–0297.

Title: Section 80.503 Cooperative use of facilities.

Form No.: N/A.

Type of Review: Extension of existing collection.

Respondents: Businesses or other for-profit, individuals or households, state, local or tribal government, not-for-profit institutions.

Number of Respondents: 100.

Estimated Time Per Response: 16 hour per response.

Total Annual Burden: 1,600 hours.

Frequency of Response: Recordkeeping requirement.

Needs and Uses: The recordkeeping requirements contained in Section 80.503 are needed to ensure licensees which share private facilities operate within the specified scope of service, on a non-profit basis, and do not function as communications common carriers providing ship-shore public correspondence services. The information is used by FCC Compliance and Information Bureau personnel during inspection and investigations to insure compliance with applicable rules.

Federal Communications Commission.

Shirley Suggs,

Chief, Publications Branch.

[FR Doc. 97–25202 Filed 9–22–97; 8:45 am]

BILLING CODE 6712–01–F

FEDERAL COMMUNICATIONS COMMISSION

Sunshine Act Meeting; FCC To Hold Open Commission Meeting Thursday, September 25, 1997

The Federal Communications Commission will hold an Open Meeting on the subject listed below on Thursday, September 25, 1997, which is scheduled to commence at 9:30 a.m. in Room 856, at 1919 M Street, NW., Washington, DC.

Item No., Bureau, Subject

1—Office of Engineering and Technology—Title: Technical Requirements to Enable Blocking of Video Programming Based on Program Ratings -- Implementation of Sections 551(c), (d) and (e) of the Telecommunications Act of 1996. Summary: The Commission will consider addressing technical requirements for the implementation of ''V-Chip'' program blocking technology.

2—Wireless Telecommunications—Title: Calling Party Pays Service Option in the Commercial Mobile Radio Services. Summary: The Commission will consider action on calling party pays service options for CMRS subscribers.

Additional information concerning this meeting may be obtained from Maureen Peratino or David Fiske, Office of Public Affairs, telephone number (202) 418–0500.

Copies of materials adopted at this meeting can be purchased from the

FCC's duplicating contractor, International Transcription Services, Inc. (ITS, Inc.) at (202) 857–3800 or fax (202) 857–3805 and 857–3184. These copies are available in paper format and alternative media which includes, large print/type; digital disk; and audio tape. ITS may be reached by e-mail: its_inc@ix.netcom.com. Their Internet address is http://www.itsi.com.

This meeting can be viewed over George Mason University's Capitol Connection. For information on this service call (703) 993–3100. The audio portion of the meeting will be broadcast live on the Internet via the FCC's Internet audio broadcast page at <http://www.fcc.gov/realaudio/>. The meeting can also be heard via telephone, for a fee, from National Narrowcast Network, telephone (202) 966–2211 or fax (202) 966–1770; and from Conference Call USA (available only outside the Washington, DC metropolitan area), telephone 1–800–962–0044. Audio and video tapes of this meeting can be obtained from the Office of Public Affairs, Television Staff, telephone (202) 418–0460, or TTY (202) 418–1398; fax numbers (202) 418–2809 or (202) 418–7286.

Dated September 18, 1997.

Federal Communications Commission.

Shirley Suggs,

Chief, Publications Branch.

[FR Doc. 97–25325 Filed 9-19-97; 2:54 pm]

BILLING CODE 6712–01–F

FEDERAL TRADE COMMISSION

[File No. 971–0093]

Jitney-Jungle Stores of America, Inc.; Bruckmann, Rosser, Sherrill & Co., L.P.; Delta Acquisition Corp.; Delchamps, Inc.; Analysis To Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Proposed consent agreement.

SUMMARY: The consent agreement in this matter settles alleged violations of federal law prohibiting unfair or deceptive acts or practices or unfair methods of competition. The attached Analysis to Aid Public Comment describes both the allegations in the draft complaint that accompanies the consent agreement and the terms of the consent order—embodied in the consent agreement—that would settle these allegations.

DATES: Comments must be received on or before November 24, 1997.

ADDRESSES: Comments should be directed to: FTC/Office of the Secretary, Room 159, 6th St. and Pa. Ave. NW, Washington, DC 20580.

FOR FURTHER INFORMATION CONTACT: George S. Cary, Federal Trade Commission, H–374, 6th St. and Pennsylvania Ave. NW, Washington, DC 20580, (202) 326–3741. Phillip L. Broyles, Federal Trade Commission, S–2105, 6th St. and Pennsylvania Ave. NW, Washington, DC 20580. (202) 326–2805.

SUPPLEMENTARY INFORMATION: Pursuant to section 6(f) of the Federal Trade Commission Act, 38 Stat. 721, 15 U.S.C. 46, and § 2.34 of the Commission's rules of practice (16 CFR 2.34), notice is hereby given that the above-captioned consent agreement containing a consent order to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of sixty (60) days. The following Analysis to Aid Public Comment describes the terms of the consent agreement, and the allegations in the accompanying complaint. An electronic copy of the full text of the consent agreement package can be obtained from the Commission Actions section of the FTC Home Page (for September 12, 1997), on the World Wide Web, at ''http://www.ftc.gov/os/actions97.htm.'' A paper copy can be obtained from the FTC Public Reference Room, Room H–130, Sixth Street and Pennsylvania Avenue, NW, Washington, DC 20580, either in person or by calling (202) 326–3627. Public comment is invited. Such comments or views will be considered by the Commission and will be available for inspection and copying at its principal office in accordance with § 4.9(b)(6)(ii) of the Commission's rules of practice (16 CFR 4.9(b)(6)(ii)).

Analysis of Proposed Consent Order To Aid Public Comment

I. Introduction

The Federal Trade Commission (''Commission'') has accepted for public comment from Jitney-Jungle Stores of America, Inc. (''Jitney-Jungle''), Bruckmann, Rosser, Sherrill & Co., L.P. (''Bruckmann''), Delta Acquisition Corporation (''Delta''), and Delchamps, Inc. (''Delchamps'') (collectively ''the proposed Respondents'') an Agreement Containing Consent Order (''the proposed consent order''). Bruckmann owns a majority of the voting securities of Jitney-Jungle, and Delta is wholly-owned subsidiary of Jitney-Jungle. The proposed consent order is designed to remedy likely anticompetitive effects arising from Jitney-Jungle and Delta's proposed acquisition of the outstanding shares of Delchamps.

II. Description of the Parties and the Acquisition

Jitney-Jungle, which is headquartered in Jackson, Mississippi, is one of the leading supermarket chains in the Southeast. Jitney-Jungle operates 105 supermarkets in the states of Alabama, Arkansas, Louisiana, Mississippi, Florida, and Tennessee. The company is the largest supermarket operator in Mississippi with 72 stores. The company operates under three formats: (1) 78 conventional supermarkets under the ''Jitney-Jungle'' trade name; (2) 23 discount supermarkets under the ''Sack and Save,'' ''Mega Market,'' and ''Mega Pantry'' trade names; and (3) four premium supermarkets under the ''Jitney Premier'' trade name. Jitney-Jungle has sales of approximately $1.13 billion at its supermarkets, and total sales of $1.28 billion, in its 1997 fiscal year. The ultimate parent entity of Jitney-Jungle is Bruckmann, which owns a majority of the voting securities of Jitney-Jungle.

Delchamps, which is headquartered in Mobile, Alabama, is another leading supermarket chain in the Southeast. Delchamps operates a total of 118 conventional supermarkets under the ''Delchamps'' trade name. Delchamps' supermarkets are located in Alabama, Florida, Louisiana, and Mississippi. In addition, the company operates ten liquor stores in the state of Florida. Louisiana, and Mississippi. In addition, the company operates ten liquor stores in the state of Florida. Delchamps had sales of approximately $1.08 billion at its supermarkets, and total sales of $1.1 billion, in its 1997 fiscal year.

On or about July 8, 1997, Jitney-Jungle and Delta, a wholly-owned subsidiary of Jitney-Jungle, entered into a cash tender offer agreement with Delchamps to acquire all of the outstanding common stock of Delchamps for $30 per share. The total value of the proposed acquisition is approximately $228 million.

III. The Complaint

The draft complaint accompanying the proposed consent order alleges that the acquisition, as well as the agreement to enter into the acquisition, would substantially lessen competition in violation of section 7 of the Clayton Act, as amended, 15 U.S.C. 18, and section 5 of the FTC Act, as amended, 15 U.S.C. 45.

According to the draft complaint, the relevant line of commerce (i.e., the product market) is the retail sale of food and grocery items in supermarkets, and Jitney-Jungle and Delchamps are direct competitors. Stores other than

supermarkets are not in the relevant product market because they do not have a significant price-constraining effect on food and grocery products sold at supermarkets. Most consumers shopping for food and grocery products at supermarkets are not likely to shop elsewhere in response to a small price increase by supermarkets. In addition, supermarkets do not regularly price-check food and grocery products sold at other types of stores and do not typically change their food and grocery prices in response to prices at other types of stores.

Food stores other than supermarkets, such as convenience stores, ''mom & pop'' stores, and specialty food stores (e.g., seafood markets, bakeries, etc.) are not in the relevant product market because they typically offer far fewer items than the average supermarket and charge higher prices for many of the same or similar items. Other types of stores that sell some food and grocery products, such as large drug stores and mass merchandisers, offer only a limited number of items sold in the typical supermarket. The small number of membership club stores in the relevant market, which offer only a limited number of food and grocery products primarily in bulk sizes, do not have a significant effect on market concentration.

Military commissaries are also not in the relevant product market. Military commissaries, which are not open to the public, operate as supermarkets for eligible military personnel and their families with retail prices substantially below the average retail prices at supermarkets for the same or similar items in the Gulfport-Biloxi area in Mississippi, and in Pensacola, Florida. Retail prices at military commissaries are not advertised and are uniform throughout the country based on the actual cost of the item plus a nationwide uniform surcharge determined by rules established by the Secretary of Defense. Retail prices at military commissaries are not based on local market conditions. Supermarkets do not price-check food and grocery products sold at military commissaries and do not base their prices on the retail prices at the military commissaries.

According to the draft complaint, the relevant sections of the country (i.e., the geographic markets) in which to analyze the acquisition of Delchamps by Jitney and Delta are the following:

a. The Gulfport-Biloxi area of Mississippi, which consists of the parts of Hancock, Harrison, and Jackson counties that include Waveland, Bay Saint Louis, Pass Christian, Long Beach, Gulfport, Biloxi, D'Iberville, and Ocean Springs, and narrower markets contained therein, including Waveland/Bay Saint Louis, Gulfport, north Gulfport, and Biloxi/D'Iberville.

b. Pensacola, Florida, and narrower markets contained therein;

c. Hattiesburg, Mississippi, and the area immediately west of Hattiesburg; and

d. Vicksburg, Mississippi.

According to the draft compliant, these markets are highly concentrated, whether measured by the Herfindahl-Hirschman Index (commonly referred to as ''HHI'') or by two-firm and four-firm concentration ratios. The HHI is a measurement of market concentration calculated by summing the squares of the individual market shares of all the participants. The acquisition would significantly increase the HHIs in each of the already highly concentrated markets.

According to the draft complaint, entry into the retail sale of food and grocery products in supermarkets in the relevant sections of the country is difficult and would not be timely, likely, or sufficient to prevent anticompetitive effects in the relevant geographic markets.

Jitney-Jungle and Delta's acquisition of Delchamps may reduce competition in these markets by eliminating the direct competition between Jitney-Jungle and Delchamps, by increasing the likelihood that Jitney-Jungle will unilaterally exercise market power, or by increasing the likelihood of, or facilitating, collusion or coordinated interaction among the remaining competitors. Each of these effects increases the likelihood that the prices of food, groceries or services will increase, and the quality and selection of food, groceries or services will decrease, in the relevant sections of the country.

IV. Terms of the Proposed Consent Order

The proposed consent order attempts to remedy the Commission's competitive concerns about the acquisition. Under the terms of the proposed consent order, the proposed Respondents must divest the ten supermarkets listed below—five Jitney-Jungle owned and operated stores (four of which are ''Jitney-Jungle'' stores and one is a ''Sack & Save'' store) and five Delchamps—to Supervalu Holdings, Inc., a wholly-owned subsidiary of Supervalu, Inc. (collectively ''Supervalu''), within either one month after the date on which the proposed consent order becomes final, or five months after the acceptance of the proposed consent order for public comment, whichever is later, or to another acquirer that receives the prior approval of the Commission within three months after the proposed consent order becomes final. A sale to Supervalu by the proposed Respondents must be in accordance with the agreement between Supervalu and Jitney-Jungle dated August 29, 1997, and all subsequent amendments thereto.

If the proposed Respondents divest the ten listed supermarkets to Supervalu within three months of the date on which the proposed consent order becomes final, Supervalu may sell any of these supermarkets to either R&M Foods, Inc. (''R&M Foods'') or Southeast Foods, Inc. (''Southeast Foods''). R&M Foods currently operates 18 supermarkets, and Southeast Foods currently operates 21 supermarkets. If Supervalu does not sell the ten listed supermarkets to either R&M Foods or Southeast Foods within three months of the date on which the proposed consent order becomes final, Supervalu cannot sell the ten listed supermarkets to anyone without the prior approval of the Commission.

Five of the ten supermarkets to be divested are located in the Gulfport-Biloxi area; two are located in Pensacola, Florida; two are located in Hattiesburg, Mississippi; and one is located in Vicksburg, Mississippi. If the proposed Respondents fail to satisfy any of the divestiture provisions, the Commission may appoint a trustee to divest supermarkets to satisfy the terms of the proposed consent order. The ten supermarkets to be divested are:

1. The following supermarket located in Hancock County, Mississippi:

a. Delchamps store no. 64 operating under the ''Delchamps'' trade name, which is located at Choctaw Plaza Shopping Center, 318 Highway 90, Waveland, MS 39576;

2. The following supermarkets located in Harrison County, Mississippi:

a. Jitney-Jungle store no. 33 operating under the ''Jitney-Jungle'' trade name, which is located at 917 Division St., Biloxi, MS 39530;

b. Jitney-Jungle store no. 32 operating under the ''Jitney-Jungle'' trade name, which is located at 1225 Pass Road, Gulfport, MS 39501;

c. Jitney-Jungle store no. 42 operating under the ''Jitney-Jungle'' trade name, which is located at Handsboro Square Shopping Center, 1345 East Pass Road, Gulfport, MS 39501; and

d. Delchamps store no. 364 operating under the ''Delchamps'' trade name, which is located at 11240-A Highway 49 North, Gulfport, MS 39503;

3. The following supermarkets located in Escambia County, Florida:

a. Jitney-Jungle store no. 54 operating under the ''Jitney-Jungle'' trade name, which is located at 4081-A East Olive Road, Pensacola, FL 32514.

b. Jitney-Jungle store no. 52 operating under the ''Sack & Save'' trade name, which is located at Brent Oaks Mall, East Brent Lane, Pensacola, FL 32503.

4. The following supermarket located in Lamar County, Mississippi:

a. Delchamps store no. 67 operating under the ''Delchamps'' trade name, which is located at Oak Grove Plaza Shopping Center, 4600 West Hardy Street, Hattiesburg, MS 39401.

5. The following supermarket located in Forrest County, Mississippi:

a. Delchamps store no. 9 operating under the ''Delchamps'' trade name, which is located at 601 Broadway Street, Hattiesburg, MS 39401.

6. The following supermarket located in Warren County, Mississippi:

a. Delchamps store no. 115 operating under the ''Delchamps'' trade name, which is located at Delchamps Plaza, 3046–D Indiana Avenue, Vicksburg, MS 39180.

For a period of ten years from the date the proposed consent order becomes final, the proposed Respondents are prohibited from acquiring, without prior notice to the Commission, supermarket assets located in, or any interest (such as stock) in any entity that owns or operates a supermarket located in Hancock, Harrison, Jackson, Lamar, Forrest, and Warren counties in Mississippi, and Escambia County, Florida. This provision does not prevent the proposed Respondents from constructing new supermarket facilities on their own; nor does it prevent the proposed Respondents from leasing facilities not operated as supermarkets within the previous six months.

For a period of ten years, the proposed consent order also prohibits the proposed Respondents from entering into or enforcing any agreement that restricts the ability of any person that acquires any supermarket, any leasehold interest in any supermarket, or any interest in any retail location used as a supermarket on or after July 1, 1997, to operate a supermarket at that site if such supermarket was formerly owned or operated by the proposed Respondents in Hancock, Harrison, Jackson, Lamar, Forrest, and Warren counties in Mississippi, and Escambia County, Florida. In addition, the proposed Respondents may not remove any equipment from a supermarket they own or operate prior to a sale, sublease, assignment, or change in occupancy, except in the ordinary course of business, or except as part of any negotiation for a sale, sublease, assignment, or change in occupancy of such supermarket.

The proposed Respondents are required to provide to the Commission a report of compliance with the proposed consent order within sixty (60) days following the date the proposed consent order becomes final, every sixty (60) days thereafter until the divestitures are completed, and annually for a period of ten years.

The proposed Respondents also entered into an Asset Maintenance Agreement. Under the terms of the Asset Maintenance Agreement, from the time Jitney-Jungle acquires the outstanding stock of Delchamps until the divestitures have been completed, the proposed Respondents must maintain their viability, competitiveness and marketability, and must not cause their wasting or deterioration, and cannot sell, transfer, or otherwise impair their marketability or viability. The Asset Maintenance Agreement specifies these obligations in detail.

V. Opportunity for Public Comment

The proposed consent order has been placed on the public record for sixty (60) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After sixty days, the Commission will again review the agreement and the comments received and will decide whether it should withdraw from the agreement or make final the agreement's proposed consent order.

By accepting the proposed consent order subject to final approval, the Commission anticipates that the competitive problems alleged in the complaint will be resolved. The purpose of this analysis is to invite public comment on the proposed consent order, including the proposed sale of supermarkets to Supervalu, R&M Foods, and Southeast Foods, to aid the Commission in its determination of whether it should make final the proposed consent order contained in the agreement. This analysis is not intended to constitute an official interpretation of the agreement and proposed consent order, nor is it intended to modify the terms of the agreement and proposed consent order in any way.

Donald S. Clark,

Secretary.

[FR Doc. 97–25185 Filed 9–22–97; 8:45 am]

BILLING CODE 6750–01–M

GENERAL SERVICES ADMINISTRATION

Privacy Act of 1974; System of Records

AGENCY: Notice of a revised record system subject to the Privacy Act of 1994.

SUMMARY: This document gives notice, under the Privacy Act of 1994, 5 U.S.C. 552a, of GSA's proposal to revise a record system maintained by GSA.

GSA proposes to revise the record system, Payroll Information Processing System, PPFM–9, to reflect that GSA plans to disclose data to: (1) The Office of Child Support Enforcement, Administration for Children and Families, Department of Health and Human Services Federal Parent Locator System (FPLS) and Federal Tax Offset System for use in locating individuals and identifying their income sources to establish paternity, establish and modify orders of support and for enforcement action; (2) the Social Security Administration for verifying social security numbers in connection with the operation of the FPLS by the Office of Child Support Enforcement; and (3) the Department of Treasury for purposes of administering the Earned Income Tax Credit Program (Section 32, Internal Revenue Code of 1986) and verifying a claim with respect to employment in a tax return. A revised system report has been filed with the Speaker of the House, the President of the Senate, and the Office of Management and Budget.

DATES: And interested party may submit written comments concerning the revision. Comments must be received on or before the 30th day after GSA publishes this notice. The system becomes effective without further notice on October 1, 1997. Unless comments received would warrant a contrary decision.

ADDRESES: Address comments to Denise Johnson, Privacy Act Officer, General Services Administration, 1800 F Street, NW, (CAI), Washington, DC 20405.

FOR FURTHER INFORMATION CONTACT: Denise W. Johnson, GSA Privacy Act Officer (202) 501–1659.

GSA/PPFM–9

SYSTEM NAME:

Payroll Information Processing System.

SYSTEM LOCATION:

The record system is located in the General Services Administration Finance Division in Kansas City, MO; in commissions, committees, and small agencies serviced by GSA; and in administrative offices throughout GSA.

INDIVIDUALS COVERED BY THE SYSTEM:

Those covered are present and former employees of GSA and of commissions, committees, and small agencies serviced by GSA, including applicants for employment and persons in interim, youth employment, and work/study programs.

CATEGORIES OF RECORDS IN THE SYSTEM:

The system holds payroll records and includes information received by operating officials as well as personnel and finance officials administering their program areas, including information regarding nonsupport of dependent children. The system also contains data needed to process personnel actions, perform detailed accounting distributions, provide for tasks such as mailing checks and bonds, and preparing and mailing tax returns and reports. The record system may contain:

a. Employee's name, social security number, date of birth, sex, work schedule, type of appointment, and position description.

b. Service computation date for assigning leave.

c. Occupational series, position, grade, step, salary, award amounts, organization location, and accounting distribution.

d. Time; attendance; leave; Federal, State, and local tax; allotments; savings bonds; and other pay allowances and deductions.

e. Tables of data for editing, reporting, and processing personnel and pay actions, which include nature-of-action code, organization table, and salary table.

f. Information regarding court-ordered payments to support dependent children, including amounts in arrears.

AUTHORITY FOR MAINTAINING THE SYSTEM:

5 U.S.C., Part III, is the basic authority. The authority for using Social Security numbers is E.O. 9397 of November 22, 1943, 26 CFR 31.6011(b)(2), and 26 CFR 31.6109–1. Authority for maintaining data on court-ordered support of a dependent child is from E.O. 12953 of February 27, 1995.

PURPOSE:

To maintain an electronic information system to support the day-to-day operating needs of the payroll program. The system can provide payroll statistics for all types of Government organizations and allows many uses for each data element entered. The system has a number of outputs. For the payroll office, they include a comprehensive payroll; accounting distribution of costs; leave data summary reports; each employee's statement of earnings, deductions, and leave every payday; State, city, and local unemployment compensation reports; Federal, State, and local tax reports; Forms W–2, Wage and Tax Statement; and reports of withholding and contributions. For the Office of Personnel, outputs include data for reports of Federal civilian employment. The system also provides data to GSA staff and administrative offices to use for management purposes.

ROUTINE USES OF THE RECORD SYSTEM, INCLUDING TYPES OF USERS AND THEIR PURPOSES IN USING THE SYSTEM:

a. To disclose information to a Federal, State, local, or foreign agency responsible for investigating, prosecuting, enforcing, or carrying out a statute, rule, regulation, or order, where GSA becomes aware of a violation or potential violation of civil or criminal law or regulation.

b. To disclose requested information to a court or other authorized agency regarding payment or nonpayment of court-ordered support for a dependent child.

c. To disclose information to a member of Congress or a congressional staff member in response to a request from the person who is the subject of the record.

d. To disclose information to an expert, consultant, or contractor employed by GSA to perform a Federal duty.

e. To disclose information to a Federal, State, or local agency maintaining civil, criminal, enforcement, or other information to obtain information needed to make a decision on hiring or retaining an employee; issuing a security clearance; letting a contract; or issuing a license, grant, or other benefit.

f. To disclose requested information to a Federal agency in connection with hiring or retaining an employee; issuing a security clearance; reporting an employee investigation; clarifying a job; letting a contract; or issuing a license, grant, or other benefit by the requesting agency to the extent the information is necessary to decide the matter.

g. To disclose information to an appeal, grievance, or formal complaints examiner; equal employment opportunity investigator; arbitrator; union official or other official engaged in investigating or settling a grievance, complaint, or appeal filed by an employee.

h. To disclose information to the Office of Management and Budget for reviewing private relief legislation at any stage of the clearance process.

i. To provide a copy of the Department of the Treasury Form W–2, Wage and Tax Statement, to the State, city, or other local jurisdiction that is authorized to tax the employee's compensation. The record is provided by a withholding agreement between the State, city, or other local jurisdiction and the Department of the Treasury under 5 U.S.C. 5516, 5517, and 5520.

j. To provide a copy of a city tax withholding certificate to a requesting city official from the Chief Financial Officer, General Services Administration (B), Washington, DC 20405.

k. To disclose information to the Office of Personnel in reporting civilian employment.

l. To disclose information to GSA administrative offices who may restructure the data for management purposes.

m. To disclose information to the Office of Child Support Enforcement, Administration for Children and Families, Department of Health and Human Services Federal Parent Locator System (FPLS) and Federal Tax Offset System for use in locating individuals and identifying their income sources to establish paternity, establish and modify orders of support and for enforcement action.

n. To disclose information to the Social Security Administration for verifying social security numbers in connection with the operation of the FPLS by the Office of Child Support Enforcement.

o. To disclose information to the Department of the Treasury for purposes of administering the Earned Income Tax Credit Program (Section 32, Internal Revenue Code of 1986) and verifying a claim with respect to employment in a tax return.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper records are kept in file folders, card files, and cabinets; microfilm records on reels and in cabinets; microfiches in cabinets; magnetic tapes and cards in cabinets and storage libraries; and computer records within a computer and attached equipment.

RETRIEVAL:

Records are filed by name or social security number at each location.

SAFEGUARDS:

Records are stored in locked containers or secured rooms when not in use by an authorized person. Electronic records are protected by a password system.

DISPOSAL:

The Finance Division disposes of the records by shredding or burning, as scheduled in the handbook GSA Records Maintenance and Disposition System (OAD P 1820.2A).

SYSTEM MANAGER AND ADDRESS:

Director, Finance Division, General Services Administration (6BC), 1500 East Bannister Road, Kansas City, MO 64131.

NOTIFICATION PROCEDURE:

An individual inquiry should be addressed to the system manager.

RECORD ACCESS PROCEDURES:

An individual request should be addressed to the system manager. Furnish full name, social security number, address, telephone number, and approximate dates and places of employment. For the identification required, see 41 CFR part 105–64, published in the **Federal Register**.

CONTESTING RECORD PROCEDURE:

GSA rules for contesting the content of a record and appealing an initial decision are in 41 CFR part 105–64,

RECORD SOURCE CATEGORIES:

The sources are individuals themselves, other employees, supervisors, officials of other agencies, State governments, record systems GSA/HRO–37, OPM/GOVT–1, EEOC/GOVT–1, and private firms.

Dated: July 8, 1997.

John H. Davenjay,

Director, Administrative Policy and Information Management Division.

[FR Doc. 97–24881 Filed 9–22–97; 8:45 am]

BILLING CODE 6820–34–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30DAY–24–97]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Office on (404) 639–7090. Send written comments to CDC, Desk Officer; Human Resources and Housing Branch, New Executive Office Building, Room 10235; Washington, DC 20503. Written comments should be received within 30 days of this notice.

Proposed Projects

1. Airways Disease in Miners—(0920–0349)—Reinstatement—A relationship between coal mining exposure and lung function loss has been demonstrated. Both smoking and coal mine dust exposure are associated with clinically important respiratory dysfunction. Their separate contributions to obstructive airway disease in coal miners appear to be additive. However, much of the apparent variation in the health risks of coal mine dust exposure remains unexplained. Miners exposed to similar levels of coal mine dust demonstrate large variations in lung function loss. Intrinsic susceptibility to the dust or some environmental factor not yet identified must be sought to explain why some individuals suffer severe lung damage and others experience stable or age related changes in lung function in response to inhalation of respirable dust.

The spectrum of respiratory disease in coal miners is certainly broad. Pneumoconiosis is widely accepted as specific to mine dust exposure. It has been observed that emphysema is more common and severe in coal miners than non-miners. Symptoms of chronic bronchitis are common in miners and the risk of their development has been related to exposure to the mine environment. Over 50% of non-smoking coal miners with identifiable airflow obstruction may have asthma. Questions that remain include: What are the predictable factors which relate variations in airflow obstruction in miners to measured respirable coal mine dust exposure? What are the specific processes responsible for lung function losses in miners?

The goals of this investigation are to: (1) Improve our understanding of the processes and mechanisms involved in the development of pulmonary diseases and accelerated lung function losses in underground coal miners and other dust exposed workers, and to further define the consequences of inhalation of coal mine and other dusts; and (2) Identify potential risk factors in the development of excessive respiratory function loss as a basis for interventions to reduce morbidity and mortality associated with respirable dust in the work place.

The data collected in this study will be used to provide a basis for improving the understanding of pulmonary disease processes in dust exposed workers, and as a basis for intervention strategies to reduce morbidity in the coal mining and possibly other industries. The total annual burden hours are 130 (259/2).

Respondents	Number of respondents	Number of responses/respondent	Avg. burden/response (in hrs.)
Physicians	40	1	0.17
Volunteers	36	1	7.0

Dated: September 17, 1997.

Wilma G. Johnson,

Acting Associate Director for Policy Planning And Evaluation, Centers for Disease Control and Prevention (CDC).

[FR Doc. 97–25170 Filed 9–22–97; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97M–0396]

Advanced Bionics™ Corp.; Premarket Approval of CLARION® Multi-Strategy™ Cochlear Implant

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Advanced Bionics™ Corp., Sylmar, CA, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of the CLARION® Multi-Strategy™ Cochlear Implant. After reviewing the recommendation of the Ear, Nose, and Throat Devices Panel, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of June 26, 1997, of the approval of the application.

DATES: Petitions for administrative review by October 23, 1997.

ADDRESSES: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: I. Sidney Jaffee, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2080.

SUPPLEMENTARY INFORMATION: On December 29, 1996, Advanced Bionics™ Corp., Sylmar, CA 91342, submitted to CDRH an application for premarket approval of the CLARION® Multi-Strategy™ Cochlear Implant. The device is a cochlear implant and is intended to restore a level of auditory sensation to individuals with profound sensorineural deafness via electrical stimulation of the auditory nerve. The CLARION® Multi-Strategy™ Cochlear Implant is indicated for the following:

Children:

- Two through 17 years of age. If x-rays demonstrate evidence of ossification, children as young as 18 months may be implanted;
- Profound, bilateral sensorineural deafness (≥90 dB);
- Undergone or be willing to undergo a hearing aid trial with appropriately fitted hearing aids; and
- Lack of benefit from appropriately fitted hearing aids. In younger children, lack of benefit with hearing aids is defined as a failure to attain basic auditory milestones such as a child's inconsistent response to his/her name in quiet or to environmental sounds (Meaningful Auditory Integration Scale). In older children, lack of aided benefit is defined as scoring 0 percent on open-set word recognition (Phonetically Balanced Kindergarten Test—Word List) administered with monitored live-voice (70 dB SPL). Both younger and older children should demonstrate only minimal ability on age appropriate open-set sentence measures and a plateau in auditory development.

On May 21, 1997, the Ear, Nose, and Throat Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, reviewed and recommended approval of the application. On June 26, 1997, CDRH approved the application by a letter to the applicant from the Deputy Director of Clinical and Policy Review of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

Opportunity for Administrative Review

Section 515(d)(3) of the act (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act, for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under 21 CFR part 12 of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under 21 CFR 10.33(b). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the **Federal Register**. If FDA grants the petition, the notice will state the issue to be reviewed, the form of the review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before October 23, 1997, file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: August 26, 1997.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 97–25163 Filed 9–22–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97M–0393]

Avanta Orthopaedics Corp.; Premarket Approval of Braun-Cutter Trapezo-metacarpal prosthesis

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Avanta Orthopaedics Corp., San Diego, CA, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of the Braun-Cutter Trapezo-metacarpal Prosthesis. After reviewing the recommendation of the Orthopedics and Rehabilitation Devices Panel, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of June 19, 1997, of the approval of the application.

DATES: Petitions for administrative review by October 23, 1997.

ADDRESSES: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Theodore R. Stevens, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2036.

SUPPLEMENTARY INFORMATION: On December 24, 1996, Avanta Orthopaedics Corp., San Diego, CA 92121, submitted to CDRH an application for premarket approval of the Braun-Cutter Trapezo-metacarpal Prosthesis. The device is a finger joint metal/polymer cemented prosthesis and is indicated for total joint replacement in skeletally mature patients with pain or instability of the trapezo-metacarpal joint due to trauma, inflammatory or degenerative disease or revision of previous procedures, as an alternative to arthrodesis or reconstructive surgery.

On June 9, 1997, the Orthopedics and Rehabilitation Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, reviewed and recommended approval of the application. On June 19, 1997, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

Opportunity for Administrative Review

Section 515(d)(3) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act, for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under 21 CFR part 12 of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under 21 CFR 10.33(b). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the **Federal Register**. If FDA grants the petition, the notice will state the issue to be reviewed, the form of the review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details. Petitioners may, at any time on or before October 23, 1997, file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: August 26, 1997.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 97–25127 Filed 9–22–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97M–0392]

Mallinckrodt, Inc.; Premarket Approval of Albunex®

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the supplemental application by Mallinckrodt, Inc., St. Louis, MO, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of Albunex® . After reviewing the recommendation of the Radiological Devices Panel, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of June 17, 1997, of the approval of the supplemental application.

DATES: Petitions for administrative review by October 23, 1997.

ADDRESSES: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Robert A. Phillips, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1212.

SUPPLEMENTARY INFORMATION: On September 3, 1995, Mallinckrodt, Inc., St. Louis, MO 63134, submitted to CDRH a supplemental application for premarket approval of Albunex . The device is an ultrasound contrast agent and is indicated for use with transvaginal ultrasound to assess fallopian tube patency.

On February 24, 1997, the Radiological Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, reviewed and recommended approval of the supplemental application. On June 17, 1997, CDRH approved the supplemental application by a letter to the applicant from the Deputy Director of Clinical and Review Policy of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

Opportunity for Administrative Review

Section 515(d)(3) of the act (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act, for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under 21 CFR part 12 of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under 21 CFR 10.33(b). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for

resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the **Federal Register**. If FDA grants the petition, the notice will state the issue to be reviewed, the form of the review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before October 23, 1997, file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: August 26, 1997.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 97–25180 Filed 9–22–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97D–0318]

Revised Precautionary Measures to Reduce the Possible Transmission of Creutzfeldt-Jakob Disease (CJD) by Blood and Blood Products; Guidance Document; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance document entitled ''Revised Precautionary Measures to Reduce the Possible Transmission of Creutzfeldt-Jakob Disease (CJD) by Blood and Blood Products,'' dated December 11, 1996. The guidance document is intended to provide recommendations to the blood industry and may include information useful to other interested persons.

DATES: Written comments may be submitted at any time.

ADDRESSES: Submit written requests for single copies of ''Revised Precautionary Measures to Reduce the Possible Transmission of Creutzfeldt-Jakob Disease (CJD) by Blood and Blood Products'' to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. The guidance document may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800, or by fax by calling the FAX Information System at 1–888–CBER–FAX or 301–827–3844. Submit written comments on the guidance document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Joseph Wilczek, Center for Biologics Evaluation and Research (HFM–350), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–3514.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a guidance document entitled ''Revised Precautionary Measures to Reduce the Possible Transmission of Creutzfeldt-Jakob Disease (CJD) by Blood and Blood Products,'' dated December 11, 1996, and sent to all registered blood and plasma establishments and all establishments engaged in manufacturing plasma derivatives.

The guidance document updates and supersedes the FDA guidance documents of August 8, 1995, entitled ''Disposition of Products Derived from Donors Diagnosed with, or at Known High Risk for, Creutzfeldt-Jakob Disease'' and ''Precautionary Measures to Further Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease by Blood and Blood Products,'' and the November 25, 1987, guidance document entitled ''Deferral of Donors Who Have Received Human Pituitary-Derived Growth Hormone.''

The guidance document presents recommendations for donor deferral, product disposition, recipient notification, and labeling. The recommendations were developed after considering donor and product risk factors and the impact such recommendations could have on the availability of blood and blood products. Topics addressed in the guidance document include: (1) Recommended questions that will help identify donors at an increased risk for CJD; (2) recommended actions to take when a donor is identified to be at an increased risk for developing CJD; (3) recommended actions to take when a donor is subsequently diagnosed with CJD; (4) recommendations for recipient notification and counseling; (5) recommendations for disposition of implicated products; and (6) recommendations for the labeling of implicated products intended for research or further manufacture into non-injectable products. The guidance document also includes FDA's recommendations regarding ''lookback'' notification of persons possibly exposed to CJD contaminated blood or blood products.

As with other guidance documents, FDA does not intend this document to be all-inclusive and cautions that not all information may be applicable to all situations. It is intended to provide recommendations and does not set forth requirements. In response to public comment, development of suitable alternatives or other new information, FDA may revise the guidance document at anytime to improve its usefulness. Any revisions to this guidance document will be announced in the **Federal Register**. The recommendations in the guidance document represent the agency's current thinking on precautionary measures to use to reduce the possible transmission of CJD by blood and blood products. 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, regulations, or both.

Interested persons may submit to the Dockets Management Branch (address above) written comments on the guidance document. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Any comments previously submitted to the Division of Blood Applications (HFM–370), CBER, FDA, do not have to be resubmitted. Comments previously submitted will be filed with the Dockets Management Branch (address above) under the docket number in the heading of this document. The guidance document and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. Received comments will be considered in determining whether further revision is warranted.

Persons with access to the Internet may obtain the guidance document

using the World Wide Web (WWW). For WWW access, connect to CBER's site at ''http://www.fda.gov/cber/memo.htm''.

Dated: September 16, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–25181 Filed 9–22–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0319]

Interim Recommendations for Deferral of Donors at Increased Risk for HIV–1 Group O Infection; Guidance Document; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance document entitled ''Interim Recommendations for Deferral of Donors at Increased Risk for HIV–1 Group O Infection,'' dated December 11, 1996. The guidance document, which discusses the appearance in 1996 of two cases of HIV–1 Group O infection in the United States, is intended to provide interim measures to reduce the risk of HIV–1 Group O transmission by blood and blood products pending the licensure of test kits specifically labeled for detection of antibodies to HIV–1 Group O viruses. The guidance document recommends adding three questions to screening questionnaires used to exclude donors at high risk of HIV–1 infection.

DATES: Written comments may be submitted at any time.

ADDRESSES: Submit written requests for single copies of ''Interim Recommendations for Deferral of Donors at Increased Risk for HIV–1 Group O Infection'' to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. The guidance document may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800, or by fax by calling the FAX Information System at 1–888–CBER–FAX or 301–827–3844.

FOR FURTHER INFORMATION CONTACT: Joseph Wilczek, Center for Biologics Evaluation and Research (HFM–350), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–3514.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a guidance document entitled ''Interim Recommendations for Deferral of Donors at Increased Risk for HIV–1 Group O Infection.'' It was dated December 11, 1996, and sent to all registered blood and plasma establishments. The guidance document, which discusses the appearance in 1996 of two cases of HIV–1 Group O infection in the United States, recommends adding three questions to screening questionnaires used to exclude donors at high risk for HIV–1 infection. These recommendations are intended to be interim measures to reduce the risk of HIV–1 Group O transmission by blood and blood products pending the licensure of test kits specifically labeled for detection of antibodies to HIV–1 Group O viruses.

As with other guidance documents, FDA does not intend this guidance document to be all-inclusive and cautions that not all information may be applicable to all situations. It is intended to provide recommendations and does not set forth requirements. In response to public comment, development of suitable alternatives or other new information, FDA may revise this guidance document at any time to improve its usefulness. Any revisions to this document will be announced in the **Federal Register**. The recommendations in the document represent the agency's current thinking on screening and deferral of donors at increased risk for HIV–1 Group O infection. 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, regulations, or both.

Interested persons may, at any time, submit to the Dockets Management Branch (address above) written comments on the guidance document. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Any comments previously submitted to the Division of Blood Applications (HFM–370), CBER, FDA, do not have to be resubmitted. Comments previously submitted will be filed with the Dockets Management Branch (address above) under the docket number in the heading of this document. The document and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. Received comments will be considered in determining whether further revision is warranted.

Persons with access to the Internet may obtain the document by using the World Wide Web (WWW). For WWW access, connect to CBER's site at ''http://www.fda.gov/cber/memo.htm''.

Dated: September 16, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–25128 Filed 9–22–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97D–0381]

Guidance for Industry on Archiving Submissions in Electronic Format—NDA's; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Archiving Submissions in Electronic Format—NDA's.'' This guidance is intended to describe how to submit records and other documents in electronic format to the Center for Drug Evaluation and Research (CDER) for archival purposes. Guidance is provided on submitting case report forms and case report tabulations as part of new drug applications (NDA's). This is the first in a series of guidances for industry that will address archiving NDA submissions in electronic format. Guidance for industry on other submission types will be made available as they are completed. The submission of records in electronic format should reduce the amount of paperwork for applicants and the agency. Submissions in electronic format are voluntary.

DATES: Written comments may be submitted at any time.

ADDRESSES: Submit written requests for single copies of the guidance for industry entitled ''Archiving Submissions in Electronic Format—NDA's'' to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Kenneth Edmunds, Center for Drug Evaluation and Research (HFD–350), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3276, e-mail: ESUB@CDER.fda.gov.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a guidance for industry entitled ''Archiving Submissions in Electronic Format—NDA's.'' Traditionally, FDA has required that regulatory submissions, such as investigational new drug applications and NDA's, be submitted as paper documents. The regulations in part 314 (21 CFR part 314), for example, set forth the requirements and procedures for submitting applications to obtain approval for the marketing of new drugs to FDA. These regulations require the submission of three copies of an application for marketing approval: (1) A complete archival copy, (2) a review copy, and (3) a field copy (§ 314.50(k)).

In the **Federal Register** of March 20, 1997 (62 FR 13430), FDA published the Electronic Records; Electronic Signatures regulation that provides for the voluntary submission of parts or all of an application, as defined in the relevant regulations, in electronic format without an accompanying paper copy (21 CFR part 11). The agency also established public docket number 92S–0251 so the agency can maintain a list of the specific types of records and submissions that can be accepted in electronic format (62 FR 13467, March 20, 1997). The agency unit(s) that are prepared to receive electronic submissions are to identify themselves in that docket. The regulation states that persons should consult with the intended agency receiving unit for details on how to proceed with the electronic submission. The guidance is intended to reduce the need on the part of sponsors to consult CDER for details on archiving electronic submissions. The guidance specifically addresses the NDA and includes subsections on how to submit case report forms and case report tabulations in electronic format to CDER for the archive. Conforming to the guidance in this document will help ensure that submissions provided to CDER in electronic format can be accessed, handled, reviewed, and maintained efficiently.

The guidance is the first in a series that will be issued on archiving electronic submissions to CDER. As a result, it is not all inclusive. CDER anticipates that, as this effort proceeds, sponsors, investigators, and CDER staff may develop alternative and more effective procedures for submitting electronic applications for the archive. For this reason, the guidance will be updated periodically.

The guidance represents the agency's current thinking on electronic submissions for the archive for NDA's. 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 requirement of the applicable statute, regulations, or both.

Interested persons may, at any time, submit written comments on the guidance to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments and requests are to be identified with the docket number found in brackets in the heading of this document. The guidance document and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

An electronic version of the guidance also is available on the Internet at ''http://www.fda.gov/cder/guidance/index.htm''.

Dated: September 17, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–25126 Filed 9–17–97; 4:58 pm]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–304A]

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, 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 the 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:* Reconciliation of State Invoice and Prior Quarter Adjustment Statement; *Form No.:* HCFA–304A; *Use:* In response to a need for improved data exchange between drug labelers and States, HCFA, in conjunction with outside consultants, developed the Reconciliation of State Invoice (ROSI), form HCFA–304, and the Prior Quarter Adjustment Statement (PQAS), form HCFA–304A. The ROSI is to be used by Drug Labelers when responding to State invoices of current quarter utilization data only and functions as a reconciliation report to assure accurate rebate payments. The PQAS is used by labelers to report only on prior quarter actions/payments. Prior quarter activity includes changes to utilization data submitted by States, revisions to previously disputed units, and prior period adjustments (URA changes). Both forms assist in reducing disputes by standardizing data exchange and improving communication between Drug labelers and States. *Frequency:* Quarterly; *Affected Public:* Business or other for-profit; *Number of Respondents:* 365; *Total Annual Responses:* 1,460; *Total Annual Hours:* 132,120.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, or to obtain the supporting statement and any related forms, E-mail your request, including your address and phone number, 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 HCFA Paperwork Clearance Officer designated at the following address:

HCFA, Office of Information Services, nformation Technology Investment Management Group, Division of HCFA Enterprise Standards, Attention: John Rudolph, Room C2–26–17, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: September 15, 1997.

John P. Burke III,

HCFA Reports Clearance Officer, Division of HCFA Enterprise Standards Health Care Financing Administration.

[FR Doc. 97–25218 Filed 9–22–97; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences Division of Intramural Research; Proposed Data Collection Available for Public Comment and Recommendation

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the National Institute of Environmental Health Sciences (NIEHS) will publish periodic summaries of proposed projects. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, call the NIEHS Project Clearance Liaison, at (919) 541–5047.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

This notice regards a request for OMB processing for a proposed study: The Johnston County ADHD Study: Environmental, Reproductive and Familial Risk Factors for Attention Deficit/Hyperactivity Disorder in accordance with 5 CFR 1320.13 of the OMB guidelines. We received emergency OMB clearance in June 1997 for conducting a pilot study for this study which is being conducted June 1997–November 1997. The OMB clearance for the pilot study expires in November 1997. We are now applying for clearance for the full study which we anticipate beginning in January 1998.

New—Proposed Project: The Johnston County ADHD Study: Environmental, Reproductive and Familial Risk Factors for Attention-Deficit/Hyperactivity Disorder. For the proposed study we plan to collect questionnaire data from 350 teachers and 2400 parents. Data will be collected over two years. Teachers will use a brief symptom checklist to screen all the children in their class; about 8,000 children will be screened in all. We will conduct telephone interviews with the mothers or guardians of children identified as possible cases and a 15% random sample of control children. If children meet DSM–IV criteria for ADHD after both screens, they will be considered cases. The primary hypotheses of the study are that preterm delivery and other reproductive risk factors increase risk of ADHD and childhood lead exposure (measured in shed baby teeth) increases risk of ADHD. In year two of the study we will use cheek swabs to collect DNA from 1,200 mothers, 1,200 children, 1,200 siblings and 1,200 fathers to study possible genetic or familial risk factors for ADHD. The data collected in this study will allow us to describe the prevalence of Attention Deficit/Hyperactivity Disorder in Johnston County, how prevalence varies by demographic profile, and to identify environmental, reproductive and familial risk factors for the disorder.

Type respondent	Estimated number of respondents	Estimated number of responses	Average # responses per respondent	Average burden hours per response	Total burden hours
Teachers	350	10,150	29	.18	1827
Mother/guardian	2400	13,200	5.5	.32	4224
Father	1,200	1,000	1	.17	204
Study child	1,200	1,000	1	.17	204
Sibling	1,200	1,200	1	.17	204

Total Burden: 6,663 hours.

Total Burden per Year: 3,331.5 hours.

REQUEST FOR COMMENTS: Written comments and/or suggestions from the public and affected agencies should address one or more of the following points: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Dr. Andrew Rowland, Senior Staff Fellow, NIEHS, DIR/EDMP/Epidemiology Branch, PO Box 12233, RTP, NC 27709, or call non-toll free number (919) 541–7886.

COMMENTS DUE DATE: Comments regarding this information collection are best assured of having their full effect if received on or before November 21, 1997.

Dated: September 10, 1997.

Charles Leasure,

Associate Director for Management, NIEHS.

[FR Doc. 97–25150 Filed 9–19–97; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMNET OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Research Resources; Notice of Meetings

Pursuant to Public Law 92–463, notice is hereby given of the meetings of the National Center for Research Resources Initial Review Group and the Scientific and Technical Review Board on Biomedical and Behavioral Research Facilities, National Center for Research

Resources (NCRR) for September and October, 1997. These meetings will be open to the public as indicated below, to discuss program planning; program accomplishments; administrative matters such as previous meeting minutes; the report of the Director, NCRR; review of budget and legislative updates; and special reports or other issues relating to committee business. Attendance by the public will be limited to space available.

These meetings will be closed to the public as indicated below in accordance with provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. and section 10(d) of Public Law 92–463, for the review, discussion and evaluation of individual grant applications. These applications and the discussions could reveal confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Ms. Kathy Kaplan, Public Affairs Specialist, NCRR, National Institutes of Health, 1 Rockledge Center, Room 5146, 6705 Rockledge Drive, MSC 7965, Bethesda, Maryland 20892–7965, (301) 435–0888, will provide summaries of meetings and rosters of committee members. Other information pertaining to the meetings can be obtained from the Scientific Review Administrator indicated. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should contact the Scientific Review Administrator listed below, in advance of the meeting.

Name of Committee: National Center for Research Resources Initial Review Group—Research Centers in Minority Institutions Review Committee.

Date of Meeting: September 29–30, 1997.

Place of Meeting: Doubletree Hotel, Halpine Room, 1750 Rockville Pike, Rockville, MD 20852, (301) 468–1100.

Open: September 29, 8:30 a.m.–10:30 a.m.

Closed: September 29, 10:30 a.m.–Until Adjournment.

Scientific Review Administrator: Dr. John Lymangrover, National Institutes of Health, 1 Rockledge Center, Room 6018, 6705 Rockledge Drive, MSC 7965, Bethesda, MD 20892–7965, Telephone: (301) 435–0820.

Name of Committee: Scientific and Technical Review Board on Biomedical and Behavioral Research Facilities.

Date of Meeting: October 7, 1997.

Place of Meeting: Holiday Inn—Chevy Chase, Palladian Center, 5520 Wisconsin Avenue, Chevy Chase, MD 20815, (301) 656–1500.

Open: 8:00 a.m.–9:30 a.m.

Closed: 9:30 a.m.–Until Adjournment.

Scientific Review Administrator: Dr. D.G. Patel, National Institutes of Health, 1 Rockledge Center, Room 6018, 6705 Rockledge Drive, MSC 7965, Bethesda, MD 20892–7965, Telephone: (301) 435–0824.

This notice is being published less than 15 days prior to the above meetings due to the urgent need to meet timing limitations imposed by the review and funding cycle.

Name of Committee: National Center for Research Resources Initial Review Group—General Clinical Research Centers Review Committee.

Dates of Meeting: October 15–16, 1997.

Place of Meeting: Bethesda Ramada Hotel, Ambassador 2 Room, 8400 Wisconsin Avenue, Bethesda, MD 20814, (301) 654–1000.

Open: October 15, 8:00 a.m.—9:30 a.m.

Closed: October 15, 9:30 a.m.—Until Adjournment.

Scientific Review Administrator: Dr. Charles Hollingsworth, National Institutes of Health, 1 Rockledge Center, Room 6018, 6705 Rockledge Drive, MSC 7965, Bethesda, MD 20892–7965, Telephone: (301) 435–0806.

Name of Committee: National Center for Research Resources Initial Review Group—Comparative Medicine Review Committee.

Dates of Meeting: October 20–22, 1997.

Place of Meeting: Woodfin Suites Hotel, Columbia Room, 1380 Piccard Drive, Rockville, MD 20850, (301) 590–9880.

Closed: Ocotober 20, 6:30 p.m.—Recess.

Open: October 21, 8:00 a.m.—9:30.a.m.

Closed: October 21, 9:30 a.m.—Until Adjournment.

Scientific Review Administrator: Dr. Raymond O'Neill, National Institutes of Health, 1 Rockledge Center, Room 6018, 6705 Rockledge Drive, MSC 7965, Bethesda, MD 20892–7965. Telephone: (301) 435–0820.

(Catalog of Federal Domestic Assistance Program Nos. 93.306, Laboratory Animal Sciences and Primate Research; 93.333, Clinical Research: 93.389, Research Centers in Minority Institutions; 93.167, Research Facilities Improvement Program; 93.214 Extramural Research Facilities Construction Projects, National Institutes of Health)

Dated: September 17, 1997.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 97–25153 Filed 9–22–97; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; Notice of Meeting of Board of Scientific Counselors

Pursuant to Pub. L. 92–463, notice is hereby given of the meeting of the Board of Scientific Counselors, National Institute of Environmental Health Sciences, October 5–7, 1997, South Campus, Conference Rooms 101 ABC, National Institute of Environmental Health Sciences (NIEHS), 111 T.W. Alexander Drive, Research Triangle Park, North Carolina.

This meeting will be open to the public from 8:30 a.m. to approximately 2:45 p.m. on October 6, for the purpose of presenting an overview of the organization and conduct of research in the Laboratory of Reproductive and Developmental Toxicology. Attendance by the public will be limited to space available.

In accordance with the provisions set forth in sec. 552b(c)(6) of Title 5, U.S. Code and sec. 10 (d) of Pub. L. 92–463, the prereview meeting will be closed to the public on October 5 from approximately 8:00 p.m. to recess (Siena Hotel, 1505 E. Franklin Street, Chapel Hill, North Carolina) as will the post review discussion on October 7, at the NIEHS South Campus address above, from 8:30 a.m. to adjournment, for the evaluation of the programs of the laboratories listed above, including consideration of personnel qualifications and performance, the competence of individual investigators, and similar items, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

The Executive Secretary, Dr. Carl Barrett, Scientific Director, Division of Intramural Research, NIEHS, Research Triangle Park, N.C. 27709, telephone (919) 541–3205, will furnish rosters of committee members and program information.

Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should contact the Executive Secretary in advance of the meeting.

Dated: September 17, 1997.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 97–25154 Filed 9–22–97; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke Division of Extramural Activities; 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:

Name of Committee: National Institute of Neurological Disorders and Stroke Special Emphasis Panel (Telephone Conference Call).

Date: September 30, 1997.

Time: 9:30 a.m. (EDT).

Place: National Institutes of Health, 7550 Wisconsin Avenue, Room 9C10, Bethesda, Maryland 20892.

Contact Person: Dr. Katherine Woodbury/Mr. Philip Wiethorn, Scientific Review Administrators, National Institutes of Health, 7550 Wisconsin Avenue, Room 9C10, Bethesda, MD 20892, (301) 496–9223.

Purpose/Agenda: To review and evaluate an SBIR contract proposal.

The meeting will be closed in accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. Applications and/or proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

This notice is being published less than 15 days prior to the meeting due to the urgent need to meet timing limitations imposed by the review and funding cycle.

(Catalog of Federal Domestic Assistance Program No. 93.853, Clinical Research Related to Neurological Disorders; No. 93.854, Biological Basis Research in the Neurosciences.)

Dated: September 17, 1997.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 97–25257 Filed 9–22–97; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; Notice of Closed Meetings

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting:

Purpose/Agenda: To review and evaluate grant applications.

Name of Committee: National Institute on Alcohol Abuse and Alcoholism Special Emphasis Panel.

Date of Meeting: November 3, 1997.

Time: 8:00 A.M. to adjournment.

Place of Meeting: Residence Inn, 7335 Wisconsin Avenue, Bethesda, MD 20815.

Contact Person: Ronald Suddendorf, Ph.d., 6000 Executive Boulevard, Suite 409, Rockville MD 20892–7003, 301–443–2926.

Purpose/Agenda: To review and evaluate grant applications.

Name of Committee: National Institute on Alcohol Abuse and Alcoholism Special Emphasis Panel.

Date of Meeting: November 3, 1997.

Time: 12:00 P.M. to 1:00 P.M.

Place of Meeting: Residence Inn, 7335 Wisconsin Avenue, Bethesda, MD 20815.

Contact Person: Ronald Suddendorf, Ph.d., 6000 Executive Boulevard, Suite 409, Rockville MD 20892–7003, 301–443–2926.

The meetings will be closed in accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5 U.S.C. The proposal and discussions could reveal confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the proposal, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

(Catalog of Federal domestic Assistance, Program Nos. 93.271, Alcohol Research Career Development Awards for Scientists and Clinicians; 93.272, Alcohol National Research Service Awards for Research Training; 93.273, Alcohol Research Programs; and 93.891, Alcohol Research Center Grants; National Institutes of Health.)

Dated: September 17, 1997.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 97–25258 Filed 9–22–97; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Division of Research Grants; Notice of Closed Meetings

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following Division of Research Grants Special Emphasis Panel (SEP) meetings:

Purpose/Agenda: To review individual grant applications.

Name of SEP: Biological and Physiological Sciences.

Date: October 5, 1997.

Time: 3:00 p.m.

Place: Holiday Inn, Bethesda, MD.

Contact Person: Dr. Mushtaq Khan, Scientific Review Administrator, 6701 Rockledge Drive, Room 4124, Bethesda, MD 20892, (301) 435–1778.

Name of SEP: Biological and Physiological Sciences.

Date: October 15, 1997.

Time: 3:00 p.m.

Place: NIH, Rockledge 2, Room 4124, Telephone Conference.

Contact Person: Dr. Mushtaq Khan, Scientific Review Administrator, 6701 Rockledge Drive, Room 4124, Bethesda, Maryland 20892, (301) 435–1778.

Name of SEP: Biological and Physiological Sciences.

Date: November 3, 1997.

Time: 2:00 p.m.

Place: NIH, Rockledge 2, Room 4132, Telephone Conference.

Contact Person: Dr. Syed Quadri, Scientific Review Administrator, 6701 Rockledge Drive, Room 4132, Bethesda, Maryland 20892, (301) 435–1211.

Name of SEP: Biological and Physiological Sciences.

Date: November 5, 1997.

Time: 1:00 p.m.

Place: NIH, Rockledge 2, Room 5146, Telephone Conference.

Contact Person: Dr. Ramesh Nayak, Scientific Review Administrator, 6701 Rockledge Drive, Room 5146, Bethesda, Maryland 20892, (301) 435–1026.

Name of SEP: Chemistry and Related Sciences.

Date: November 6–8, 1997.

Time: 8:00 a.m.

Place: Harley Hotel, Lansing, MI.

Contact Person: Dr. Marjam Behar, Scientific Review Administrator, 6701 Rockledge Drive, Room 5218, Bethesda, Maryland 20892, (301) 435–1180.

Name of SEP: Biological and Physiological Sciences.

Date: November 7, 1997.

Time: 8:30 a.m.

Place: Hotel George, Washington, DC.

Contact Person: Dr. Anthony Carter, Scientific Review Administrator, 6701 Rockledge Drive, Room 5142, Bethesda, Maryland 20892, (301) 435–1024.

Name of SEP: Microbiological and Immunological Sciences.

Date: November 24, 1997.

Time: 8:30 a.m.

Place: St. James Hotel, Washington, DC.

Contact Person: Dr. Bruce Maurer, Scientific Review Administrator, 6701 Rockledge Drive, Room 4210, Bethesda, Maryland 20892, (301) 435–1225.

The meetings will be closed in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. Applications and/or proposals and the discussion could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of person privacy.

(Catalog of Federal Domestic Assistance Program Nos. 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93,893, National Institutes of Health, HHS)

Dated: September 17, 1997.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 97–25151 Filed 9–22–97; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration (SAMHSA)

Notice of Meetings

Pursuant to Public Law 92–463, notice is hereby given of the following meetings of the SAMHSA Special Emphasis Panel I and Special Emphasis Panel II in September.

A summary of the meetings and a roster of the members may be obtained from: Ms. Dee Herman, Committee Management Liaison, SAMHSA Office of Extramural Activities Review, 5600 Fishers Lane, Room 17–89, Rockville, Maryland 20857. Telephone: 301–443–4783.

Substantive program information may be obtained from the individual named as Contact for the meetings listed below.

The Special Emphasis Panel I meeting will include the review, discussion and evaluation of individual grant applications. These discussions could reveal personal information concerning individuals associated with the applications. Accordingly, this meeting is concerned with matters exempt from mandatory disclosure in Title 5 U.S.C. 552b(c)(6) and 5 U.S.C. App.2, § 10(d).

Committee Name: SAMHSA Special Emphasis Panel I (SEP I).

Meeting Dates: September 22, 1997.

Place: Embassy Suites Hotel, Suite 217, 1250 22nd Street, N.W., Washington, DC 20015–2020.

Closed: September 22, 1997 9:00 a.m.–Adjournment.

Panel: Center for Mental Health Services Cooperative Agreements for an HIV/AIDS Behavior Prevention/Intervention Model for Young Adults/Adolescents and Women.

Contact: Wendy B. Davis, Room 17–89, Parklawn Building, Telephone: 301–443–9913 and FAX: 301–443–3437.

The Special Emphasis Panel II meeting will include the review, discussion and evaluation of individual contract proposals. This discussion could reveal personal information concerning individuals associated with the proposals and confidential and financial information about an individual's proposal. This discussion could also reveal information about procurement activities exempt from disclosure by statute and trade secrets and commercial or financial information obtained from a person and privileged and confidential. Accordingly, the meeting is concerned with matters exempt from mandatory disclosure in Title 5 U.S.C. 552b(c)(3)(4), and (6) and 5 U.S.C. App., 2, § 10(d).

Committee Name: SAMHSA Special Emphasis Panel II.

Meeting Date: September 23, 1997.

Place: Parklawn Building 5600 Fishers Lane, Room 15–94, Rockville, MD 20857.

Closed: September 23, 1997, 2:00 p.m.–4:00 p.m.

Contact: Arthur Leabman, 17–89, Parklawn Building, Telephone: 301–443–4783 and FAX: 301–443–3437.

This notice is being published less than 15 days prior to the meeting due to the urgent need to meet timing limitations imposed by the review and funding cycle.

Dated: September 16, 1997.

Jeri Lipov,

Committee Management Officer Substance Abuse and Mental Health Services Administration.

[FR Doc. 97–25148 Filed 9–22–97; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4182–N–04]

Fiscal Year 1997 Notice of Funding Availability for Continuum of Care Homeless Assistance; Supportive Housing Program (SHP); Shelter Plus Care (S+C); Sec 8 Moderate Rehabilitation Single Room Occupancy Program for Homeless Individuals (SRO)

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice of funding availability (NOFA); Revision concerning receipt of applications.

SUMMARY: On April 8, 1997 (62 FR 17024), HUD published a notice announcing the availability of fiscal year (FY) 1997 funding for three of its programs that assist communities in combatting homelessness. Since the issuance of the April 8, 1997 NOFA, HUD has published two revisions, on May 5, 1997 (62 FR 24501) and on June 5, 1997 (62 FR 30873). The application deadline provided that an application would be considered received in a timely fashion if mailed to HUD Headquarters and postmarked on or before the application deadline of August 18, 1997, and received within ten (10) days after that date. Because of delays in mail delivery occasioned by the United Parcel Service strike in August, some applications took longer than the 10-day period provided. Therefore, this notice announces that the April 8, 1997 NOFA, as revised on May 5 and June 5, is revised to treat as timely applications those applications that were mailed before the deadline and were received within 30 days of the deadline.

SUPPLEMENTARY INFORMATION:

Background

On April 8, 1997 (62 FR 17024), HUD published a notice announcing the availability of fiscal year (FY) 1997 funding for three of its programs that assist communities in combatting homelessness. The three programs are: (1) Supportive Housing; (2) Shelter Plus Care; and (3) Section 8 Moderate Rehabilitation for Single Room Occupancy Dwellings for Homeless Individuals.

On May 5, 1997 (62 FR 24501), HUD published a notice announcing that the application deadline for the April 8, 1997 Continuum of Care Homeless Assistance notice of funding availability (NOFA) was extended to July 31, 1997.

HUD extended the deadline since the FY 1997 Continuum of Care NOFA introduced new procedures for awarding project renewal funds, which could require, in certain communities, additional time for reanalyzing the gaps that exist in continuum of care systems within the communities, and for reformulating plans and priorities for filling those gaps.

On June 5, 1997 (62 FR 30873), HUD published a notice announcing that the application deadline for the April 8, 1997 Continuum of Care Homeless Assistance NOFA was extended to August 18, 1997 to permit the local process to have the flexibility to request full funding for existing well-run projects that have limited ability to obtain other resources and to permit communities to revise their continuum of care priority lists to take into account this change being made to the NOFA provisions on project renewals.

Current Revision

Now, it has become evident that the United Parcel Service strike during August 1997 had an impact on the capacity of the U.S. Postal Service to deliver mail, delaying the delivery of applications that were postmarked on or before the August 18, 1997 deadline but were not delivered to HUD Headquarters until after the 10-day delivery period specified in the last revision of the April 8, 1997 NOFA. Therefore, this notice announces the revision to the portion of the **Deadline Dates** section of the NOFA that addressed applications submitted by regular mail to permit delivery to HUD Headquarters within 30 days after postmarked submission to the USPS by the deadline date to qualify as a timely submission.

Accordingly, FR Doc. 97–9034, the Fiscal Year 1997 Notice of Funding Availability for Continuum of Care Homeless Assistance; Supportive Housing Program (SHP); Shelter Plus Care (S+C); Sec. 8 Moderate Rehabilitation Single Room Occupancy Program for Homeless Individuals (SRO), published in the **Federal Register** on April 8, 1997 (62 FR 17024), is amended on page 17024, column 2, in the **Deadline Date** section, by revising the text under the subheading ''Applications Mailed.'' to read as follows:

Deadline Date

* * * * *

Applications Mailed. Applications will be considered timely filed if postmarked before midnight on August 18, 1997, and received by HUD Headquarters within thirty (30) days after that date.

* * * * *

Dated: September 17, 1997.

Jacquie Lawing,

General Deputy Assistant Secretary for Community Planning and Development.

[FR Doc. 97–25184 Filed 9–22–97; 8:45 am]

BILLING CODE 4210–29–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[AK–910–0777–74]

Alaska Resource Advisory Council Meeting

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of Alaska Resource Advisory Council Meeting.

SUMMARY: The Alaska Resource Advisory Council will conduct an open meeting Monday, October 27, 1997, from 9 a.m. until 4:30 p.m. and Tuesday, October 28, 1997, from 8:30 a.m. until 4 p.m. The purpose of the meeting is to elect a council chair and provide orientation for new members. The meeting will be held at the BLM Campbell Creek Science Center off Abbott Loop Road in Anchorage.

Public comments will be taken from 2–3 p.m. Monday, October 27. Written comments may be submitted at the meeting or mailed to the address below prior to the meeting.

ADDRESSES: Inquiries about the meeting should be sent to External Affairs, Bureau of Land Management, 222 W. 7th Avenue, #13, Anchorage, AK 99513–7599.

FOR FURTHER INFORMATION CONTACT: Teresa McPherson, (907) 271–5555.

Brenda Zenan,

Acting Associate State Director.

[FR Doc. 97–25169 Filed 9–22–97; 8:45 am]

BILLING CODE 4310–JA–P–M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[CA–350–1020–00]

Notice of Resource Advisory Council Meeting

AGENCY: Bureau of Land Management; Northeast California Resource Advisory Council, Susanville, California; Interior.

ACTION: Notice of meeting.

SUMMARY: The U.S. Bureau of Land Management's Northeast California Resource Advisory Council will meet Friday, Oct. 17, 1997, at the BLM's Eagle Lake Resource Area Office, 2950 Riverside Drive, Susanville, CA 96130

SUPPLEMENTARY INFORMATION: The meeting begins at 10 a.m. in the Conference Room of the Eagle Lake Resource Area Office. Items on the agenda include a status report from the California State Office, discussion about phase 1 fire management planning, discussion about the California Environmental Impact Statement on Standards and Guidelines for Healthy Rangelands, a report from the recreation fee subcommittee, wild horse and burro gather plans, status of work by technical review teams in the Surprise Resource Area, and election of new officers. Public comments will be taken at 1 p.m. Depending on the number of people wishing to speak, a time limit may be established.

FOR FURTHER INFORMATION: Contact Jeff Fontana, Public Affairs Officer, (916) 257–5381.

Linda D. Hansen,

Area Manager.

[FR Doc. 97–25171 Filed 9–22–97; 8:45 am]

BILLING CODE 4310–40–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[AZ–050–97–1430–01; AZA 25991, AZA 29964–AZA–29989]

Arizona: Notice of Realty Action

AGENCY: Bureau of Land Management, Interior.

ACTION: Extension of Notice for Competitive Sale of Public Land and Termination of Classifications in Quartzsite, La Paz County, Arizona.

SUMMARY: This notice extends the Notice of Realty Action published in the **Federal Register** on December 20, 1996, on Page 67342 of Vol. 61, No. 246, by the Yuma Field Office for a public land sale. The following land in Quartzsite, La Paz County, Arizona has been found suitable for disposal under sections 203 and 209 of the Federal Land Policy and Management Act of 1976 (90 Stat. 2750, 43 U.S.C. 1713). In addition, this Notice terminates the following Recreation and Public Purposes (R&PP) Act classifications for lease/conveyance on the subject sale parcels: AZA 23973 published July 5, 1989; AZA 24512 published May 23, 1990, AZA 25991 published November 21, 1991, September 28, 1994, and January 25, 1996.

The public land affected by this Notice is:

Gila and Salt River Meridian, Arizona

T. 4 N., R. 19 W.,
Sec. 22, NE¼SE¼, E½E½NW¼SE¼;
Sec. 23, N½SW¼, S½NE¼SW¼SW¼, NW¼SW¼SW¼, N½SE¼SW¼, SW¼SE¼SW¼;
Sec. 29, N½NE¼NE¼, NW¼NE¼, N½NW¼.

Aggregating 315.00 acres, more or less.

SUPPLEMENTARY INFORMATION: The December 20, 1996, Notice segregated the subject public land from appropriation under the public land laws, including the mining laws, pending disposition of the action or 270 days from the date of publication of the notice in the **Federal Register**. Upon publication of this notice in the **Federal Register**, that segregation will be extended pending completion of the sale or for another 270-day period, whichever occurs first

EFFECTIVE DATE OF TERMINATION OF R&PP CLASSIFICATION: September 23, 1997.

FOR FURTHER INFORMATION CONTACT: Debbie DeBock, Realty Specialist, Yuma Field Office, 2555 East Gila Ridge Road, Yuma, AZ 85365, (520) 317–3208.

Dated: September 11, 1997.

Maureen A. Merrell,

Program Manager, Business and Fiscal Services.

[FR Doc. 97–25160 Filed 9–22–97; 8:45 am]

BILLING CODE 4310–32–M

DEPARTMENT OF THE INTERIOR

National Park Service

Public Notice

AGENCY: National Park Service, Interior.

ACTION: Public notice.

SUMMARY: Public notice is hereby given that the National Park Service proposes to award a concession contract authorizing ferry services for the public between Sayville, New York and Sailors Haven, New York within Fire Island National Seashore for a period of ten (10) years from date of contract execution.

EFFECTIVE DATE: November 24, 1997.

ADDRESSES: Interested parties should contact National Park Service, Fire Island National Seashore, 120 Laurel Street, Patchogue, New York 11772 to obtain a copy of the prospectus describing the requirements of the proposed contract.

SUPPLEMENTARY INFORMATION: This contract has been determined to be categorically excluded from the procedural provisions of the National Environmental Policy Act and no environmental document will be prepared.

The existing concessioner has performed its obligations to the satisfaction of the Secretary under an existing contract which expired by limitation of time on December 31, 1996, and therefore pursuant to the provisions of Section 5 of the Act of October 9, 1965 (79 Stat. 969; 16 U.S.C. § 20), is entitled to be given preference in the renewal of the contract and in the negotiation of a new contract, providing that the existing concessioner submits a responsive offer (a timely offer which meets the terms and conditions of the Prospectus). This means that the contract will be awarded to the party submitting the best offer, provided that if the best offer was not submitted by the existing concessioner, then the existing concessioner will be afforded the opportunity to match the best offer. If the existing concessioner agrees to match the best offer, then the contract will be awarded to the existing concessioner.

If the existing concessioner does not submit a responsive offer, the right of preference in renewal shall be considered to have been waived, and the contract will then be awarded to the party that has submitted the best responsive offer.

The Secretary will consider and evaluate all proposals received as a result of this notice. Any proposal, including that of the existing concessioner, must be received by the Senior Concessions Program Manager, Concession Management Division, not later than the sixtieth (60th) day following publication of this notice to be considered and evaluated.

Dated: August 25, 1997.

Chrysandra L. Walter,

Field Director, Northeast Field Area.

[FR Doc. 97–25178 Filed 9–22–97; 8:45 am]

BILLING CODE 4310–70–M

DEPARTMENT OF THE INTERIOR

Boston Harbor Islands National Recreation Area, (Boston, Massachusetts) General Management Plan; Notice of Intent To Prepare an Environmental Impact Statement and Notice of Public Scoping

In accordance with section 102(c) of the National Environmental Policy Act of 1969, the National Park Service (NPS) is preparing an Environmental Impact Statement (EIS) for the General Management Plan (GMP) for Boston Harbor Islands National Recreation Area, Boston, Massachusetts (referred to in the law as an Integrated Resource Management Plan). The GMP/EIS will provide general management direction for the park's natural and cultural resources as well as alternatives addressing visitor use and services, treatment of the cultural landscape, interpretation, and any appropriate boundary adjustments.

The NPS and the Boston Harbor Islands Partnership will hold public meetings, which will be announced, between now and the end of January, 1998, in various locations in the Boston area. The purpose of these meetings is to solicit from the public both written and oral comments concerning possible environmental impact topics for consideration in preparation of the EIS. A summary of public scoping will be prepared and made available before the Draft Environmental Impact Statement is prepared.

A draft EIS is expected to be available for public review in Spring 1999 with the final EIS scheduled for Fall 1999.

The responsible official for the EIS is Marie Rust, Regional Director, Northeast Field Area, National Park Service. Written comments and requests for information should be directed to George Price, Project Manager, NPS, 15 State Street, Boston, Massachusetts 02109, Telephone 617–223–5060.

Lawrence P. Gall,

Acting Regional Director.

[FR Doc. 97–25179 Filed 9–22–97; 8:45 am]

BILLING CODE 4310–70–M

DEPARTMENT OF THE INTERIOR

National Park Service

Mojave National Preserve Advisory Commission; Notice of Meeting

Notice is hereby given in accordance with the Federal Advisory Committee Act that a meeting of the Mojave National Preserve Advisory Commission will be held October 9 and 10, 1997; assemble at 9:00 AM at the Hotel Nipton, Nipton, California.

The agenda: Desert Tortoise: Its History, Biology, and Legalities.

The Advisory Commission was established by PL #03–433 to provide for the advice on development and implementation of the General Management Plan.

Members of the Commission are: Michael Attaway, Irene Ausmus, Rob Blair, Peter Burk, Dennis Casebier, Donna Davis, Kathy Davis, Nathan ''Levi'' Esquerra, Gerald Freeman, Willis Herron, Eldon Hughes, Claudia Luke, Clay Overson, Norbert Riedy, Mal Wessel.

This meeting is open to the public.

Mary G. Martin,

Superintendent, Mojave National Preserve.

[FR Doc. 97–25177 Filed 9–22–97; 8:45 am]

BILLING CODE 4310–70–P

DEPARTMENT OF JUSTICE

Criminal Division; Agency Information Collection Activities: Existing Collection; Comment Request

ACTION: Extension of an Existing Collection: Registration Statement of Individuals (Foreign Agents).

The Department of Justice, Criminal Division has submitted the following information collection request (ICR) utilizing emergency review procedures, to the Office of Management and Budget (OMB) for review and clearance in accordance with the section 1320.13(a)(1)(ii) and (a)(2)(iii) of the Paperwork Reduction Act of 1995. The Criminal Division has determined that it cannot reasonably comply with the normal clearance procedures under this Part because normal clearance procedures are reasonably likely to prevent or disrupt the collection of information. This information collection is needed prior to the expiration of established time periods as set forth in the Foreign Agents Registration Act of 1938, as amended, 22 U.S.C. § 611, *et seq.* (FARA or the Act). The information provided is required by the provisions of FARA and is maintained in the public office of the Registration Unit, Internal Security Section, Criminal Division where it is available for review by the public. Without expedited approval for the collection of necessary data from registered foreign agents, the required information will not be available for review by the public. Therefore, OMB approval has been requested by September 26, 1997. If granted, the emergency approval is only valid for 180 days. All comments and/or questions pertaining to this pending request for emergency approval MUST be directed to OMB, Office of Information and Regulatory Affairs, Attention Ms. Victoria Wassmer/Mr. Patrick Boyd, 202–395–5871, Department of Justice Desk Officer, Washington, DC 20530. Comments regarding the emergency submission of this information collection may also be telefaxed to Ms. Wassmer/Mr. Boyd at 202–395–5871.

During the first 60 days of this same period, a regular review of this information collection is also being undertaken. During the regular review period, the Criminal Division requests written comments and suggestions from the public and affected agencies concerning the proposed collection. Comments are encouraged and will be accepted until November 24, 1997. During the 60-day regular review all comments and suggestions, or questions regarding additional information, to include obtaining a copy of the proposed information collection instrument with instructions, should be directed to Marshall R. Williams, 202–514–1229, Chief, Registration Unit, Internal Security Section, Criminal Division, U.S. Department of Justice, Room 9300, 1400 New York Avenue, N.W., Washington, DC 20530. Your comments should address one or more of the following four points.

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility.

(2) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of this information collection:

(1) *Type of Information Collection:* Extension of a Currently Approved Collection.

(2) *Title of the Form/Collection:* Registration Statement of Individuals (Foreign Agents).

(3) *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* Form CRM–153—Registration Statement.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Business or other for-profit, not-for-profit institutions, and individuals or households. Form contains registration statement and information used for registering foreign agents under 22 U.S.C. 611, *et seq.*

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 100 respondents at 1.5 hours per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 150 annual burden hours.

If additional information is required during the first 60 days of this same regular review period contact Mr. Robert B. Briggs, Clearance Officer, United States Department of Justice, Information Management and Security Staff, Justice Management Division, Suite 850, Washington Center, 1001 G Street, NW, Washington, DC 20530.

Dated: September 17, 1997.

Robert B. Briggs,

Department Clearance Officer, United States Department of Justice.

[FR Doc. 97–25251 Filed 9–22–97; 8:45 am]

BILLING CODE 4410–14–M

DEPARTMENT OF JUSTICE

Criminal Division; Agency Information Collection Activities: Existing Collection; Comment Request

ACTION: Extension of an Existing Collection: Supplemental Registration Statement of Individuals (Foreign Agents).

The Department of Justice, Criminal Division has submitted the following information collection request (ICR) utilizing emergency review procedures, to the Office of Management and Budget (OMB) for review and clearance in accordance with section 1320.13 (a)(1)(ii) and (a)(2)(iii) of the Paperwork Reduction Act of 1995. The Criminal Division has determined that it cannot reasonably comply with the normal clearance procedures under this Part because normal clearance procedures are reasonably likely to prevent or disrupt the collection of information. This information collection is needed prior to the expiration of established time periods as set forth in the Foreign Agents Registration Act of 1938, as amended, 22 U.S.C. § 611, *et seq.* (FARA or the Act). The information provided is required by the provisions of FARA and is maintained in the public office of the Registration Unit, Internal Security Section, Criminal Division where it is available for review by the public. Without expedited approval for the collection of necessary data from registered foreign agents, the required information will not be available for review by the public. Therefore, OMB approval has been requested by September 26, 1997. If granted, the emergency approval is only valid for 180 days. All comments and/or questions pertaining to this pending request for emergency approval MUST be directed to OMB, Office of

Information and Regulatory Affairs, Attention Ms. Victoria Wassmer/Mr. Patrick Boyd, 202–395–5871, Department of Justice Desk Officer, Washington, DC 20530. Comments regarding the emergency submission of this information collection may also be telefaxed to Ms. Wassmer/Mr. Boyd at 202–395–5871.

During the first 60 days of this same period, a regular review of this information collection is also being undertaken. During the regular review period, the Criminal Division requests written comments and suggestions from the public and affected agencies concerning the proposed collection. Comments are encouraged and will be accepted until November 24, 1997. During the 60-day regular review ALL comments and suggestions, or questions regarding additional information, to include obtaining a copy of the proposed information collection instrument with instructions, should be directed to Marshall R. Williams, 202–514–1229, Chief, Registration Unit, Internal Security Section, Criminal Division, U.S. Department of Justice, Room 9300, 1400 New York Avenue, N.W., Washington, DC 20530. Your comments should address one or more of the following four points.

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility.

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of this information collection:

(1) *Type of Information Collection:* Extension of a Currently Approved Collection.

(2) *Title of the Form/Collection:* Supplemental Registration Statement of Individuals (Foreign Agents).

(3) *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* Form CRM–154—Supplemental Registration Statement.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Business or other for-profit, Not-for-profit institutions, and individuals or households. Form contains supplemental registration and information used in registering foreign agents under 22 U.S.C. 611 *et seq.*

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 1,200 respondents at 1.375 hours per response (2 responses annually).

(6) *An estimate of the total public burden (in hours) associated with the collection:* 3,300 annual burden hours.

If additional information is required during the first 60 days of this same regular review period contact Mr. Robert B. Briggs, Clearance Officer, United States Department of Justice, Information Management and Security Staff, Justice Management Division, Suite 850, Washington Center, 1001 G Street NW., Washington, DC 20530.

Dated: September 17, 1997.

Robert B. Briggs,

Department Clearance Officer, United States Department of Justice.

[FR Doc. 97–25252 Filed 9–22–97; 8:45 am]

BILLING CODE 4410–14–M

DEPARTMENT OF JUSTICE

Criminal Division; Agency Information Collection Activities: Existing Collection; Comment Request

ACTION: Extension of an Existing Collection: Exhibit A to Registration Statement (Foreign Agents).

The Department of Justice, Criminal Division has submitted the following information collection request (ICR) utilizing emergency review procedures, to the Office of Management and Budget (OMB) for review and clearance in accordance with section 1320.13 (a)(1)(ii) and (a)(2)(iii) of the Paperwork Reduction Act of 1995. The Criminal Division has determined that it cannot reasonably comply with the normal clearance procedures under this Part because normal clearance procedures are reasonably likely to prevent or disrupt the collection of information. This information collection is needed prior to the expiration of established time periods as set forth in the Foreign Agents Registration Act of 1938, as amended, 22 U.S.C. § 611, *et seq.* (FARA or the Act). The information provided is required by the provisions of FARA and is maintained in the public office of the Registration Unit, Internal Security Section, Criminal Division where it is available for review by the public. Without expedited approval for the collection of necessary data from registered foreign agents, the required information will not be available for review by the public. Therefore, OMB approval has been requested by September 26, 1997. If granted, the emergency approval is only valid for 180 days. All comments and/or questions pertaining to this pending request for emergency approval MUST be directed to OMB, Office of Information and Regulatory Affairs, Attention Ms. Victoria Wassmer/Mr. Patrick Boyd, 202–395–5871, Department of Justice Desk Officer, Washington, DC 20530. Comments regarding the emergency submission of this information collection may also be telefaxed to Ms. Wassmer/Mr. Boyd at 202–395–5871.

During the first 60 days of this same period, a regular review of this information collection is also being undertaken. During the regular review period, the Criminal Division requests written comments and suggestions from the public and affected agencies concerning the proposed collection. Comments are encouraged and will be accepted until November 24, 1997. During the 60-day regular review ALL comments and suggestions, or questions regarding additional information, to include obtaining a copy of the proposed information collection instrument with instructions, should be directed to Marshall R. Williams, 202–514–1229, Chief, Registration Unit, Internal Security Section, Criminal Division, U.S. Department of Justice, Room 9300, 1400 New York Avenue, N.W., Washington, DC 20530. Your comments should address one or more of the following four points.

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility.

(2) Evaluate the accuracy of the agencies' estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of this information collection:

(1) *Type of Information Collection:* Extension of a Currently Approved Collection.

(2) *Title of the Form/Collection:* Exhibit A to Registration Statement (Foreign Agents).

(3) *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* Form CRM–157—Exhibit A to Registration Statement.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:*

Primary: Business or other for-profit, Not-for-profit institutions, and individuals or households.

Form is used to register foreign agents as required by 22 U.S.C. 611, *et seq.*, and must be utilized within 10 days of date contract is made or when initial activity occurs, whichever is first.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 75 respondents at .49 hours per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 38 annual burden hours.

If additional information is required during the first 60 days of this same regular review period contact Mr. Robert B. Briggs, Clearance Officer, United States Department of Justice, Information Management and Security Staff, Justice Management Division, Suite 850, Washington Center, 1001 G Street NW., Washington, DC 20530.

Dated: September 17, 1997.

Robert B. Briggs,

Department Clearance Officer, United States Department of Justice.

[FR Doc. 97–25253 Filed 9–22–97; 8:45 am]

BILLING CODE 4410–14–M

DEPARTMENT OF JUSTICE

Criminal Division; Agency Information Collection Activities: Existing Collection; Comment Request

ACTION: Extension of an Existing Collection: Amendment to Registration or Supplemental Registration Reports (Foreign Agents).

The Department of Justice, Criminal Division has submitted the following information collection request (ICR) utilizing emergency review procedures, to the Office of Management and Budget (OMB) for review and clearance in accordance with section 1320.13(a)(1)(ii) and (a)(2)(iii) of the Paperwork Reduction Act of 1995. The Criminal Division has determined that it cannot reasonably comply with the normal clearance procedures under this Part because normal clearance procedures are reasonably likely to prevent or disrupt the collection of information. This information collection is needed prior to the expiration of established time periods as set forth in the Foreign Agents Registration Act of 1938, as amended, 22 U.S.C. § 611, *et seq.* (FARA or the Act). The information provided is required by the provisions of FARA and is maintained in the public office of the Registration Unit, Internal Security Section, Criminal Division where it is available for review by the public. Without expedited approval for the collection of necessary data from registered foreign agents, the required information will not be available for review by the public. Therefore, OMB approval has been requested by September 26, 1997. If granted, the emergency approval is only valid for 180 days. All comments and/or questions pertaining to this pending request for emergency approval MUST be directed to OMB, Office of Information and Regulatory Affairs, Attention Ms. Victoria Wassmer/Mr. Patrick Boyd, 202–395–5871, Department of Justice Desk Officer, Washington, DC 20530. Comments regarding the emergency submission of this information collection may also be telefaxed to Ms. Wassmer/Mr. Boyd at 202–395–5871.

During the first 60 days of this same period, a regular review of this information collection is also being undertaken. During the regular review period, the Criminal Division requests written comments and suggestions from the public and affected agencies concerning the proposed collection. Comments are encouraged and will be accepted until November 24, 1997. During the 60-day regular review ALL comments and suggestions, or questions regarding additional information, to include obtaining a copy of the proposed information collection instrument with instructions, should be directed to Marshall R. Williams, 202–514–1229, Chief, Registration Unit, Internal Security Section, Criminal Division, U.S. Department of Justice, Room 9300, 1400 New York Avenue, NW., Washington, DC 20530. Your comments should address one or more of the following four points.

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility.

(2) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of this information collection:

(1) *Type of Information Collection:* Extension of a Currently Approved Collection.

(2) *Title of the Form/Collection:* Amendment to Registration or Supplemental Registration Reports (Foreign Agents)

(3) *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* Form CRM–156—Amendment to Registration or Supplemental Registration Reports

(4) *Affected public who will be asked for or required to respond, as well as a brief abstract:* Primary: Business or other for-profit, Not-for-profit institutions, and individuals or households.

Form is used in registration of foreign agents when changes are required under provisions of 22 U.S.C. 611, *et seq.*

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 200 respondents at 1.5 hours per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 300 annual burden hours.

If additional information is required during the first 60 days of this same regular review period contact Mr. Robert B. Briggs, Clearance Officer, United States Department of Justice, Information Management and Security Staff, Justice Management Division, Suite 850, Washington Center, 1001 G Street, NW, Washington, DC 20530.

Dated: September 17, 1997.

Robert B. Briggs,

Department Clearance Officer, United States Department of Justice.

[FR Doc. 97–25254 Filed 9–22–97; 8:45 am]

BILLING CODE 4410–14–M

DEPARTMENT OF JUSTICE

Criminal Division; Agency Information Collection Activities: Existing Collection; Comment Request

ACTION: Extension of an Existing Collection: Exhibit B to Registration Statement (Foreign Agents).

The Department of Justice, Criminal Division has submitted the following information collection request (ICR) utilizing emergency review procedures, to the Office of Management and Budget (OMB) for review and clearance in accordance with section 1320.13(a)(1)(ii) and (a)(2)(iii) of the Paperwork Reduction Act of 1995. The Criminal Division has determined that it cannot reasonably comply with the normal clearance procedures under this Part because normal clearance procedures are reasonably likely to prevent or disrupt the collection of information. This information collection is needed prior to the expiration of established time periods as set forth in the Foreign Agents Registration Act of 1938, as amended, 22 U.S.C. § 611, *et seq.* (FARA or the Act). The information provided is required by the provisions of FARA and is maintained in the public office of the Registration Unit, Internal Security Section, Criminal Division where it is available for review by the public. Without expedited approval for the collection of necessary data from registered foreign agents, the required information will not be available for review by the public. Therefore, OMB approval has been requested by September 26, 1997. If granted, the emergency approval is only valid for 180 days. All comments and/or questions pertaining to this pending request for emergency approval MUST be directed to OMB, Office of Information and Regulatory Affairs, Attention Ms. Victoria Wassmer/Mr. Patrick Boyd, 202–395–5871, Department of Justice Desk Officer, Washington, DC 20530. Comments regarding the emergency submission of this information collection may also be telefaxed to Ms. Wassmer/Mr. Boyd at 202–395–5871.

During the first 60 days of this same period, a regular review of this information collection is also being undertaken. During the regular review period, the Criminal Division requests written comments and suggestions from the public and affected agencies concerning the proposed collection. Comments are encouraged and will be accepted until November 24, 1997. During the 60-day regular review ALL comments and suggestions, or questions regarding additional information, to include obtaining a copy of the proposed information collection instrument with instructions, should be directed to Marshall R. Williams, 202–514–1229, Chief, Registration Unit, Internal Security Section, Criminal Division, U.S. Department of Justice, Room 9300, 1400 New York Avenue, N.W., Washington, DC 20530. Your comments should address one or more of the following four points.

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility.

(2) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of this information collection:

(1) *Type of Information Collection:* Extension of a Currently Approved Collection.

(2) *Title of the Form/Collection:* Exhibit B to Registration Statement (Foreign Agents).

(3) *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* Form CRM–155—Exhibit B to Registration Statement.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary Business or other for-profit, Not-for-profit institutions, and individuals or households. Form is used to augment the registration statement of foreign agents as required by the provisions of 22 U.S.C. 611, *et seq.*, within 10 days of the date a contract is made or when initial activity occurs, whichever is first.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 75 respondents at .33 hours per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 25 annual burden hours.

If additional information is required during the first 60 days of this same regular review period contact Mr. Robert B. Briggs, Clearance Officer, United States Department of Justice, Information Management and Security Staff, Justice Management Division, Suite 850, Washington Center, 1001 G Street, NW, Washington, DC 20530.

Dated: September 17, 1997.

Robert B. Briggs,

Department Clearance Officer, United States Department of Justice.

[FR Doc. 97–25255 Filed 9–22–97; 8:45 am]

BILLING CODE 4410–14–M

DEPARTMENT OF JUSTICE

Criminal Division; Agency Information Collection Activities: Existing Collection; Comment Request

ACTION: Extension of an Existing Collection: Short-Form Registration or Statement of Individuals (Foreign Agents).

The Department of Justice, Criminal Division has submitted the following information collection request (ICR) utilizing emergency review procedures, to the Office of Management and Budget (OMB) for review and clearance in accordance with section 1320.13(a)(1)(ii) and (a)(1)(iii) of the Paperwork Reduction Act of 1995. The Criminal Division has determined that it cannot reasonably comply with the normal clearance procedures under this Part because normal clearance procedures are reasonably likely to prevent or disrupt the collection of information. This information collection is needed prior to the expiration of established time periods as set forth in the Foreign Agents Registration Act of 193, as amended, 22 U.S.C. § 611, *et seq.* (FARA or the Act). The information provided is required by the provisions of FARA and is maintained in the public office of the Registration Unit, Internal Security Section, Criminal Division where it is available for review by the public. Without expedited approval for the collection of necessary data from registered foreign agents, the required information will not be available for review by the public. Therefore, OMB approval has been requested by September 26, 1997. If granted, the emergency approval is only valid for 180 days. All comments and/or questions pertaining to this pending request for emergency approval MUST be directed to OMB, Office of Information and Regulatory Affairs, Attention Victoria Wassmer/Patrick Boyd, 202–395–5871, Department of Justice Desk Office, Washington, DC 20530. Comments regarding the

emergency submission of this information collection may also be telefaxed to Ms. Wasserman/Mr. Boyd at 202–395–5871.

During the first 60 days of this same period, a regular review of this information collection is also being undertaken. During the regular review period, the Criminal Division requests written comments and suggestions from the public and affected agencies concerning the proposed collection. Comments are encouraged and will be accepted until November 24, 1997. During the 60-day regular review ALL comments and suggestions, or questions regarding additional information, to include obtaining a copy of the proposed information collection instrument with instructions, should be directed to Marshall R. Williams, 202–514–1229, Chief, Registration Unit, Internal Security Section, Criminal Division, U.S. Department of Justice, Room 9300, 1400 New York Avenue, N.W., Washington, DC 20530. Your comments should address one or more of the following four points.

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility.

(2) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of this information collection:

(1) *Type of Information Collection:* Extension of a Currently Approved Collection.

(2) *Title of the Form/Collection:* Short-form Registration Statement of Individuals (Foreign Agents).

(3) *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* For CRM–156—Short-form Registration Statement.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Business or other for-profit, Not-for-profit institutions, and individuals or households. Form is used to register foreign agents as required by 22 U.S.C. 611, *et seq.*

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 350 respondents at .429 hours per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 150 annual burden hours.

If additional information is required during the first 60 days of this same regular review period contact Mr. Robert B. Briggs, Clearance Officer, United States Department of Justice, Information Management and Security Staff, Justice Management Division, Suite 850, Washington Center, 1001 G Street, NW, Washington, DC 20530.

Dated: September 17, 1997.

Robert B. Briggs,

Department Clearance Officer, United States Department of Justice.

[FR Doc. 97–25256 Filed 9–22–97; 8:45 am]

BILLING CODE 4410–14–M

DEPARTMENT OF JUSTICE

Notice of Lodging of Consent Decree Pursuant to the Comprehensive Environmental Response Compensation and Liability Act

Notice is hereby given that a proposed consent decree in *United States* v. *Atlantic Richfield Co.*, Civil No. 3–91–CV–248, was lodged on August 27, 1997, with the United States District Court for the District of Connecticut. The decree resolves claims against Litton Systems, Inc. in the above-referenced action under the Comprehensive Environmental Response, Compensation, and Liability Act (''CERCLA''), for contamination at the Laurel Park Landfill Superfund Site in the Borough of Naugatuck, Connecticut (the ''Site''). In the proposed consent decree, the settling defendant agrees to reimburse the United States for $30,000 in past response costs incurred by the Environmental Protection Agency at the Site, and to reimburse the State of Connecticut $6,000 for past State costs. The Consent Decree includes a covenant not to sue by the United States under Sections 106 and 107 of CERCLA.

The Department of Justice will receive, for a period of thirty (30) days from the date of this publication, comments relating to the proposed consent decree. Comments should be addressed to the Assistant Attorney General for the Environment and Natural Resources Division, Department of Justice, Washington, D.C. 20530, and should refer to *United States* v. *Atlantic Richfield Co.*, DOJ Ref. Number 90–11–2–703.

The proposed consent decree may be examined at the Office of the United States Attorney, Connecticut Financial Center, 157 Church St., New Haven, CT 06510, the New England Region Office of the Environmental Protection Agency, JFK Federal Building, Boston, MA 02203–2211; and at the Consent Decree Library, 1120 G Street, N.W., 4th Floor, Washington, D.C. 20005, (202) 624–0892. A copy of the proposed consent decree may be obtained in person or by mail from the Consent Decree Library, 1120 G Street, N.W. 4th Floor, Washington, D.C. 20005. In requesting a copy, please refer to the referenced case and enclose a check in the amount of $8.00 for the Consent Decree (25 cents per page reproduction costs), payable to the Consent Decree Library.

Bruce S. Gelber,

Deputy Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 97–25219 Filed 9–22–97; 8:45 am]

BILLING CODE 4410–15–M

DEPARTMENT OF JUSTICE

Notice of Lodging of Consent Decree Pursuant to the Comprehensive Environmental Response Compensation and Liability Act

Notice is hereby given that a proposed consent decree in *United States* v. *Atlantic Richfield Co. (''ARCO'')*, Civil No. 3–91–CV–248, was lodged on August 27, 1997, with the United States District Court for the District of Connecticut. The decree resolves claims against ARCO, in the above-referenced action under the Comprehensive Environmental Response, Compensation, and Liability Act (''CERCLA''), for contamination at the Laurel Park Landfill Superfund Site in the Borough of Naugatuck, Connecticut (the ''Site''). In the proposed consent decree, the settling defendant agrees to reimburse the United States for $30,000 in past response costs incurred by the United States Environmental Protection Agency at the Site, and to reimburse the State of Connecticut $6,000 for the past Site costs. The Consent Decree includes a covenant not to sue by the United States under Section 106 and 107 of CERCLA.

The Department of Justice will receive, for a period of thirty (30) days from the date of this publication, comments relating to the proposed consent decree. Comments should be addressed to the Assistant Attorney

General for the Environment and Natural Resources Division, Department of Justice, Washington, D.C. 20530, and should refer to *United States* v. *Atlantic Richfield Co.*, DOJ Ref. Number 90–11–2–703.

The proposed consent decree may be examined at the Office of the United States Attorney, Connecticut Financial Center, 157 Church St., New Haven, CT 06510, the New England Region Office of the Environmental Protection Agency, JFK Federal Building, Boston, MA 02203–2211; and at the Consent Decree Library, 1120 G Street, N.W., 4th Floor, Washington, D.C. 20005, (202) 624 0892. A copy of the proposed consent decree may be obtained in person or by mail from the Consent Decree Library, 1120 G Street, N.W. 4th Floor, Washington, D.C. 20005. In requesting a copy, please refer to the referenced case and enclose a check in the amount of $7.25 for the Consent Degree (25 cents per page reproduction costs), payable to the Consent Decree Library.

Bruce S. Gelber,

Deputy Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 97–25220 Filed 9–22–97; 8:45 am]

BILLING CODE 4410–15–M

DEPARTMENT OF LABOR

Office of the Secretary

Submission for OMB Review; Comment Request

September 18, 1997.

The Department of Labor (DOL) has submitted the following public information collection request (ICR) 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 this individual ICR, with applicable supporting documentation, may be obtained by calling the Department of Labor, Departmental Clearance Officer, Theresa M. O'Malley ((202) 219–5096 ext. 143) or by E-Mail to OMalley-Theresa@dol.gov. Individuals who use a telecommunications device for the deaf (TTY/TDD) may call (202) 219–4720 between 1 p.m. and 4 p.m. Eastern time, Monday–Friday.

Comments should be sent to Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for MSHA, 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.

Agency: Mine Safety and Health Administration.

Title: Main Fan Operation and Inspection.

OMB Number: 1219–0030 (reinstatement).

Frequency: Daily.

Affected Public: Business or other for-profit-profit.

Number of Respondents: 7.

Estimated Time Per Respondent: 30 minutes.

Total Burden Hours: 1,313.

Total Annualized capital/startup costs: $735.

Total annual costs (operating/maintaining systems or purchasing services): $735.

Description: Requires operators of metal and nonmetal underground mines that are categorized as gassy, to have main fans with pressure-recording systems. Main fans are to be inspected daily, certification of the inspection made, and records kept of the results of the inspections.

Theresa M. O'Malley,

Departmental Clearance Officer.

[FR Doc. 97–25239 Filed 9–22–97; 8:45 am]

BILLING CODE 4510–43–M

NUCLEAR REGULATORY COMMISSION

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: U.S. Nuclear Regulatory Commission (NRC).

ACTION: Notice of 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:* Revision.

2. *The title of the information collection:* NRC Form 790, ''Classification Record''.

3. *The form number if applicable:* NRC Form 790.

4. *How often the collection is required:* On occasion.

5. *Who will be required or asked to report:* NRC employees, NRC contractors, NRC licensees, and certificate holders who classify and declassify NRC information.

6. *An estimate of the number of responses:* 2,200.

7. *The estimated number of annual respondents:* 175.

8. *An estimate of the total number of hours needed annually to complete the requirement or request:* 147.

9. *Abstract:* The NRC Form 790 is being revised to add three additional fields and revise several existing fields for easier completion. In addition, an electronic reporting format is being made available for those wishing to use it. Completion of the NRC Form 790 is a mandatory requirement for licensees, contractors, and certificate holders who classify and declassify NRC information in accordance with Executive Order 12958, ''Classified National Security Information,'' the Atomic Energy Act, and implementing directives.

A copy of the submittal may be viewed free of charge at the NRC Public Document Room, 2120 L Street NW, (lower level), Washington, DC. Members of the public who are in the Washington, DC, area can access this document via modem on the Public Document Room Bulletin Board (NRC's Advanced Copy Document Library), NRC subsystem at FedWorld, 703–321–3339. Members of the public who are located outside of the Washington, DC, area can dial FedWorld, 1–800–303–9672, or use the FedWorld Internet address: fedworld.gov (Telnet). The document will be available on the bulletin board for 30 days after the signature date of this notice. If

assistance is needed in accessing the document, please contact the FedWorld help desk at 703–487–4608. Additional assistance in locating the document is available from the NRC Public Document Room, nationally at 1–800–397–4209, or within the Washington, DC, area at 202–634–3273.

Comments and questions should be directed to the OMB reviewer by October 24, 1997: Norma Gonzales, Office of Information and Regulatory Affairs (3150–0052), NEOB–10202, Office of Management and Budget, Washington, DC 20503.

Comments can also be submitted by telephone at (202) 395–3084.

The NRC Clearance Officer is Brenda Jo Shelton, (301) 415–7233.

Dated at Rockville, Maryland, this 16th day of September 1997.

For the Nuclear Regulatory Commission.

Arnold E. Levin,

Acting Designated Senior, Official for Information Resources Management.

[FR Doc. 97–25211 Filed 9–22–97; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 030–30691–CivP; ASLBP No. 97–730–02–CivP]

Atomic Safety and Licensing Board; Notice of Hearing

September 17, 1997.

In the matter of Barnett Industrial X-ray, Inc. (Stillwater, Oklahoma).

Notice is hereby given that, by Memorandum and Order dated September 8, 1997, the Atomic Safety and Licensing Board has granted the request of Barnett Industrial X-Ray, Inc. for a hearing in the captioned proceeding. The hearing concerns the Order Imposing a Civil Monetary Penalty, issued by the NRC Staff on May 23, 1997 and published in the **Federal Register** at 62 FR 30347 (1997). The parties to the proceeding are the Licensee and the NRC Staff.

The issues to be considered at the hearing are: (1) Whether the violations represent a security Level 2 matter in accordance with the ''General Statement of Policy and Procedures for NRC Enforcement Actions,'' NUREG–1600 (July 1995); and, (2) whether a $4,000.00 civil penalty is warranted in light of the mitigating actions taken by the Licensee.

Materials concerning this proceeding are on file at the Commission's Public Document Room, 2120 L St. N.W., Washington, D.C. 20555, and at the Commission's Region IV Office, Harris Tower, 611 Ryan Plaza Drive, Suite 400, Arlington, TX 76011–8064.

During the course of this proceeding, the Licensing Board, as necessary, may conduct one or more prehearing conferences. The time and place of these sessions, which will be open to the public, will be announced in later Licensing Board Orders. The evidentiary hearing will be held in Stillwater, Oklahoma on November 5, 1997, at 10:00 a.m. in the Payne County Courthouse, 606 S. Husband Street.

Issued at Rockville, Maryland, September 17, 1997.

For the Atomic Safety and Licensing Board.

B. Paul Cotter, Jr.,

Chairman, Administrative Judge.

[FR Doc. 97–25221 Filed 9–22–97; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket 70–7001]

Notice of Amendment to Certificate of Compliance GDP–1 for the U.S. Enrichment Corporation, Paducah Gaseous Diffusion Plant, Paducah, Kentucky

The Director, Office of Nuclear Material Safety and Safeguards, has made a determination that the following amendment request is not significant in accordance with 10 CFR 76.45. In making that determination the staff concluded that: (1) there is no change in the types or significant increase in the amounts of any effluents that may be released offsite; (2) there is no significant increase in individual or cumulative occupational radiation exposure; (3) there is no significant construction impact; (4) there is no significant increase in the potential for, or radiological or chemical consequences from, previously analyzed accidents; (5) the proposed changes do not result in the possibility of a new or different kind of accident; (6) there is no significant reduction in any margin of safety; and (7) the proposed changes will not result in an overall decrease in the effectiveness of the plant's safety, safeguards or security programs. The basis for this determination for the amendment request is shown below.

The Nuclear Regulatory Commission staff has reviewed the certificate amendment application and concluded that it provides reasonable assurance of adequate safety, safeguards, and security, and compliance with NRC requirements. Therefore, the Director, Office of Nuclear Material Safety and Safeguards, is prepared to issue an amendment to the Certificate of Compliance for the Paducah Gaseous Diffusion Plant. The staff has prepared a Compliance Evaluation Report which provides details of the staff's evaluation.

The NRC staff has determined that this amendment satisfies the criteria for a categorical exclusion in accordance with 10 CFR 51.22. Therefore, pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared for this amendment.

U.S. Enrichment Corporation (USEC) or any person whose interest may be affected may file a petition, not exceeding 30 pages, requesting review of the Director's Decision. The petition must be filed with the Commission not later than 15 days after publication of this **Federal Register** Notice. A petition for review of the Director's Decision shall set forth with particularity the interest of the petitioner and how that interest may be affected by the results of the decision. The petition should specifically explain the reasons why review of the Decision should be permitted with particular reference to the following factors: (1) the interest of the petitioner; (2) how that interest may be affected by the Decision, including the reasons why the petitioner should be permitted a review of the Decision; and (3) the petitioner's areas of concern about the activity that is the subject matter of the Decision. Any person described in this paragraph (USEC or any person who filed a petition) may file a response to any petition for review, not to exceed 30 pages, within 10 days after filing of the petition. If no petition is received within the designated 15-day period, the Director will issue the final amendment to the Certificate of Compliance without further delay. If a petition for review is received, the decision on the amendment application will become final in 60 days, unless the Commission grants the petition for review or otherwise acts within 60 days after publication of this **Federal Register** Notice.

A petition for review must be filed with the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemakings and Adjudications Staff, or may be delivered to the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW, Washington, DC, by the above date.

For further details with respect to the action see (1) the application for amendment and (2) the Commission's Compliance Evaluation Report. These items are available for public inspection

at the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW, Washington, DC, and at the Local Public Document Room.

Date of amendment request: April 14, 1997, as revised June 13, June 23, and August 18, 1997.

Brief description of amendment: The amendment proposes to revise the Technical Safety Requirement (TSR) on the cell trip function to provide clarification of battery cell parameters, to provide for alternate means of verifying functionality of the cascade cell trip circuit, and to provide a definition of planned and unplanned cell shutdown.

Basis for finding of no significance:

1. The proposed amendment will not result in a change in the types or significant increase in the amounts of any effluents that may be released offsite.

The proposed changes will provide an alternative surveillance test to verify the functionality of the cascade cell trip circuit and will provide clarification for battery cell parameters. There are no effluent releases associated with this change, the proposed changes will not affect the effluent.

2. The proposed amendment will not result in a significant increase in individual or cumulative occupational radiation exposure.

The proposed changes do not relate to controls used to minimize occupational radiation exposures, therefore, the changes will not increase exposure.

3. The proposed amendment will not result in a significant construction impact.

The proposed changes will not result in any construction, therefore, there will be no construction impacts.

4. The proposed amendment will not result in a significant increase in the potential for, or radiological or chemical consequences from, previously analyzed accidents.

The proposed changes provide for the clarification of battery parameters and ability to test cell trip function by a second method. This surveillance method can be performed on cells that are shutdown, providing a means to meet the surveillance requirements and restart the shutdown cell. The test is functionally equivalent to the surveillance currently specified in the TSR. The proposed changes do not represent an increase in the potential for, or radiological or chemical consequences from, previously evaluated accidents.

5. The proposed amendment will not result in the possibility of a new or different kind of accident.

The proposed changes to the TSR do not result in any situation whereby components are not capable of performing the required safety functions. The proposed changes would not create new operating conditions or new plant configuration that could lead to a new or different type of accident.

6. The proposed amendment will not result in a significant reduction in any margin of safety.

Although the timing of the surveillance for testing cell trip function is modified by addition of the alternative test, system operability is still ensured before the cell is restarted. The other changes to the TSR do not result in any situation whereby the components are not capable of performing the required safety function. These changes do not decrease the margins of safety.

7. The proposed amendment will not result in an overall decrease in the effectiveness of the plant's safety, safeguards or security programs.

Implementation of the proposed changes do not change the safety, safeguards, or security programs. Therefore, the effectiveness of the safety, safeguards, and security programs is not decreased.

Effective date: The amendment to Certificate of Compliance GDP–1 becomes effective 15 days after being signed by the Director, Office of Nuclear Material Safety and Safeguards.

Certificate of Compliance No. GDP–1: Amendment will revise the Technical Safety Requirement for the cell trip function.

Local Public Document Room location: Paducah Public Library, 555 Washington Street, Paducah, Kentucky 42003.

Dated at Rockville, Maryland, this 15th day of September 1997.

For the Nuclear Regulatory Commission.

Carl J. Paperiello,

Director, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 97–25212 Filed 9–22–97; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket 70–7001]

Notice of Amendment to Certificate of Compliance GDP–1 for the U.S. Enrichment Corporation Paducah Gaseous Diffusion Plant, Paducah, Kentucky

The Director, Office of Nuclear Material Safety and Safeguards, has made a determination that the following amendment request is not significant in accordance with 10 CFR 76.45. In making that determination, the staff concluded that: (1) There is no change in the types or significant increase in the amounts of any effluents that may be released offsite; (2) there is no significant increase in individual or cumulative occupational radiation exposure; (3) there is no significant construction impact; (4) there is no significant increase in the potential for, or radiological or chemical consequences from, previously analyzed accidents; (5) the proposed changes do not result in the possibility of a new or different kind of accident; (6) there is no significant reduction in any margin of safety; and (7) the proposed changes will not result in an overall decrease in the effectiveness of the plant's safety, safeguards or security programs. The basis for this determination for the amendment request is shown below.

The NRC staff has reviewed the certificate amendment application and concluded that it provides reasonable assurance of adequate safety, safeguards, and security, and compliance with NRC requirements. Therefore, the Director, Office of Nuclear Material Safety and Safeguards, is prepared to issue an amendment to the Certificate of Compliance for the Paducah Gaseous Diffusion Plant. The staff has prepared a Compliance Evaluation Report which provides details of the staff's evaluation.

The NRC staff has determined that this amendment satisfies the criteria for a categorical exclusion in accordance with 10 CFR 51.22. Therefore, pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared for this amendment.

USEC or any person whose interest may be affected may file a petition, not exceeding 30 pages, requesting review of the Director's Decision. The petition must be filed with the Commission not later than 15 days after publication of this **Federal Register** Notice. A petition for review of the Director's Decision shall set forth with particularity the interest of the petitioner and how that interest may be affected by the results of the decision. The petition should specifically explain the reasons why review of the Decision should be permitted with particular reference to the following factors: (1) The interest of the petitioner; (2) how that interest may be affected by the Decision, including the reasons why the petitioner should be permitted a review of the Decision; and (3) the petitioner's areas of concern about the activity that is the subject matter of the Decision. Any person described in this paragraph (USEC or

any person who filed a petition) may file a response to any petition for review, not to exceed 30 pages, within 10 days after filing of the petition. If no petition is received within the designated 15-day period, the Director will issue the final amendment to the Certificate of Compliance without further delay. If a petition for review is received, the decision on the amendment application will become final in 60 days, unless the Commission grants the petition for review or otherwise acts within 60 days after publication of this **Federal Register** Notice.

A petition for review must be filed with the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemakings and Adjudications Staff, or may be delivered to the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW, Washington, DC, by the above date.

For further details with respect to the action see: (1) The application for amendment; and (2) the Commission's Compliance Evaluation Report. These items are available for public inspection at the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW, Washington, DC, and at the Local Public Document Room.

Date of amendment request: August 11, 1997.

Brief description of amendment: The amendment proposes to revise Compliance Plan Issue 3, Action 7 which provides for the modification of the C–360 autoclave controls to add a low instrument air pressure switch to initiate containment upon loss of instrument air. Instead of adding a low instrument air pressure switch, USEC proposes to provide a second channel for high pressure containment that does not rely on instrument air. USEC also proposes to extend the due date from August 31, 1997 to October 31, 1997.

Basis for finding of no significance:

1. The proposed amendment will not result in a change in the types or significant increase in the amounts of any effluents that may be released offsite.

The proposed change involves the High Pressure Isolation and Steam Pressure Control Systems. The change will not affect the function of the system. Because there are no effluent releases associated with this change, the proposed change will not affect effluents.

2. The proposed amendment will not result in a significant increase in individual or cumulative occupational radiation exposure.

The proposed changes will not significantly increase any exposure to radiation. Therefore, the changes will not result in a significant increase in individual or cumulative radiation exposure.

3. The proposed amendment will not result in a significant construction impact.

The proposed changes will not result in any building construction, only equipment modification, therefore, there will be no construction impacts.

4. The proposed amendment will not result in a significant increase in the potential for, or radiological or chemical consequences from, previously analyzed accidents.

The proposed changes will not increase the probability of occurrence or consequence of any postulated accident currently identified in the safety analysis report. The proposed change will reduce the failure modes of the High Pressure Isolation and Steam Pressure Control Systems. The extension of the completion date will not significantly increase the probability of an accident. The existing Justification for Continued Operation will remain in effect during the two-month extension. There is no significant increase in the potential for or radiological or chemical consequences from previously evaluated accidents.

5. The proposed amendment will not result in the possibility of a new or different kind of accident.

The function of the High Pressure Isolation and Steam Pressure Control systems will not be changed by the modifications. The proposed changes will not create any new or different type of accident.

6. The proposed amendment will not result in a significant reduction in any margin of safety.

The safety limit associated with the modifications remains unchanged. The proposed change will provide for two safety channels for initiating autoclave containment that do not rely on instrument air. These changes do not decrease the margins of safety.

7. The proposed amendment will not result in an overall decrease in the effectiveness of the plant's safety, safeguards or security programs.

Implementation of the proposed changes do not change the safety, safeguards, or security programs. Therefore, the effectiveness of the safety, safeguards, and security programs is not decreased.

Effective date: The amendment to Certificate of Compliance GDP–1 becomes effective immediately after being signed by the Director, Office of Nuclear Material Safety and Safeguards.

Certificate of Compliance No. GDP–1: Amendment will revise the Compliance Plan Issue 3, Action 7 on the autoclave upgrades to extend the due date by two months and to allow for mechanical-electrical pressure switches instead of pneumatic switches.

Local Public Document Room location: Paducah Public Library, 555 Washington Street, Paducah, Kentucky 42003.

Dated at Rockville, Maryland, this 15th day of September 1997.

For the Nuclear Regulatory Commission.

Carl J. Paperiello,

Director, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 97–25213 Filed 9–22–97; 8:45 am]

BILLING CODE 7590–01–P

SECURITIES AND EXCHANGE COMMISSION

[Rel. No. IC–22823; File No. 812–10692]

Variable Annuity Portfolios, et al.; Notice of Application

September 17, 1997.

AGENCY: Securities and Exchange Commission (the ''SEC'' or the ''Commission'').

ACTION: Notice of Application for an order under Section 6(c) of the Investment Company Act of 1940 (the ''1940 Act'') granting relief from the provisions of Sections 9(a), 13(a), 15(a) and 15(b) of the 1940 Act and Rules 6e–2(b)(15) and 6e–3(T)(b)(15) thereunder.

SUMMARY OF APPLICATION: Applicants seek exemptive relief to the extent necessary to permit shares of the Variable Annuity Portfolio (the ''Trust'') to be sold to and held by: (1) separate accounts (''Separate Accounts'') funding variable annuity and variable life insurance contracts issued by both affiliated and unaffiliated life insurance companies (''Participating Insurance Companies''); (2) qualified pension and retirement plans; and (3) subadvisers to certain series of the Trust.

APPLICANTS: Variable Annuity Portfolios and Citibank, N.A. (''Citibank'').

FILING DATE: The application was filed on June 5, 1997, and an amendment was filed on September 5, 1997.

HEARING OR NOTIFICATION OF HEARING: An order granting the application will be issued unless the Commission orders a hearing. Interested persons may request a hearing on this application by writing to the Secretary of the Secretary of the SEC and serving Applicants with a copy of the request, in person or by mail.

Hearing requests must be received by the Commission by 5:30 on October 14, 1997, and accompanied by proof or service on the Applicants in the form of an affidavit or, for lawyers, a certificate of service. Hearings requests should state the nature of the requester's interest, the reason for the request and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Secretary of the SEC.

ADDRESSES: Secretary, SEC, 450 Fifth Street, N.W., Washington, D.C. 20549. Applicants, Lea Anne Copenhefer, Esq., Bingham, Dana & Gould, LLP, 150 Federal Street, Boston, Massachusetts, 02110.

FOR FURTHER INFORMATION CONTACT: Megan L. Dunphy, Attorney, or Mark Amorosi, Branch Chief, Office of Insurance Products, Division of Investment Management, at (202) 942–0670.

SUPPLEMENTARY INFORMATION: Following is a summary of the application. The complete application is available for a fee from the Public Reference Branch of the SEC, 450 Fifth Street, N.W., Washington, D.C. 20549 (tel. (202) 942–8090).

Applicant's Representations

1. Trust is organized as a Massachusetts business trust and is registered under the 1940 Act as an open-end, management investment company. The Trust currently offers shares in five separate investment portfolios and may in the future offer shares in additional portfolios (collectively, the ''Portfolios'').

2. Citibank serves as investment adviser to each Portfolio. Responsibility for the day to day investment management of certain securities has been delegated to other investment advisers (the ''Subadvisers'').

3. Shares of the Portfolios will initially be offered only to Citicorp Life Variable Annuity Separate Account and First Citicorp Life Variable Annuity Separate Account, separate accounts of Citicorp Life Insurance Company and First Citicorp Life Insurance Company (the ''Citicorp Insurance Companies''). The Citicorp Insurance Companies are indirect subsidiaries of Citicorp, a bank holding company organized under the laws of Delaware. The Trust intends to offer shares of the Portfolios to separate accounts of other insurance companies, including insurance companies that are not affiliated with the Citicorp Insurance Companies, to serve as investment vehicles for various types of insurance products (''variable contracts'').

4. Each Portfolio may offer its shares to qualified pension or retirement plans (''Plans'') described in Treasury Regulation § 1.817–6(f)(3)(iii).

5. Each Portfolio may offer its shares to any Subadviser, or its affiliates, either directly or through a qualified pension or retirement plan. Any shares in a Portfolio purchased by a Subadviser will be automatically redeemed if and when the Subadviser's subadvisory agreement with that Portfolio terminates.

6. Citibank may act as an investment adviser to one or more of the Plans which purchases shares of the Portfolios. A Subadviser may act as an investment adviser to one or more Plans which may invest in the Portfolios.

Applicant's Legal Analysis

1. Applicants request that the Commission issues an order under Section 6(c) of the 1940 Act granting exemptions from Sections 9(a), 13(a), 15(a) and 15(b) thereof, and Rules 6e–2(b)(15) and 6e–3(T)(b)(15) thereunder, to the extent necessary to permit shares of the Portfolios or of any Other Portfolios to be offered and sold to, and held by: (1) both variable annuity separate accounts and variable life insurance separate accounts of the same life insurance company or of affiliated life insurance companies (''mixed funding''); (2) separate accounts of unaffiliated life insurance companies (including both variable annuity separate accounts and variable life insurance separate accounts) (''shared funding''); (3) trustees of Plans; and (4) Subadvisers to the Portfolios.

2. Section (6)(c) authorizes the Commission to grant exemptions from the provisions of the 1940 Act, and rules thereunder, if and to the extent that an exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the 1940 Act.

3. In connection with the funding of scheduled premium variable life insurance contracts issued through a separate account registered under the 1940 Act as a unit investment trust (the ''Trust Account''), Rule 6e–2(b)(15) provides exemptions from Sections 9(a), 13(a), 15(a) and 15(b) of the 1940 Act. The exemptions granted by Rule 6e–2(b)(15) are available only where the management investment company underlying the Trust Account (''underlying fund'') offers its shares ''*exclusively* to variable life insurance separate accounts of the life insurer, or of any affiliated life insurance company'' (emphasis added). Therefore, the relief granted by Rule 6e–2(b)(15) is not available if the scheduled premium variable life insurance separate account owns shares of an underlying fund that also offers its shares to a variable annuity or a flexible premium variable life insurance separate account of the same insurance company or an affiliated or unaffiliated life insurance company. Also, the relief granted by Rule 6e–2(b)(15) is not available if the scheduled premium variable life insurance separate account owns shares of an underlying fund that also offers its shares to Plans or to the Portfolios' Subadvisers.

4. In connection with the funding of flexible premium variable life insurance contracts issued through a Trust Account, Rule 6e–3(T)(b)(15) provides partial exemptions from Sections 9(a), 13(a), 15(a), and 15(b) of the 1940 Act. The exemptions granted by Rule 6e–3(T)(b)(15) are available only where the Trust Account's underlying fund offers its shares ''*exclusively* to separate accounts of the life insurer, or of any affiliated life insurance company, offering either scheduled or flexible contracts, or both; or which offer their shares to variable annuity separate accounts of the life insurer or of an affiliated life insurance company'' (emphasis added). Thus, Rule 6e–3(T) grants an exemption if the underlying fund engages in mixed funding, but not if it engages in shared funding or sells its shares to Plans or to the Portfolios' Subadvisers.

5. Applicants state that the current tax law permits the Portfolios or any Other Portfolios to increase its asset base through the sale of shares to Plans. Section 817(h) of the Internal Revenue Code of 1986, as amended (the ''Code''), imposes certain diversification standards on the underlying assets of variable contracts held in the Portfolios. The Code provides that such variable contracts shall not be treated as an annuity contract or life insurance contract for any period in which the underlying assets are not adequately diversified as prescribed by the Treasury regulations. To meet the diversification requirements, all of the beneficial interests in an underlying fund must be held by the segregated asset accounts of one or more insurance companies. Treas. Reg. § 1.817–5. The regulations do contain certain exceptions to this requirement, however, one of which allows shares in an investment company to be held by the trustee of a qualified pension or retirement plan without adversely affecting the ability of shares in the same investment company also to be held by the separate accounts of insurance companies in connection

with their variable contracts. Treas. Reg. § 1.817–5(f)(3)(iii).

6. The promulgation of Rules 6e–2 and 6e–3(T) preceded the issuance of these Treasury regulations. Applicants state that, given the then-current tax law, the sale of shares of the same investment company to both separate accounts and Plans could not have been envisioned at the time of the adoption of Rules 6e–2(b)(15) and 6e–3(T)(b)(15).

7. Section 9(a)(3) of the 1940 Act provides that it is unlawful for any company to serve as investment adviser to or principal underwriter for any registered open-end investment company if an affiliated person of that company is subject to a disqualification enumerated in Section 9(a)(1) or (2). Rules 6e–2(b)(15)(i) and (ii) and Rule 6e–3(T)(b)(15)(i) and (ii) provide partial exemptions from Section 9(a), subject to the limitations discussed above on mixed and shared funding. These exemptions limit the application of the eligibility restrictions to affiliated individuals or companies that directly participate in the management of the underlying management company.

8. Applicants assert that the partial relief granted in Rules 6e–2(b)(15) and 6e–3(T)(b)(15) from the requirements of Section 9, in effect, limits the amount of monitoring necessary to ensure compliance with Section 9 to that which is appropriate in light of the policy and purposes of Section 9. Applicants state that it is not necessary for the protection of investors or the purposes fairly intended by the policy and provisions of the 1940 Act to apply the provisions of Section 9(a) to the many individuals in an insurance company complex, most of whom will have no involvement in matters pertaining to investment companies in that organization. Applicants also assert that it is unnecessary to apply the restrictions of Section 9(a) to individuals in various unaffiliated insurance companies (or affiliated companies of Participating Insurance Companies) that may utilize a Portfolio as the funding medium for variable contracts.

9. Applicants maintain that there is no regulatory purpose in extending the Section 9(a) monitoring requirements because of mixed and shared funding and sales to Plans. The Participating Insurance Companies and participating Plans are not expected to play any role in the management or administration of the Portfolios. Those individuals who participate in the management or administration of the Portfolios will remain the same regardless of which separate accounts, insurance companies or Plans use the Portfolios. The increased monitoring costs would reduce the net rates of return realized by contract owners and Plan participants. In addition, since the Plans are not investment companies and will not be deemed affiliates by virtue of their shareholdings, no additional relief is required with respect to Plans.

10. Applicants further state that no regulatory purpose is served by extending the Section 9(a) monitoring requirements in the context of the Portfolios selling shares to the Subadvisers. Rules 6e–2 and 6e–3(T) provide relief from the eligibility restrictions of Section 9(a) only for officers, directors or employees of Participating Insurance Companies or their affiliates. Applicants state that it is not anticipated that any of the Subadvisers will be the Participating Insurance Companies or their affiliates, and if they were, the eligibility restrictions would apply to those who participate directly in the management or administration of the Portfolios. Applicants also maintain that the monitoring requirements should not extend to all officers, directors and employees of the Participating Insurance Companies and their affiliates simply because the Portfolios sell certain shares to the Shareadvisers. This monitoring would not benefit contract owners and Plan participants and would only increase costs, thereby reducing net rates of return.

11. Rules 6e–2(b)(15)(iii) and 6e–3(T)(b)(15)(iii) assume the existence of a ''pass-through voting'' requirement with respect to management investment company shares held by a separate account. Rules 6e–2(b)(15)(iii)(A) and 6e–3(T)(b)(15)(iii)(A)(*1*) provide that an insurance company may disregard the voting instructions of its contract owners in connection with the voting of shares of an underlying fund if such instructions would require such shares to be voted to cause such companies to make (or refrain from making) certain investments which would result in changes in the subclassification or investment objectives of such companies or to approve or disapprove any contract between a Portfolio and its investment adviser, when required to do so by an insurance regulatory authority, subject to certain requirements. Rules 6e–2(b)(15)(iii)(B) and 6e–3(T)(b)(15)(iii)(A)(*2*) provide that an insurance company may disregard the voting instructions of its contract owners if the contract owners initiate any change in the company's investment policies, principal underwriter, or any investment adviser, provided that disregarding such voting instructions is reasonable and complies with the other provisions of Rules 6e–2 and 6e–3(T).

12. Rule 6e-2 recognizes that a variable life insurance contract has important elements unique to insurance contracts; and is subject to extensive state regulation. Applicants assert that in adopting Rule 6e-2(b)(15)(iii), the Commission expressly recognized that state insurance regulators have authority, pursuant to state insurance laws or regulations, to disapprove or require change in investment policies, investment advisers or principal underwriters. The Commission also expressly recognized that state insurance regulators have authority to require an insurer to draw from its general account to cover costs imposed upon the insurer by a change approved by contract owners over the insurer's objection. The Commission therefore deemed such exemptions necessary ''to assure the solvency of the life insurer and performance of its contractual obligations by enabling an insurance regulatory authority or the life insurer to act when certain proposals reasonably could be expected to increase the risks undertaken by the life insurer.'' Applicants state that, in this respect, flexible premium variable life insurance contracts are identical to scheduled premium variable life insurance contracts; therefore, the corresponding provisions of Rule 6e-3(T) were adopted in recognition of the same factors.

13. Applicants further represent that the offer and sale of the Portfolio's shares to Plans will not have any impact on the relief requested in this regard. Shares of the Portfolios sold to Plans would be held by the Trustees of the Plans as required by Section 403(a) of the Employee Retirement Income Security Act of 1974 (''ERISA''). Section 403(a) also provides that the trustee(s) must have exclusive authority and discretion to manage and control the Plan with two exceptions: (a) when the Plan expressly provides that the trustee(s) is (are) subject to the direction of a named fiduciary who is not a trustee, in which case the trustee(s) is (are) subject to proper directions made in accordance with the terms of the Plan and not contrary to ERISA; and (b) when the authority to manage, acquire or dispose of assets of the Plan is delegated to one or more investment managers pursuant to Section 402(c)(3) of ERISA. Unless one of the two exceptions stated in Section 403(a) applies, Plan trustees have the exclusive authority and responsibility for voting proxies. Where a named fiduciary appoints an investment manager, the investment manager has the responsibility to vote the shares held unless the right to vote

such shares is reserved to the trustees or to the named fiduciary. In any event, ERISA does not require pass-through voting to the participants in Plans. Accordingly, Applicants note that, unlike the case with insurance company separate accounts, the issue of the resolution of material irreconcilable conflicts with respect to voting is not present with Plans because they are not entitled to pass-through voting privileges.

14. Some Plans, however, may provide participants with the right to give voting instructions. However, Applicants note that there is no reason to believe that participants in Plans generally, or those in a particular Plan, either as a single group or in combination with other Plans, would vote in a manner that would disadvantage contract owners. Therefore, Applicants submit that the purchase of Portfolio shares by Plans that provide voting rights to their participants does not present any complications not otherwise occasioned by mixed and shared funding.

15. Applicants state that the prohibitions on mixed and shared funding may reflect some concern with possible divergent interests among different classes of investors. Applicants submit that shared funding does not present any issues that do not already exist where a single insurance company is licensed to do business in several states. In this regard, Applicants not that a particular state insurance regulatory body could require action that is inconsistent with the requirements of other states in which the insurance company offers its policies. Accordingly, Applicants submit that the fact that different insurers may be domiciled in different states does not create a significantly different or enlarged problem.

16. Applicants submit that shared funding by unaffiliated insurers, in this respect, is no different than the use of the same investment company as the funding vehicle for affiliated insurers, which Rules 6e–2(b)(15) and 6e–3(T)(b)(15) permit. Affiliated insurers may be domiciled in different states and be subject to differing state law requirements. Applicants state that affiliation does not reduce the potential, if any exists, for differences in state regulatory requirements. In any event, the conditions discussed below are designed to safeguard against, and provide procedures for resolving, any adverse effects that differences among state regulatory requirements may produce.

17. Rule 6e–2(b)(15) and 6e–3(T)(b)(15) give the insurance company the right to disregard the voting instructions of the contract owners. This right does not raise any issues different from those raised by the authority of state insurance administrators over separate accounts. Affiliation does not eliminate the potential for divergent judgments as to the advisability or legality of a change in investment policies, principle underwriter, or investment adviser initiated by contract owners. The potential for disagreement is limited by the requirements in Rules 6e–2 and 6e–3(T) that the insurance company's disregard of voting instruction be reasonable and based on specific good-faith determinations.

18. A particular insurer's disregard of voting instructions nevertheless could conflict with the majority of contract owner voting instructions. If the insurer's judgment represents a minority position or would preclude a majority vote, then the insurer may be required, at the election of the Portfolio, to withdraw its separate account's investment in such Portfolio, and no charge or penalty will be imposed as a result of such withdrawal.

19. Applicants submit that investment by the Plans in any of the Portfolios will present no conflict. Applicants assert that the likelihood that voting instructions of insurance company separate account holders will be disregarded or the possible withdrawal referred to immediately above is extremely remote and this possibility will be known, through prospectus disclosure, to any Plan choosing to invest in the Portfolios. Moreover, Applicants state that even if a material irreconcilable conflict involving Plans arises, the Plans may simply redeem their shares and make alternative investments.

20. Applicants submit that investments by the Subadvisers will similarly present no conflict. Applicants state that each Subadviser will agree to vote its shares of a Portfolio in the same proportion as all contract owners having voting rights with respect to that Portfolio or in such other manner as may be required by the Commission or its staff.

21. Applicants state that there is no reason why the investment policies of any Portfolio would or should be materially different from what those policies would or should be if any such Portfolio funded only variable annuity contracts or variable life insurance products, whether flexible premium or scheduled premium contracts. In this regard, Applicants note that each type of variable contract is designed as a long-term investment program, and that Plans also have long-term investment goals. Moreover, Applicants submit that the Portfolios will be managed to attempt to achieve their investment objectives, and not to favor or disfavor any particular Participating Insurance Company or type of insurance product.

22. Applicants further note that Section 817(h) imposes certain diversification standards on the underlying assets of variable annuity contracts and variable life insurance contracts held in the portfolios of management investment companies. Treasury Regulation 1.817–5(f)(3)(iii), which established diversification requirements for such portfolios, specifically permits ''qualified pension or retirement plans'' and insurance company separate accounts to share the same underlying investment company. Therefore, Applicants have concluded that neither the Code, nor the Treasury Regulations, nor the revenue rulings thereunder present any inherent conflicts of interest if Plans, variable annuity separate account and variable life insurance separate accounts all invest in the same management investment company.

23. Applicants note that while there are differences in the manner in which distributions are taxed for variable annuity contracts, variable life insurance contracts and Plans, these tax consequences do not raise any conflicts of interest. When distributions are to be made, and the Separate Account or the Plan is unable to net purchase payments to make the distributions, the Separate Account or the Plan will redeem shares of the Portfolios at their respective net asset value. The Plans will then make distributions in accordance with the terms of the Plan, and a Participating Insurance Company will make distributions in accordance with the terms of the variable contract.

24. Applicants state that it is possible to provide an equitable means of giving voting rights to contract owners and to Plans. Applicants represent that the Portfolios will inform each shareholder, including each variable contract and each Plan, of its respective share of ownership in the respective Portfolio. Each Participating Insurance Company will then solicit voting instructions in accordance with the ''pass-through'' voting requirement.

25. Applicants submit that the ability of the Portfolios to sell their respective shares directly to Plans does not create a ''senior security,'' as that term is defined under Section 18(g) of the 1940 Act, with respect to any contract owner as opposed to a participant under a Plan. Regardless of the rights and benefits of participants and contract owners under the respective Plans and

contracts, the Plans and the Separate Accounts have rights only with respect to their share of the Portfolios. Such shares may be redeemed only at net asset value. No shareholder of any of the Portfolios has any preference over any other shareholder with respect to distribution of assets or payment of dividends.

26. Finally, Applicants state that there are no conflicts between contract owners and participants under the Plans with respect to the state insurance commissioners' powers over investment objectives. The basic premise of shareholder voting is that not all shareholders may agree with a particular proposal. The state insurance commissioners have been given the veto power in recognition of the fact that insurance companies cannot simply redeem shares of one underlying fund held by their Separate Accounts and invest the proceeds in another underlying fund. Complex and time-consuming transactions must be undertaken to accomplish such redemptions and transfers. Conversely, trustees of Plans may redeem shares of an investment vehicle, and reinvest the proceeds in another investment vehicle without the same regulatory impediments; most Plans may even hold cash pending suitable investment. Based on the foregoing, Applicants represent that should issues arise where the interests of contract owners and the interest of Plans conflict, the issues can be resolved almost immediately because trustees of the Plans can redeem shares out of the Portfolios independently.

27. Applicants submit that mixed and shared funding should provide benefits to contract owners by eliminating a significant portion of the costs of establishing and administering separate funds. Participating Insurance Companies will benefit not only from the investment and administrative expertise of the Portfolios' investment adviser, but also from the cost efficiencies and investment flexibility afforded by a large pool of funds. Mixed and shared funding also would permit a greater amount of assets available for investment by the Portfolios thereby promoting economies of scale, by permitting increased safety through greater diversification or by making the addition of Portfolios more feasible. Therefore, making the Portfolio available for mixed and shared funding may encourage more insurance companies to offer variable contracts, and this should result in increased competition with respect to both variable contract design and pricing, which can be expected to result in more product variation and lower charges.

28. Applicants assert that there is no significant legal impediment to permitting mixed and shared funding. Separate accounts organized as unit investment trusts historically have been employed to accumulate shares of mutual funds which have not been affiliated with the depositor or sponsor of the separate account. Applicants do not believe that mixed and shared funding, and sales to qualified Plans and Subadvisers, will have any adverse federal income tax consequences.

Applicants' Conditions

Applicants have consented to the following conditions:

1. A majority of the Board of Trustees of the Trust (the ''Board'') shall consist of persons who are not ''interested persons'' of the Trust, as defined by Section 2(a)(19) of the 1940 Act and the rules thereunder, and as modified by any applicable orders of the Commission, except that if this condition is not met by reason of the death, disqualification, or bona fide resignation of any trustee or trustees, then the operation of this condition shall be suspended: (a) for a period of 45 days, if the vacancy or vacancies may be filled by the Board; (b) for a period of 60 days, if a vote of shareholders is required to fill the vacancy or vacancies; or (c) for such longer period as the Commission may prescribe by order upon application.

2. The Board will monitor the Trust for the existence of any material irreconcilable conflict among the interests of the contract owners of all Separate Accounts and of the Plan participants investing in any Portfolio. A material irreconcilable conflict may arise for a variety of reasons, including: (a) an action by any state insurance regulatory authority; (b) a change in applicable federal or state insurance, tax, pension or securities laws or regulations, or a public ruling, private letter ruling, no-action or interpretative letter, or any similar action by insurance, tax, pension, or securities regulatory authorities; (c) an administrative or judicial decision in any relevant proceeding; (d) the manner in which the investments of any Portfolio are being managed; (e) a difference in voting instructions given by variable annuity contract owners and variable life contract owners and trustees of Plans; (f) a decision by a Participating Insurance Company to disregard the voting instructions of contract owners; or (g) if applicable, a decision by a Plan to disregard voting instructions of Plan participants.

3. The Participating Insurance Companies, the investment adviser and any other investment adviser to the Trust, and any Plan that executes a fund participation agreement upon becoming an owner of 10% or more of the assets of the Trust (the ''Participants'') will report any potential or existing conflicts to the Board. Participants will be obligated to assist the Board in carrying out its responsibilities by providing the Board with all information reasonably necessary for the Board to consider any issues raised. This responsibility includes, but is not limited to, an obligation by each Participating Insurance Company to inform the Board whenever contract owner voting instructions are disregarded and, if pass-through voting is applicable, an obligation by Citibank and each Plan to inform the Board whenever it is determined to disregard Plan participant voting instructions. These responsibilities will be contractual obligations of all Participating Insurance Companies and Plans investing in a Portfolio under their agreements governing participation therein. Responsibilities will be carried out with a view only to the interest of contract owners and Plan participants.

4. If a majority of the Board, or a majority of the disinterested members of the Board, determine that a material irreconcilable conflict exists, the relevant Participating Insurance Companies and Plans shall, at their expense and to the extent reasonably practicable (as determined by a majority of the disinterested members of the Board), take whatever steps are necessary to remedy or eliminate the material irreconcilable conflict, up to and including: (a) withdrawing the assets allocable to some or all of the Separate Accounts from a Portfolio and reinvesting such assets in a different investment medium (including another Portfolio, if any) or submitting the question whether such segregation should be implemented to a vote of all affected contract owners and, as appropriate, segregating the assets of any appropriate group (*i.e.*, annuity contract owners, life insurance contract owners, or variable contract owners of one or more Participating Insurance Companies) that votes in favor of such segregation, or offering to the affected variable contract owners the option of making such a change; and (b) establishing a new registered management investment company or managed separate account. If a material irreconcilable conflict arises because of a Participating Insurance Company's decision to disregard contract owner voting instructions, and the decision represents a minority position or would

preclude a majority vote, the Participating Insurance Company may be required, at the election of the Portfolio, to withdraw its Separate Account's investment therein, and no charge or penalty will be imposed as a result of such withdrawal. If a material irreconcilable conflict arises because of a Plan's decision to disregard Plan participant voting instructions, if applicable, and that decision represents a minority position or would preclude a majority vote, the Plan may be required, at the election of the Portfolio, to withdraw its investment therein and no charge or penalty will be imposed as a result of such withdrawal. The responsibility to take remedial action in the event of a Board determination of a material irreconcilable conflict and to bear the cost of such remedial action shall be a contractual obligation of all Participating Insurance Companies and Plans under their agreements governing their participation in a Portfolio. Responsibilities will be carried out with a view only to the interests of contract owners and Plan participants.

For purposes of condition 4, a majority of the disinterested members of the Board shall determine whether or not any proposed action adequately remedies any irreconcilable material conflict, but in no event will the Trust or the investment adviser be required to establish a new funding medium for any variable contract. No Participating Insurance Company shall be required by condition 4 to establish a new funding medium for any variable contract if an offer to do so has been declined by a vote of a majority of the contract owners materially affected by the material irreconcilable conflict. Further, no Plan shall be required by condition 4 to establish a new funding medium for such Plan if (a) a majority of Plan participants materially and adversely affected by the material irreconcilable conflict vote to decline such offer, or (b) pursuant to governing Plan documents and applicable law, the Plan makes such decision without a vote by Plan participants.

5. The determination by the Board of the existence of an irreconcilable material conflict and its implications shall be made known promptly in writing to all Participants.

6. Participating Insurance Companies will provide pass-through voting privileges to all contract owners so long as the Commission continues to interpret the 1940 Act as requiring pass-through voting privileges for variable contract owners. Accordingly, the Participating Insurance Companies will vote shares of each Portfolio held in their Separate Accounts in a manner consistent with timely voting instructions received from contract owners. Each Participating Insurance Company also will vote shares of each Portfolio held in its Separate Accounts for which no timely voting instructions from contract owners are received, as well as shares it owns, in the same proportion as those shares for which voting instructions are received. Participating Insurance Companies shall be responsible for assuring that each of their Separate Accounts participating in a Portfolio calculates voting privileges in a manner consistent with other Participating Insurance Companies. Each Plan will vote as required by applicable law and governing Plan documents. The obligation to calculate voting privileges in a manner consistent with all other Separate Accounts investing in the Trust will be a contractual obligation of all Participating Insurance Companies under their agreements governing their participation in the Trust.

7. As long as the Commission continues to interpret the 1940 Act as requiring pass-through voting privileges for contract owners, each Subadviser will vote its shares of any Portfolio in the same proportion as all contract owners having voting rights with respect to that Portfolio; provided, however, that the Subadviser shall vote its shares in such other manner as may be required by the Commission or its staff.

8. Each Portfolio will notify all Participating Insurance Companies that separate account prospectus disclosure regarding potential risks of mixed and shared funding may be appropriate. Each Portfolio shall disclose in its prospectus that: (a) its shares may be offered to Separate Accounts that fund both annuity and life insurance contracts of affiliated and unaffiliated Participating Insurance Companies and variable life insurance contracts offered by various insurance companies and for qualified pension and retirement plans; (b) due to differences of tax treatment or other considerations, the interests of various contract owners participating in the Portfolios and the interests of Plans in the Portfolios might at some time be in conflict; and (c) the Board will monitor the Trust for any material conflicts and determine what action, if any, should be taken.

9. All reports received by the Board regarding potential or existing conflicts, and all Board action with respect to determining the existence of a conflict, notifying Participants of a conflict, and determining whether any proposed action adequately remedies a conflict, will be properly recorded in the minutes of the Board or other appropriate records, and such minutes or other records shall be made available to the Commission upon request.

10. If and to the extent that Rules 6e–2 and 6e–3(T) are amended, or Rule 6e–3 is adopted, to provide exemptive relief from any provision of the 1940 Act or the rules thereunder with respect to mixed and shared funding on terms and conditions materially different from any exemptions granted in the order requested, then each Portfolio, and/or the Participating Insurance Companies, as appropriate, shall take such steps as may be necessary to comply with Rule 6e–2 and 6e–3(T), as amended, and Rule 6e–3, as adopted, to the extent such rules are applicable.

11. The Trust will comply with all provisions of the 1940 Act requiring voting by shareholders (which, for these purposes, shall be the persons having a voting interest in the shares of the Trust) and, in particular, the Trust will either provide for annual meetings (except insofar as the Commission may interpret Section 16 not to require such meetings) or comply with Section 16(c) of the 1940 Act (although, as noted above, the Trust is a Massachusetts business trust which was organized in 1996 under a Declaration of Trust which provides for the election of Trustees by shareholders except in certain circumstances, and as such is not one of the trusts described in Section 16(c)) as well as with Section 16(a) and, if and when applicable, Section 16(b). Further, the Trust will act in accordance with the Commission's interpretation of the requirements of Section 16(a) with respect to periodic elections of directors (or trustees) and with whatever rules the Commission may promulgate with respect thereto.

12. The Participants, and where appropriate the investment adviser and any other investment adviser to the Trust, at least annually, shall submit to the Board such reports, materials, or data as the Board reasonably may request so that it may fully carry out the obligations imposed upon it by the conditions contained in the application and said reports, materials and data shall be submitted more frequently if deemed appropriate by the Board. The obligations of the Participants to provide these reports, materials, and data to the Board, when it so reasonably requests, shall be a contractual obligation of all Participants under their agreements governing their participating in each Portfolio.

13. If a Plan should ever become a holder of 10% or more of the assets of a Portfolio, such Plan will execute a participation agreement with the Trust. A Plan will execute an application

containing an acknowledgment of this condition upon such Plan's initial purchase of the shares of any Portfolio.

Conclusion

For the reasons stated above, Applicants assert that the requested exemptions from Sections 9(a), 13(a), 15(a) and 15(b) of the 1940 Act and Rules 6e–2(b)(15) and 6e–3(T)(b)(15) thereunder are appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provision of the 1940 Act.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Margaret H. McFarland,

Deputy Secretary.

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–39084; File No. SR–MSRB–97–5]

Self-Regulatory Organizations; Notice of Filing and Immediate Effectiveness of Proposed Rule Change by the Municipal Securities Rulemaking Board Relating to Interpretation of Rule G–37 on Political Contributions and Prohibitions on Municipal Securities Business

September 16, 1997.

On September 9, 1997, the Municipal Securities Rulemaking Board (''Board'' or ''MSRB'') filed with the Securities and Exchange Commission (''Commission'' or ''SEC'') a proposed rule change (File No. SR–MSRB–97–5), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''), 15 U.S.C. 78s(b)(1), and Rule 19b–4 thereunder. The proposed rule change is described in Items I, II, and III below, which Items have been prepared by the Board. The Board has designated this proposal as constituting a stated policy, practice, or interpretation with respect to the meaning, administration, or enforcement of an existing rule of the Board under Section 19(b)(3)(A) of the Act, which renders the proposal effective upon receipt of this filing by the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Board is filing herewith a notice of interpretation concerning rule G–37 on political contributions and prohibitions on municipal securities business (hereafter referred to as ''the proposed rule change''). The proposed rule change is as follows:

Rule G–37: Political Contributions and Prohibitions on Municipal Securities Business

Transition and Inaugural Expenses

1. Q: May a municipal finance professional who is entitled to vote for an issuer official make contributions to pay for such official's transition or inaugural expenses without causing a prohibition on municipal securities business with the issuer?

A: Yes, under certain conditions. The de minimis exception allows a municipal finance professional to contribute up to $250 per candidate per election if the municipal finance professional is entitled to vote that issuer official. The de minimis exception is keyed to an election cycle; therefore, if a municipal finance professional contributed $250 to the general election of an issuer official, the municipal finance professional would not be able to make any contributions to pay for transition or inaugural expenses without causing a prohibition on municipal securities business with the issuer. If a municipal finance professional made no contributions to an issuer official prior to the election, then the municipal finance professional may, if entitled to vote for the candidate, contribute up to $250 to pay for transition or inaugural expenses and payment of debt incurred in connection with the election without causing a prohibition on municipal securities business.

Definition of Issuer Official

2. Q: An incumbent was seeking re-election as an issuer official but she lost the election. She is now soliciting money to pay for the debt incurred in connection with this election. Would there be a prohibition on engaging in municipal securities business with the issuer if a dealer or a municipal finance professional provides money for the payment of this debt?

A: No, under certain conditions. If the incumbent is out of office at the time she is soliciting money to pay for the election debt, then she is no longer considered to be within the definition of ''official of an isssuer'' and any monies given for the payment of debt incurred in connection with the election in this instance is not subject to rule G–37. If the incumbent still holds her issuer official position at the time she is soliciting money to pay for the election debt, then, if a municipal finance professional contributed $250 to her during the general election, the municipal finance professional would not be able to make any contributions for the payment of debt without causing a prohibition on municipal securities business with the issuer. If a municipal finance professional made no contributions to the incumbent prior to the election, then the municipal finance professional may, if entitled to vote for the candidate, contribute up to $250 for the payment of debt incurred in connection with the election while the incumbent is still in office without causing a prohibition on municipal securities business. A dealer may not contribute any monies towards the payment of debt while the incumbent is still in office without causing a prohibition on municipal securities business with the issuer.

Definitions of Municipal Finance Professional and Executive Officer

3. Q: In making the determination of which associated persons of a dealer meet the definitions of municipal finance professional and executive officer, is it correct to designate all the executives of the dealer (e.g., President, Executive Vice Presidents) under the category of executive officers?

A: No. In making the determination of whether someone is a municipal finance professional or executive officer, one must review the activities of the individual and not his or her title.

Rule G–37(g)(iv) defines the term ''municipal finance professional'' as:

(A) any associated person primarily engaged in municipal securities representative activities, as defined in rule G–3(a)(i);

(B) any associated person who solicits municipal securities business, as defined paragraph (vii);

(C) any associated person who is both (i) a municipal securities principal or a municipal securities sales principal and (ii) a supervisor of any persons described in subparagraphs (A) or (B);

(D) any associated person who is a supervisor of any person described in subparagraph (C) up through and including, in the case of a broker, dealer or municipal securities dealer other than a bank dealer, the Chief Executive Officer or similarly situated official and, in the case of a bank dealer, the officer or officers designated by the board of directors of the bank as responsible for the day-to-day conduct of the bank's municipal securities dealer activities, as required pursuant to rule G–1(a); or

(E) any associated person who is a member of the broker, dealer or municipal securities dealer (or, in the case of a bank dealer, the separately identifiable department or division of the bank, as defined in rule G–1) executive or management committee or

similarly situated officials, if any; provided, however, that, if the only associated persons meeting the definition of municipal finance professional are those described in this subparagraph (E), the broker, dealer or municipal securities dealer shall be deemed to have no municipal finance professionals.

Rule G–37(g)(v) defines the term ''executive officer'' as:

An associated person in charge of a principal business unit, division or function or any other person who performs similar policy making functions for the broker, dealer or municipal securities dealer (or, in the case of a bank dealer, the separately identifiable department or division of the bank, as defined in rule G–1), but does not include any municipal finance professional, as defined in paragraph (iv) of this section (g); provided, however, that, if no associated person of the broker, dealer or municipal securities dealer meets the definition of municipal finance professional, the broker, dealer or municipal securities dealer shall be deemed to have no executive officers. [emphasis added].

Dealers should first review the activities of their associated persons to determine whether they are municipal finance professionals, and then once that list of individuals has been established, conduct a review of the remaining associated persons to determine whether they are executive officers. Dealers should pay close attention to those associated persons who are soliciting municipal securities business and, thus, will be considered municipal finance professionals. The Board has previously stated that solicitation activities may include, but are not limited to, responding to issuer Requests for Proposals, making presentations of public finance and/or municipal marketing capabilities to issuer officials, and engaging in other activities calculated to appeal to issuer officials for municipal securities business, or which effectively do so. (See ''Additional Rule G–37 Questions & Answers,'' MSRB Reports, Vol. 14, No. 5 (December 1994) at 8).

Reporting by Syndicate Members

4. Q: Rule G–37(e) requires, among other things, that dealers submit information to the Board on Form G–37/G–38 about the municipal securities business in which they engaged. Is information about the municipal securities business engaged in required to be submitted by all syndicate and selling group members, or is it only the responsibility of the manager(s) to submit such information on behalf of the syndicate?

A: All manager(s) and syndicate members (excluding selling group members) must separately report the municipal securities business in which they engaged.

* * * * *

II. Self-Regulatory Organization's Statement of the Purpose of and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Board included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The texts of these statements may be examined at the places specified in Item IV below. The Board has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

On April 7, 1994, the Commission approved Board rule G–37, concerning political contributions and prohibitions on municipal securities business.[1] Since that time, the Board has received numerous inquiries concerning the application of the rule. In order to assist the municipal securities industry and, in particular, brokers, dealers and municipal securities dealers in understanding and complying with the provisions of the rule, the Board published seven prior notices of interpretation which set forth, in question-and-answer format, general guidance on rule G–37.[2] In prior filings with the Commission, the Board stated that it will continue to monitor the application of rule G–37, and, from to time, will publish additional notices of interpretations, as necessary.[3] In light of questions recently received from market participants concerning the applicability of the rule to transition and inaugural expenses, the definition of issuer official, the definitions of municipal finance professional and executive officer, and reporting by syndicate members, the Board has determined that it is necessary to provide further guidance to the municipal industry. Accordingly, the Board is publishing this eighth set of questions and answers.

The Board believes the proposed rule change is consistent with Section 15B(b)(2)(C) of the Act.[4]

B. Self-Regulatory Organization's Statement on Burden on Competition

The Board does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act, because it would apply equally to all brokers, dealers and municipal securities dealers.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Board has designated this proposal as constituting a stated policy, practice, or interpretation with respect to the meaning, administration, or enforcement of an existing rule of the Board under Section 19(b)(3)(A) of the Act, which renders the proposal effective upon receipt of this filing by the Commission.

At any time within sixty days of the filing of this proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purpose of the Act.

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[1] Securities Exchange Act Release No. 33868 (April 7, 1994), 59 FR 17621 (April 13, 1994). The rule applies to contributions made on and after April 25, 1994.

[2] *See* Securities Exchange Act Release No. 34161 (June 6, 1994), 59 FR 30379 (June 14, 1994); Securities Act Release No. 34603 (Aug. 25, 1994), 59 FR 45049 (Aug. 31, 1994); Securities Exchange Act Release No. 35128 (Dec. 20, 1994), 59 FR 66989 (Dec. 28, 1994); Securities Exchange Act Release No. 35544 (March 28, 1995), 60 FR 16896 (April 3, 1995); Securities Exchange Act Release No. 35879 (June 21, 1995), 60 FR 33447 (June 28, 1995); Securities Exchange Act Release No. 36857 (Feb. 16, 1996), 61 FR 7034 (Feb. 23, 1996); Securities Exchange Act Release No. 37675 (Sept. 12, 1996), 61 FR 49368 (Sept. 18, 1996).

See MSRB Reports, Vol. 14, No. 3 (June 1994) at 11–16; Vol. 14, No. 4 (August 1994) at 27–31; Vol. 14, No. 5 (December 1994) at 8; Vol. 15, No. 1 (April 1995) at 21; Vol. 15, No. 2 (July 1995) at 3–4; Vol. 16, No. 1 (January 1996) at 31; and Vol. 16, No. 3 (September 1996) at 35–36. See also CCH Manual paragraph 3681.

[3] *See* Securities Exchange Act Release No. 34161 (June 6, 1994), 59 FR 30379 (June 13, 1994) (SR–MSRB–94–06) and Securities Exchange Act Release No. 34603 (August 25, 1994), 59 FR 45049 (August 31, 1994) (SR–MSRB–94–15).

[4] Section 15B(b)(2)(C) states in pertinent part that the rules of the Board ''shall be 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 municipal securities, to remove impediments to and perfect the mechanism of a free and open market in municipal securities, and, in general, to protect investors and the public interest.''

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, N.W., Washington, D.C. 20549. Copies of the submissions, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be with held from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of the filing will also be available for inspection and copying at the Board's principal offices. All submissions should refer to File No. SR–MSRB–97–5 and should be submitted by October 14, 1997.

For the Commission by the Division of Market Regulation, pursuant to delegated authority.[5]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 97–25217 Filed 9–22–97; 8:45 am]

BILLING CODE 8010–01–M

SECURITIES AND EXCHANGE COMMISSION

[Release No: 34–39082; File No. SR–NASD–97–51]

Self-Regulatory Organizations; National Association of Securities Dealers, Inc.; Notice of Filing of Proposed Rule Change Regarding the Transfer of Securities of Issuers Listed on the Nasdaq Stock Market That Are Held Pursuant to a Direct Registration Program

September 16, 1997.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] notice is hereby given that on July 16, 1997, 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 primarily by Nasdaq. The Commission is publishing this notice to solicit comments from interested persons on the proposed rule change.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Nasdaq is proposing to amend Rules 4200, 4310, 4320, and 4460 of the National Association of Securities Dealers, Inc. (''NASD'') to require Nasdaq issuers that elect to offer a direct registration program to shareholders to participate in an electronic link, either directly or through the issuer's transfer agent, with a securities depository registered under Section 17A of the Act.[2]

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, Nasdaq included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. Nasdaq has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of such statements.

(A) Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

The purpose of the proposed rule change is to facilitate the clearance and settlement of securities held in book-entry form in the context of recent developments concerning the direct registration concept. Over the past twelve years, regulators, representatives of private industry, and the transfer agent community have worked together to explore alternatives to maintaining ownership interest in securities without certificates. In 1990, the Commission held a Roundtable on Clearance and Settlement to discuss recommendations of the Group of Thirty U.S. Working Committee which, among other things, discussed ways in which investors could obtain benefits of a direct registration system (''DRS''). The Commission has been promoting the DRS concept, and in 1994 requested that the industry work to develop DRS in order to provide investors with additional options to holding their securities in certificate form.[3] A basic structure for DRS has been developed and agreed to by a joint committee of representatives of the Securities Industry Association, the Securities Transfer Association, the Corporate Transfer Agents Association, and registered securities depositories.

The concept of DRS is modeled after systems used in dividend reinvestment and stock purchase programs, which are currently offered by many issuers or transfer agents. It is being considered by issuers in connection with the move to a faster settlement cycle and reflects investor trends away from physical certificates. DRS promotes investor choice, while encouraging efficient clearance and settlement procedures. Specifically, DRS offers shareholders the ability to: (1) receive an account statement instead of a negotiable certificate; (2) get a certificate upon demand; and (3) direct the book-entry transfer of the underlying position to a broker-dealer upon request.

A key component of DRS has been the initiation of an electronic communication system linking issuers or their transfer agents with registered securities depositories. Assuming an issuer and its transfer agent elect to offer direct registration services, this link would permit a broker-dealer to deliver to a transfer agent a customer's request that the securities be registered on the books of the issuer in book-entry form. Such a system also will allow the transfer agent to send an electronic acknowledgment to the broker-dealer that the securities have been registered in the customer's name on the books of the issuer in book-entry form. thus, DRS helps promote efficiencies in the prompt and accurate clearance and settlement of securities transactions by providing individual investors that do not want to have broker-dealers hold their securities for them in street name the option of holding in book-entry form on the books of the issuers and most importantly, the ability to subsequently have such positions transferred electronically to banks or broker-dealers in connection with the sales or disposition of the securities.

Recently, The Depository Trust Co. (''DTC'') received Commission approval to establish the procedures and the necessary electronic link to implement DRS. Under this system, an investor will have the right at any time to transfer its DRS position from the issuer to a broker-dealer through the facilities of DTC in order to sell or pledge the security. Alternatively, an investor will have the right at any time to request a certificate. Under DTC's rule change, to participate in DRS, a transfer agent

[5] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78q–1.

[3] Securities Exchange Act Release No. 35038 (December 1, 1994), 59 FR 63652 (Concept Release discussing direct registration).

would need to become a ''DRS Limited Participant'' at DTC.[4]

Therefore, Nasdaq is proposing to amend its rules to establish a qualification requirement for all securities to be included in Nasdaq that if the issuer establishes a direct registration program it shall participate in an electronic link with a securities depository in order to facilitate the electronic transfer of interests held pursuant to the direct registration program. This link is permitted by the proposed rule to be direct or through the issuer's transfer agent.

Nasdaq believes that the proposed rule change is consistent with the provisions of Section 15A(b)(6) of the Act[5] in that it fosters cooperation and coordination with persons engaged in the clearing and settling of transactions in securities, and in general, protects investors and the public interest. The proposed rule change ensures that there is a quick and efficient means for financial intermediaries, such as broker-dealers and banks, to transfer these interests on behalf of shareholders. In addition, Nasdaq believes the proposed rule change is consistent with Section 17A which sets forth Congress' findings that the prompt and accurate clearance and settlement of securities transactions are necessary for the protection of investors. In particular, the proposed rule change is consistent with Section 17A(a)(1) in that it takes advantage of new date processing and communications techniques and linked or coordinated facilities, and thus provides for more efficient, effective, and safe procedures for the clearance and settlement of securities transactions.

[4] According to DTC, a party wishing to open a Limited Participant account must (1) be registered as a transfer agent with the SEC; (2) participate as a transfer agent in DTC's Fast Automated Securities Transfer (''FAST'') program; (3) provide Direct Mail Service on transfers; and (4) communicate with DTC through a computer-to-computer interface using DTC's CCF platforms.

DTC charges a DRS Limited Participant an account holder fee of $225 per month regardless of the number of DRS eligible issues for which the Limited Participant is participating. In addition, DTC charges $.045 per transaction. DTC participants also will be charged $0.45 per transaction. In addition, when a DTC participant instructs a transfer agent to establish a DRS account for a shareholder and the transfer agent subsequently mails a transaction advice to the shareholder confirming that such an account has been established at the transfer agent, the transfer agent's fee of $0.55 for mailing and handling the DRS transactions advice will be charged to the DTC participant directly by DTC. This fee is periodically remitted to the transfer agent.

[5] 15 U.S.C. 78o–3.

(B) Self-Regulatory Organization's Statement on Burden on Competition

Nasdaq does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act, as amended.

(C) Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within thirty-five days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to ninety days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which Nasdaq consents, the Commission will:

(A) by order approve such proposed rule change or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, N.W., Washington, D.C. 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Section, 450 Fifth Street, N.W., Washington, D.C. 20549. Copies of such filing also will be available for inspection and copying at the principal office of Nasdaq. All submissions should refer to File No. SR–NASD–97–51 and should be submitted by October 14, 1997.

For the Commission by the Division of Market Regulation, pursuant to delegated authority.[6]

[6] 17 CFR 200.30–3(a)(12).

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 97–25216 Filed 9–22–97; 8:45 am]

BILLING CODE 8010–01–M

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

1997–98 Allocations of the Tariff-Rate Quotas for Raw Cane Sugar, Refined Sugar, and Sugar Containing Products

AGENCY: Office of the United States Trade Representative.

ACTION: Notice.

SUMMARY: The Office of the United States Trade Representative (USTR) is providing notice of the country-by-country allocations of the in-quota quantity of the tariff-rate quotas for imported raw cane sugar, refined sugar, and sugar containing products for the period that begins October 1, 1997 and ends September 30, 1998.

EFFECTIVE DATE: October 1, 1997.

ADDRESSES: Inquiries may be mailed or delivered to Audrae Erickson, Senior Economist, Office of Agricultural Affairs (Room 421), Office of the United States Trade Representative, 600 17th Street, NW., Washington, DC 20508.

FOR FURTHER INFORMATION CONTACT: Audrae Erickson, Office of Agricultural Affairs, 202–395–6127.

SUPPLEMENTARY INFORMATION: Pursuant to Additional U.S. Note 5 to chapter 17 of the Harmonized Tariff Schedule of the United States (HTS), the United States maintains tariff-rate quotas for imports of raw cane and refined sugar. Pursuant to additional U.S. Note 8 to Chapter 17 of the Harmonized Tariff Schedule, the United States also maintains a tariff-rate quota for certain sugar-containing products.

Section 404(d)(3) of the Uruguay Round Agreements Act (19 U.S.C. 3601(d)(3)) authorizes the President to allocate the in-quota quantity of a tariff-rate quota for any agricultural product among supplying countries or customs areas. The President delegated this authority to the United States Trade Representative under paragraph (3) of Presidential Proclamation No. 6763 (60 FR 1007).

The in-quota quantity of the raw cane tariff-rate quota for the period October 1, 1997–September 30, 1998, has been established by the Secretary of Agriculture at 1,200,000 metric tons, raw value (1,322,773 short tons). This quantity is being allocated to the following countries in metric tons, raw value:

Country	FY 1998 allocation
Argentina	48,101
Australia	92,846
Barbados	7,830
Belize	12,305
Bolivia	8,949
Brazil	162,201
Columbia	26,847
Congo	7,258
Cote d'Ivoire	7,258
Costa Rica	16,779
Dominican Republic	196,878
Ecuador	12,305
El Salvador	29,084
Fiji	10,068
Gabon	7,258
Guatemala	53,694
Guyana	13,424
Haiti	7,258
Honduras	11,186
India	8,949
Jamaica	12,305
Madagascar	7,258
Malawi	11,186
Mauritius	13,424
Mexico	25,000
Mozambique	14,542
Nicaragua	23,491
Panama	32,440
Papua New Guinea	7,258
Paraguay	7,258
Peru	45,864
Philippines	151,015
South Africa	25,728
St. Kitts & Nevis	7,258
Swaziland	17,898
Taiwan	13,424
Thailand	15,661
Trinidad-Tobago	7,830
Uruguay	7,258
Zimbabwe	13,424
Total	1,200,000

This allocation includes the following minimum quota-holding countries: Congo, Cote d'Ivoire, Gabon, Haiti, Madagascar, Papua New Guinea, Paraguay, St. Kitts & Nevis, and Uruguay.

The in-quota quantity of the tariff-rate quota for refined sugar for the period October 1, 1997–September 30, 1998, has been established by the Secretary of Agriculture at 50,000 metric tons, raw value (55,116 short tons), of which the Secretary has reserved 4,656 metric tons (5,132 short tons) for specialty sugars. Of the quantity not reserved for specialty sugars, a total of 10,300 metric tons (11,354 short tons) is being allocated to Canada and 2,954 metric tons (3,256 short tons) is being allocated to Mexico. An additional 25,000 metric tons (27,558 short tons) of this quantity is being allocated to Mexico to fulfill obligations pursuant to the North American Free Trade Agreement (NAFTA). Under the NAFTA, the United States is to provide total access for raw and refined sugar from Mexico of 25,000 metric tons, raw value, for this quota period in conjunction with Mexico's net surplus producer status. This allocation is subject to NAFTA rules of origin and to the condition that the total imports of raw and refined sugar from Mexico, combined, is not to exceed 25,000 metric tons raw value. The remaining 7,090 metric tons (7,815 short tons) of the in-quota quantity not reserved for specialty sugars is not being allocated among supplying countries and may be supplied by any country, subject to any other provision of law. The 4,656 metric tons (5,132 short tons) reserved for specialty sugars is also not being allocated among supplying countries and may be supplied by any country, subject to any other provision of law.

With respect to the tariff-rate quota for certain sugar-containing products maintained pursuant to additional U.S. Note 8 to Chapter 17 of the Harmonized Tariff Schedule, 59,250 metric tons (65,312 short tons) of sugar containing products is being allocated to Canada. The remaining in-quota quantity for this tariff-rate quota is available to other countries.

Charlene Barshefsky,

United States Trade Representative.

[FR Doc. 97–25121 Filed 9–22–97; 8:45 am]

BILLING CODE 3190–01–M

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

Reports, Forms and Recordkeeping Requirements, Agency Information Collection Activity Under OMB Review

AGENCY: Office of the Secretary, 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 Information Collection Request (ICR) abstracted below has been forwarded to the Office of Management and Budget (OMB) for review and comment. The ICR describes the nature of the information collection and its expected burden. The Federal Register Notice with a 60-day comment period soliciting comments on the following collection of information was published in 62 FR 19159–19162, April 18,1997.

DATES: Comments must be submitted on or before October 23, 1997.

FOR FURTHER INFORMATION CONTACT: Mr. Morris Oliver, (202) 366–2251, Federal Highway Administration, Department of Transportation, 400 Seventh Street, SW., Washington, DC 20590.

SUPPLEMENTARY INFORMATION:

Federal Highway Administration (FHWA)

Title: Implementation Plan, Traffic Surveillance and Control.

OMB Number: 2125–0512.

Type of Request: Reinstatement, without change, of a previously approved collection for which approval has expired.

Affected Public: State and local transportation agencies who utilize federal funds for traffic management projects and contractors involved in ITS/Traffic Management, who may write the implementation plan for the State and local transportation agency.

Abstract: An implementation plan for a federal aid traffic control project is required from the States and local agencies to assure that there are adequate provisions and resources for the acquisition and operational phases of the project.

Estimated Annual Burden Hours: 4,000.

Number of Respondents: 25.

ADDRESSES: Send comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725–17th Street, NW., Washington, DC 20503, Attention DOT Desk Officer. 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 estimate 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 September 15, 1997.

Vanester M. Williams,

Clearance Officer, United States Department of Transportation.

[FR Doc. 97–25207 Filed 9–22–97; 8:45 am]

BILLING CODE 4910–62–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. PE–97–47]

Petitions for Exemption; Summary of Petitions Received; Dispositions of Petitions Issued

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of petitions for exemption received and of dispositions of prior petitions.

SUMMARY: Pursuant to FAA's rulemaking provisions governing the application, processing, and disposition of petitions for exemption (14 CFR part 11), this notice contains a summary of certain petitions seeking relief from specified requirements of the Federal Aviation Regulations (14 CFR Ch. I), dispositions of certain petitions previously received, and corrections. The purpose of this notice is to improve the public's awareness of, and participation in, this aspect of FAA's regulatory activities. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of any petition or its final disposition.

DATES: Comments on petitions received must identify the petition docket number involved and must be received on or before October 13, 1997.

ADDRESSES: Send comments on any petition in triplicate to: Federal Aviation Administration, Office of the Chief Counsel, Attn: Rule Docket (AGC–200), Petition Docket No. _____, 800 Independence Avenue, SW., Washington, D.C. 20591.

Comments may also be sent electronically to the following internet address: 9–NPRM–CMNTS@faa.dot.gov.

The petition, any comments received, and a copy of any final disposition are filed in the assigned regulatory docket and are available for examination in the Rules Docket (AGC–200), Room 915G, FAA Headquarters Building (FOB 10A), 800 Independence Avenue, SW., Washington, D.C. 20591; telephone (202) 267–3132.

FOR FURTHER INFORMATION CONTACT: Heather Thorson (202) 267–7470 or Angela Anderson (202) 267–9681 Office of Rulemaking (ARM–1), Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591.

This notice is published pursuant to paragraphs (c), (e), and (g) of § 11.27 of Part 11 of the Federal Aviation Regulations (14 CFR Part 11).

Issued in Washington, DC., on September 17, 1997.

Donald P. Byrne,

Assistant Chief Counsel for Regulations.

Petitions for Exemption

Docket No.: 28952.

Petitioner: Minebea Technologies PTE Ltd.

Sections of the FAR Affected: 14 CFR 119.5(h).

Description of Relief Sought: To permit Minebea Technologies, the holder of a 14 CFR part 125 operating certificate to conduct common carriage operations.

Docket No.: 28955.

Petitioner: James W. Shafer.

Sections of the FAR Affected: 14 CFR 91.307(c).

Description of Relief Sought: To permit the petitioner to permanently mount and use a BRS 1050 ballistic parachute in his Rans S–10 experimental category aircraft (Registration No. N141EB) in lieu of the individual approved parachutes required by § 91.307(c).

Docket No.: 28909.

Petitioner: Casey Holdings, Inc.

Sections of the FAR Affected: 14 CFR 91.307(c)(2).

Description of Relief Sought: To permit the petitioner to perform certain intentional maneuvers in its Boeing 707–300 aircraft that cause the aircraft to exceed 30 degrees of pitch altitude, without requiring each occupant aboard that aircraft to wear an approved parachute.

Dispositions of Petitions

Docket No.: 28977.

Petitioner: Freight Runners Express.

Sections of the FAR Affected: 14 CFR 135.143(c)(2).

Description of Relief Sought/ Disposition: To permit the petitioner to operate its aircraft under part 135 without a TSO–C112 (Mode S) transponder installed.

Grant, 9/8/97, Exemption No. 6675.

Docket No.: 12656.

Petitioner: Department of Defense.

Sections of the FAR Affected: 14 CFR part 139.

Description of Relief Sought/ Disposition: To permit the issuance of FAA Airport Operating Certificates for those DOD airports equipped and operated in accordance with applicable DOD standards and procedures that serve, or expect to serve, air carrier aircraft having a seating capacity of more than 30 passenger seats, without those airports complying with the certification and operating requirements of part 139.

Grant, 9/2/97, Exemption No. 5750B.

Docket No.: 29002.

Petitioner: Peninsula Airways, Inc.

Sections of the FAR Affected: 14 CFR 121.709(b)(3).

Description of Relief Sought/ Disposition: To permit properly trained PenAir flight crewmembers to install and/or remove medevac stretchers on PenAir Fairchild Metro III aircraft and make the appropriate entries in the aircraft maintenance records.

Grant, 8/29/97, Exemption No. 6674.

Docket No.: 21882.

Petitioner: China Airlines, Ltd.

Sections of the FAR Affected: 14 CFR 61.77(a) and (b), and 63.23(a) and (b).

Description of Relief Sought/ Disposition: To permit CAL airmen who operate two U.S.-registered Boeing 747–SP aircraft (Registration Nos. N4508H and N4522V) and three U.S.-registered Airbus A300–600R aircraft (Registration Nos. N88881, N88887, and N8888B) that are leased to a person who is not a citizen of the United States, for carrying persons or property for compensation or hire, to be eligible for special purpose airmen certificates.

Grant, 8/29/97, Exemption No. 4849G.

Docket No.: 28952.

Petitioner: Minebea Technologies PTE Ltd.

Section 14 CFR 119.5(h).

To permit Minebea Technologies, the holder of a 14 CFR part 125 operating certificate to conduct common carriage operations.

[FR Doc. 97–25182 Filed 9–22–97; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[STB Finance Docket No. 33452]

Brownsville & Rio Grande International Railroad—Lease and Operation Exemption—Union Pacific Railroad Company

Brownsville & Rio Grande International Railroad, a Class III rail carrier, has filed a verified notice of exemption under 49 CFR 1150.41 to lease and operate a total of approximately 7.92 miles of rail line (known as the Port Lead) owned by Union Pacific Railroad Company (UPRR) between milepost 0.0 at Brownsville, TX (from the Port Lead connection with UPRR's rail yard in downtown Brownsville) and milepost 7.92 at the Port of Brownsville, TX. The transaction was expected to be consummated on or after September 8, 1997.

If the notice contains false or misleading information, the exemption is void *ab initio.* Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the transaction.

An original and 10 copies of all pleadings, referring to STB Finance Docket No. 33452, must be filed with the Surface Transportation Board, Office of the Secretary, Case Control Unit, 1925 K Street, N.W., Washington, DC 20423–0001 and served on: Robert A. Wimbish, Rea, Cross & Auchincloss, 1920 N Street, Suite 420, N.W., Washington, DC 20036.

Decided: September 15, 1997.

By the Board, David M. Konschnik, Director, Office of Proceedings.

Vernon A. Williams,

Secretary.

[FR Doc. 97–25238 Filed 9–22–97; 8:45 am]

BILLING CODE 4915–00–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[STB Finance Docket No. 33451]

Delta Southern Railroad Company—Lease and Operation Exemption—Union Pacific Railroad Company

Delta Southern Railroad (DSR), a Class III rail carrier, has filed a verified notice of exemption under 49 CFR 1150.41 to lease and operate a total of approximately 39.42 miles of rail line owned by Union Pacific Railroad Company (UPRR) between milepost 422.32 at Dermott, AR, and milepost 461.74 at Warren, AR.[1] In addition, DSR will acquire approximately 5.56 miles of incidental overhead trackage rights between milepost 415.26 at Dermott and milepost 409.7 at McGehee, AR, over UPRR's main line to facilitate railcar interchange between UPRR and DSR at UPRR's yard tracks at McGehee. The transaction was expected to be consummated on or after September 6, 1997.

If the notice contains false or misleading information, the exemption is void *ab initio.* Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the transaction.

[1] In addition, DSR will lease from UPRR a railcar repair facility (including storage tracks) and an adjacent office building and parking facility in UPRR's rail yard at McGehee, AR. DSR states that these aspects of the lease agreement are not subject to Board jurisdiction.

An original and 10 copies of all pleadings, referring to STB Finance Docket No. 33451, must be filed with the Surface Transportation Board, Office of the Secretary, Case Control Unit, 1925 K Street, N.W., Washington, DC 20423–0001 and served on: Robert A. Wimbish, Rea, Cross & Auchincloss, 1920 N Street, Suite 420, N.W., Washington, DC 20036.

Decided: September 15, 1997.

By the Board, David M. Konschnik, Director, Office of Proceedings.

Vernon A. Williams,

Secretary.

[FR Doc. 97–25241 Filed 9–22–97; 8:45 am]

BILLING CODE 4915–00–P

DEPARTMENT OF THE TREASURY

Submission for OMB review; comment request

September 16, 1997.

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, Pub. L. 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.

Financial Management Service (FMS)

OMB Number: 1510–0066.

Form Number: None.

Type of Review: Reinstatement.

Title: Management of Federal Agency Disbursements.

Description: Recipients of Federal disbursements must furnish the Financial Management Service (FMS) with their bank account number and the name and Routing and Transit Number (RTN) of their bank. Recipients without a bank account must certify that in writing to FMS.

Respondents: Business or other for-profit, Individuals or households, Not-for-profit institutions.

Estimated Number of Respondents: 1,300 .

Estimated Burden Hours Per Response: 15 minutes.

Frequency of Response: On occasion.

Estimated Total Reporting Burden: 325 hours.

Clearance Officer: Jacqueline R. Perry (301) 344–8577, Financial Management Service, 3361–L 75th Avenue, Landover, MD 20785.

OMB Reviewer: Alexander T. Hunt (202) 395–7860, Office of Management and Budget, Room 10202, New Executive Office Building, Washington, DC 20503.

Lois K. Holland,

Departmental Reports, Management Officer.

[FR Doc. 97–25155 Filed 9–22–97; 8:45 am]

BILLING CODE 4810–35–P

DEPARTMENT OF THE TREASURY

Submission to OMB for Review; Comment Request

September 16, 1997.

The Department of the 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.

Internal Revenue Service (IRS)

OMB Number: 1545–0054.

Form Number: IRS Form 1000.

Type of Review: Extension.

Title: Ownership Certificate.

Description: Form 1000 is used by citizens, resident individuals, fiduciaries, partnerships and nonresident partnerships in connection with interest on bonds of a domestic, resident foreign, or nonresident foreign corporation containing a tax-free covenant and issued before January 1, 1934. IRS uses the information to verify that the correct amount of tax was withheld.

Respondents: Bureau or other for-profit, Individuals or households.

Estimated Number of Respondents/Recordkeepers: 1,500.

Estimated Burden Hours Per Respondent/Recordkeeper: 3 hours, 22 minutes.

Frequency of Response: On occasion.

Estimated Total Reporting/Recordkeeping Burden: 5,040 hours.

OMB Number: 1545–0975.

Form Number: IRS Form 5500–EZ.

Type of Review: Extension.

Title: Annual Return of One-Participant (Owners and Their Spouses) Retirement Plan.

Description: Form 5500–EZ is an annual return filed by a one-participant or one-participant and spouse pension plan. The IRS uses this data to

determine if the plan appears to be operating properly as required under the law or whether the plan should be audited.

Respondents: Bureau or other for-profit.

Estimated Number of Respondents/ Recordkeepers: 193,299.

Estimated Burden Hours Per Respondent/Recordkeeper:

Recordkeeping—11 hr., 43 min.
Learning about the law or the form—1 hr., 22 min.
Preparing the form—2 hr., 32 min.
Copying, assembling, and sending the form to the IRS—16 min.

Frequency of Response: Annually.

Estimated Total Reporting/ Recordkeeping Burden: 3,073,454 hours.

Clearance Officer: Garrick Shear (202) 622–3869, Internal Revenue Service, Room 5571, 1111 Constitution Avenue, NW, Washington, DC 20224.

OMB Reviewer: Alexander T. Hunt (202) 395–7860, Office of Management and Budget, Room 10226, New Executive Office Building, Washington, DC 20503.

Lois K. Holland,

Departmental Reports Management Officer.

[FR Doc. 97–25156 Filed 9–22–97; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

General Counsel; Appointment of Members of the Legal Division to the Performance Review Board, Internal Revenue Service

Under the authority granted to me as Chief Counsel of the Internal Revenue Service by the General Counsel of the Department of the Treasury by General Counsel Order No. 21 (Rev. 4), and pursuant to the Civil Service Act, I hereby appoint the following persons to the Legal Division Performance Review Board, Internal Revenue Service Panel:

1. Chairperson, Marlene Gross, Deputy Chief Counsel;
2. Neal S. Wolin, Deputy General Counsel;
3. Martha Sullivan, Western Regional Counsel;
4. Judith C. Dunn, Associate Chief Counsel (Domestic);
5. Cynthia Mattson, Assistant Chief Counsel (International); and
6. Matthew Magnone, New Jersey District Counsel.

This publication is required by 5 U.S.C. 4314(c)(4).

Stuart L. Brown,

Chief Counsel.

[FR Doc. 97–25247 Filed 9–22–97; 8:45 am]

BILLING CODE 4830–01–U

DEPARTMENT OF THE TREASURY

Bureau of the Public Debt

Proposed Collection: Comment Request

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, Pub. L. 104–13 (44 U.S.C. 3506(c)(2)(A). Currently the Bureau of the Public Debt within the Department of the Treasury is soliciting comments concerning the Application By Survivors for Payment of Bond or Check Issued Under the Armed Forces Leave Act of 1946, as amended.

DATES: Written comments should be received on or before November 24, 1997, to be assured of consideration.

ADDRESSES: Direct all written comments to Bureau of the Public Debt, Vicki S. Thorpe, 200 Third Street, Parkersburg, WV 26106–1328.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to Vicki S. Thorpe, Bureau of the Public Debt, 200 Third Street, Parkersburg, WV 26106–1328, (304) 480–6553.

SUPPLEMENTARY INFORMATION:

Title: Application By Survivor For Payment of Bond or Check Issued Under The Armed Forces Leave Act of 1946, As Amended.

OMB Number: 1535–0104.

Form Number: PD F 2066.

Abstract: The information is requested to support payment of bonds or checks issued under the Armed Forces Leave Act of 1946, as amended.

Current Actions: None.

Type of Review: Extension.

Affected Public: Individuals.

Estimated Number of Respondents: 400.

Estimated Time Per Respondent: 30 minutes.

Estimated Total Annual Burden Hours: 200.

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.

Dated: September 17, 1997.

Vicki S. Thorpe,

Manager, Graphics, Printing and Records Branch.

[FR Doc. 97–25173 Filed 9–22–97; 8:45 am]

BILLING CODE 4810–39–P

DEPARTMENT OF THE TREASURY

Bureau of the Public Debt

Proposed Collection: Comment Request

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, Pub. L. 104–13 (44 U.S.C. 3506(c)(2)(A). Currently the Bureau of the Public Debt within the Department of the Treasury is soliciting comments concerning the Certificate to Support Application For Relief on Account of Lost, Stolen, or Destroyed U.S. Securities.

DATES: Written comments should be received on or before November 24, 1997, to be assured of consideration.

ADDRESSES: Direct all written comments to Bureau of the Public Debt, Vicki S. Thorpe, 200 Third Street, Parkersburg, WV 26106–1328.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to Vicki S. Thorpe, Bureau of the Public Debt, 200 Third Street, Parkersburg, WV 26106–1328, (304) 480–6553.

SUPPLEMENTARY INFORMATION:

Title: Certificate To Support Application For Relief On Account of

Lost, Stolen, or Destroyed United States Securities.

OMB Number: 1535–0108.

Form Number: PD F 2471.

Abstract: The information is to support an application for relief on account of lost, stolen, or destroyed United States Securities.

Current Actions: None.

Type of Review: Extension.

Affected Public: Individuals.

Estimated Number of Respondents: 400.

Estimated Time Per Respondent: 30 minutes.

Estimated Total Annual Burden Hours: 200.

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.

Dated: September 17, 1997.

Vicki S. Thorpe,

Manager, Graphics, Printing and Records Branch.

[FR Doc. 97–25174 Filed 9–22–97; 8:45 am]

BILLING CODE 4810–39–P

DEPARTMENT OF THE TREASURY

Bureau of the Public Debt

Proposed Collection: Comment Request

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 Bureau of the Public Debt within the Department of the Treasury is soliciting comments concerning the Application For Recognition as Natural Guardian of a Minor Not Under Legal Guardianship and for Disposition of Minor's Interest in Registered Securities.

DATES: Written comments should be received on or before November 24, 1997, to be assured of consideration.

ADDRESSES: Direct all written comments to Bureau of the Public Debt, Vicki S. Thorpe, 200 Third Street, Parkersburg, WV 26106–1328.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to Vicki S. Thorpe, Bureau of the Public Debt, 200 Third Street, Parkersburg, WV 26106–1328, (304) 480–6553.

SUPPLEMENTARY INFORMATION:

Title: Application For Recognition As Natural Guardian Of A Minor Not Under Legal Guardianship And For Disposition Of Minor's Interest In Registered Securities.

OMB Number: 1535–0105.

Form Number: PD F 2481.

Abstract: The information is to support disposition of registered securities belonging to a minor.

Current Actions: None.

Type of Review: Extension.

Affected Public: Individuals.

Estimated Number of Respondents: 25.

Estimated Time Per Respondent: 30 minutes.

Estimated Total Annual Burden Hours: 13.

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.

Dated: September 17, 1997.

Vicki S. Thorpe,

Manager, Graphics, Printing and Records Branch.

[FR Doc. 97–25175 Filed 9–22–97; 8:45 am]

BILLING CODE 4810–39–P

DEPARTMENT OF VETERANS AFFAIRS

Wage Committee, Notice of Meetings

The Department of Veterans Affairs (VA), in accordance with Pub. L. 92–463, gives notice that meetings of the VA Wage Committee will be held on:

Wednesday, October 8, 1997, at 2:00 p.m.
Wednesday, October 22, 1997, at 2:00 p.m.
Wednesday, November 5, 1997, at 2:00 p.m.
Wednesday, November 19, 1997, at 2:00 p.m.
Wednesday, December 3, 1997, at 2:00 p.m.
Wednesday, December 17, 1997, at 2:00 p.m.

The meetings will be held in Room 246, Department of Veterans Affairs Central Office, 810 Vermont Avenue, NW., Washington, DC 20420.

The Committee's purpose is to advise the Under Secretary for Health on the development and authorization of wage schedules for Federal Wage System (blue-collar) employees.

At these meetings the Committee will consider wage survey specifications, wage survey data, local committee reports and recommendations, statistical analyses, and proposed wage schedules.

All portions of the meetings will be closed to the public because the matters considered are related solely to the internal personnel rules and practices of the Department of Veterans Affairs and because the wage survey data considered by the Committee have been obtained from officials of private business establishments with a guarantee that the data will be held in confidence. Closure of the meetings is in accordance with subsection 10(d) of Pub. L. 92–463, as amended by Pub. L. 94–409, and 5 U.S.C. 552b(c) (2) and (4).

However, members of the public are invited to submit material in writing to the Chairperson for the Committee's attention.

Additional information concerning these meetings may be obtained from the Chairperson, VA Wage Committee (05), 810 Vermont Avenue, NW., Washington, DC 20420.

Dated: September 16, 1997.

By Direction of the Secretary.

Heyward Bannister,

Committee Management Officer.

[FR Doc. 97–25147 Filed 9–22–97; 8:45 am]

BILLING CODE 8320–01–M

Corrections

Federal Register

Vol. 62, No. 184

Tuesday, September 23, 1997

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 HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Part 440

[MB-071-F]

RIN 0938-AH00

Medicaid Program; Coverage of Personal Care Services

Correction

In rule document 97–24266 beginning on page 47896, in the issue of Thursday, September 11, 1997, make the following correction:

On page 47896, in the first column, in the **EFFECTIVE DATE** section, ''November 10, 1977'' should read ''November 10, 1997''.

BILLING CODE 1505-01-D

DEPARTMENT OF THE INTERIOR

National Park Service

Notice of Inventory Completion for Native American Human Remains and Associated Funerary Objects from the Illinois counties of La Salle, Madison, Perry, and Randolph in the Possession of the Anthropology Section, Illinois State Museum, Springfield, IL

Correction

In notice document 97–24375, beginning on page 48303 in the issue of Monday, September 15, 1997, make the following correction:

On page 48304, in the third column, beginning in the seventh line from the end, ''[thirty days after publication in the **Federal Register**]'' should read ''October 15, 1997''.

BILLING CODE 1505-01-D

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Registration

Correction

In notice document 97–22570 appearing on page 45274, in the issue of Tuesday, August 26, 1997, the heading is corrected to read as set forth above.

BILLING CODE 1505-01-D

Federal Register

Tuesday
September 23, 1997

Part II

Department of Transportation

Federal Railroad Administration

49 CFR Part 216, et al.

Passenger Equipment Safety Standards; Proposed Rule

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

49 CFR Parts 216, 223, 229, 231, 232, and 238

[FRA Docket No. PCSS–1, Notice No. 2]

RIN 2130–AA95

Passenger Equipment Safety Standards

AGENCY: Federal Railroad Administration (FRA), Department of Transportation (DOT).

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: FRA is proposing a rule establishing comprehensive Federal safety standards for railroad passenger equipment. The proposed rule contains requirements concerning equipment design and performance criteria related to passenger and crew survivability in the event of a passenger train accident; the inspection, testing, and maintenance of passenger equipment; and the safe operation of passenger train service. The proposed rule is designed to address the safety of passenger train service in an environment where technology is advancing, and equipment is being designed for operation at higher speeds. The rule would amend existing regulations concerning special notice for repairs, safety glazing, locomotive safety, safety appliances, and railroad power brakes as applied to passenger equipment.

The proposed rule does not apply to tourist and historic railroad operations. However, after consulting with the excursion railroad associations to determine appropriate applicability in light of financial, operational, or other factors unique to such operations, FRA may prescribe requirements for these operations that are different from those affecting other types of passenger operations.

DATES: (1) *Written comments:* Written comments must be received on or before November 24, 1997. Comments received after that date will be considered by FRA and the Passenger Equipment Safety Standards Working Group to the extent possible without incurring substantial additional expense or delay. The docket will remain open until the Working Group proceedings are concluded. Requests for formal extension of the comment period must be made by November 7, 1997.

(2) *Public hearing*: FRA intends to hold a public hearing to allow interested parties the opportunity to comment on specific issues addressed in the NPRM. The date and location of the hearing will be set forth in a forthcoming notice that will be published in the **Federal Register**. Anyone who desires to make an oral statement at the hearing must notify the Docket Clerk by telephone (202–632–3198), and must submit three copies of the oral statement that he or she intends to make at the hearing. The notification should also provide the Docket Clerk with the participant's mailing address. FRA reserves the right to limit participation in the hearings of persons who fail to provide such notification. The date by which the Docket Clerk must be notified about the oral statement and receive copies of it will be set forth in the notice announcing the hearing.

ADDRESSES: Written comments should identify the docket number and must be submitted in triplicate to the Docket Clerk, Office of Chief Counsel, Federal Railroad Administration, 400 Seventh Street, S.W., Mail Stop 10, Washington, D.C. 20590. Persons desiring to be notified that their comments have been received by FRA should submit a stamped, self-addressed postcard with their comments. The Docket Clerk will indicate on the postcard the date on which the comments were received and will return the card to the addressee. Written comments will be available for examination, both before and after the closing date for written comments, during regular business hours in Room 7051 of FRA headquarters at 1120 Vermont Avenue, N.W., in Washington, D.C.

FOR FURTHER INFORMATION CONTACT: Edward Pritchard, Acting Staff Director, Motive Power and Equipment Division, Office of Safety Assurance and Compliance, FRA, 400 Seventh Street, S.W., Mail Stop 25, Washington, D.C. 20590 (telephone: 202–632–3362); Daniel Alpert, Trial Attorney, Office of Chief Counsel, FRA, 400 Seventh Street, S.W., Mail Stop 10, Washington, D.C. (telephone: 202–632–3186); or Thomas Herrmann, Trial Attorney, Office of Chief Counsel, FRA, 400 Seventh Street, S.W., Mail Stop 10, Washington, D.C. 20590 (telephone: 202–632–3167).

SUPPLEMENTARY INFORMATION:

Background

To enhance rail safety, the Secretary of Transportation convened a meeting of representatives from all sectors of the rail industry in September, 1994. As one of the initiatives arising from this Rail Safety Summit, the Secretary announced that DOT would begin developing safety standards for rail passenger equipment over a five-year period. In November, 1994, Congress adopted the Secretary's schedule for implementing rail passenger equipment regulations and included it in the Federal Railroad Safety Authorization Act of 1994 (the Act), Pub. L. No. 103–440, 108 Stat. 4619, 4623–4624 (November 2, 1994). Section 215 of the Act, as now codified at 49 U.S.C. 20133, requires:

(a) MINIMUM STANDARDS.—The Secretary of Transportation shall prescribe regulations establishing minimum standards for the safety of cars used by railroad carriers to transport passengers. Before prescribing such regulations, the Secretary shall consider—

(1) The crashworthiness of the cars;

(2) Interior features (including luggage restraints, seat belts, and exposed surfaces) that may affect passenger safety;

(3) Maintenance and inspection of the cars;

(4) Emergency response procedures and equipment; and

(5) Any operating rules and conditions that directly affect safety not otherwise governed by regulations.

The Secretary may make applicable some or all of the standards established under this subsection to cars existing at the time the regulations are prescribed, as well as to new cars, and the Secretary shall explain in the rulemaking document the basis for making such standards applicable to existing cars.

(b) INITIAL AND FINAL REGULATIONS.—(1) The Secretary shall prescribe initial regulations under subsection (a) within 3 years after the date of enactment of the Federal Railroad Safety Authorization Act of 1994. The initial regulations may exempt equipment used by tourist, historic, scenic, and excursion railroad carriers to transport passengers.

(2) The Secretary shall prescribe final regulations under subsection (a) within 5 years after such date of enactment.

(c) PERSONNEL.—The Secretary may establish within the Department of Transportation 2 additional full-time equivalent positions beyond the number permitted under existing law to assist with the drafting, prescribing, and implementation of regulations under this section.

(d) CONSULTATION.—In prescribing regulations, issuing orders, and making amendments under this section, the Secretary may consult with Amtrak, public authorities operating railroad passenger service, other railroad carriers transporting passengers, organizations of passengers, and organizations of employees. A consultation is not subject to the Federal Advisory Committee Act (5 U.S.C. App.), but minutes of the consultation shall be placed in the public docket of the regulatory proceeding.

The Secretary of Transportation has delegated these rulemaking responsibilities to the Federal Railroad Administrator. 49 CFR 1.49(m).

Consistent with the intent of Congress that FRA consult with the railroad industry in prescribing these regulations, FRA invited various organizations to participate in a working

group to focus on the issues related to railroad passenger equipment safety and assist FRA in developing Federal safety standards. The Passenger Equipment Safety Standards Working Group (or the ''Working Group'') first met on June 7, 1995, [1] and continues to meet in support of this rulemaking. This proposed rule was developed by FRA in consultation with the Working Group, and FRA will again convene the Working Group to consider comments received in response to this Notice and develop the final rule. Notice of any Working Group meetings will be available through the FRA Docket Clerk.

The Working Group has evolved since its initial meeting, and its membership currently includes representatives from the following organizations:

American Association of Private Railroad Car Owners, Inc. (AAPRCO),
American Association of State Highway and Transportation Officials (AASHTO),
American Public Transit Association (APTA),
Association of American Railroads (AAR),
Brotherhood of Locomotive Engineers (BLE),
Brotherhood Railway Carmen (BRC),
FRA,
Federal Transit Administration (FTA) of DOT,
National Railroad Passenger Corporation (Amtrak),
National Association of Railroad Passengers (NARP),
Railway Progress Institute (RPI),
Safe Travel America (STA),
Transportation Workers Union of America (TWU), and
United Transportation Union (UTU).

The Working Group is chaired by FRA, and supported by FRA program, legal, and research staff, including technical personnel from the Volpe National Transportation Systems Center (Volpe Center) of the Research and Special Programs Administration of DOT. FRA has included vendor representatives designated by RPI as associate members of the Working Group. FRA has also included the AAPRCO as an associate Working Group member. The National Transportation Safety Board has designated staff members to advise the Working Group.

In developing proposed safety standards for passenger equipment operating at speeds greater than 125 mph but not exceeding 150 mph, FRA formed a subgroup (the ''Tier II Equipment Subgroup'') of Working Group members representing interests associated with the provision of rail passenger service at such high speeds. FRA invited representatives from organizations including Amtrak, the BLE, BRC, RPI, and UTU to participate in this effort.

In accordance with 49 U.S.C. 20133(d), the evolving positions of the Working Group members—as reflected in the minutes of the group's meetings and associated documentation, together with data provided by the members during their deliberations— have been placed in the public docket of this rulemaking.

On June 17, 1996, FRA published an Advance Notice of Proposed Rulemaking (ANPRM) concerning the establishment of comprehensive safety standards for railroad passenger equipment (61 FR 30672). The ANPRM provided background information on the need for such standards, offered preliminary ideas on approaching passenger safety issues, and presented questions on various topics including: system safety programs and plans; passenger equipment crashworthiness; inspection, testing, and maintenance requirements; training and qualification requirements for mechanical personnel and train crews; excursion, tourist, and private equipment; commuter equipment and operations; train make-up and operating speed; tiered safety standards; fire safety; and operating practices and procedures.

FRA's commitment to developing proposed regulations through the Working Group necessarily influenced the role and purpose of the ANPRM. FRA specifically asked that members of the Working Group not respond formally to the ANPRM. The issues and ideas presented in the ANPRM had already been placed before the Working Group, and the Working Group had commented on drafts of the ANPRM. As a result, FRA solicited the submission of written comments that might be of assistance in developing a proposed rule from interested persons not involved in the Working Group's deliberations.

FRA received 12 comments in response to the ANPRM, including a request from a member of the Working Group to extend the ANPRM's comment period. In addition, the United States Small Business Administration (SBA) commented that the length of the comment period was inadequate for the industry, especially small railways, to prepare a thorough response to the ANPRM. FRA had closed the comment period on July 9, 1996, so that all comments could be shared with the Working Group before its meeting on July 10, 1996.

Although FRA did not formally extend the comment period, comments received after the closing date of the comment period have been shared with the Working Group at subsequent meetings. Such comments have been considered (and identified in this Notice) to the extent possible without incurring additional delay in preparing this Notice. Moreover, the Working Group is broadly representative of interests involved in the provision of intercity and commuter rail service nationwide, and its members had the opportunity to comment on the issues raised in the ANPRM before the document's publication, as noted above.

Need for Safety Standards

Effective Federal safety standards for freight equipment have long been in place, but equivalent Federal standards for passenger equipment do not currently exist. The AAR sets industry standards for the design and maintenance of freight equipment that add materially to the safe operation of this equipment. Industry standards for the safety of railroad passenger equipment have been in place since the early part of this century, as noted by the AAPRCO in comment on the ANPRM. However, over the years, the AAR has discontinued the development and maintenance of passenger equipment standards.

Passenger railroads do offer the traveling public one of the safest forms of transportation available. In the five-year period 1991–1995, there were 1.07 passenger fatalities for every billion miles a passenger was transported by rail. However, accidents continue to occur, often as a result of factors beyond the control of the passenger railroad. Further, the rail passenger environment is rapidly changing. Worldwide, passenger equipment operating speeds are increasing. Several passenger trainsets designed to European standards have been proposed for operation at high speeds in the United States. In general, these trainsets do not meet the structural or operating standards that are common practice for current North American equipment. FRA believes that adherence to such standards by the nation's passenger railroads has in large measure contributed to the high level of safety at which rail passenger service is currently operated. However, these standards do not have the force of regulation.

In general, the North American railroad operating environment requires passenger equipment to operate commingled with very heavy and long freight trains, often over track with frequent grade crossings used by heavy highway equipment. European passenger operations are intermingled with freight equipment of lesser weight than in North America. In many cases, highway-rail grade crossings also pose

[1] This date was incorrectly identified as June 6, 1995, in the Advance Notice of Proposed Rulemaking (61 FR 30672, June 17, 1996).

lesser hazards to passenger trains in Europe due to lower highway vehicle weight. European passenger equipment design standards may therefore not be appropriate for the North American rail environment.

FRA must become more active to ensure that passenger trains continue to be designed, built, and operated with a high level of safety. A clear set of Federal safety and design standards for passenger equipment tailored to the nation's operating environment is needed to provide for the safety of future rail operations and to facilitate sound planning for those operations.

Passenger Train Safety Hazards

Passenger trains are exposed to a variety of safety hazards. Some of these hazards are endemic to the nation's rail passenger operating environment, as noted above, and result from the operation of passenger trains commingled with freight trains, often over track with frequent grade crossings used by heavy highway equipment.

Collisions with a wide range of objects may occur at various speeds under a number of different circumstances. In addition to freight trains and highway vehicles, these objects include maintenance-of-way equipment and other passenger trains. Although most of these collisions occur only in the normal running direction of the train, impact into the side of the train can occur, especially at the junction of rail lines and at highway-rail grade crossings.

A passenger train collision with another train concerns FRA because of the potential for significant harm demonstrated in actual accidents.

- On February 16, 1996, a near-head-on collision occurred between Maryland Rail Commuter Service (MARC) train 286 and Amtrak train 29 on track owned by CSX Transportation, Inc., (CSXT) at Silver Spring, Maryland. The MARC train was operating with a cab car (a car which provides passenger seating, as well as a location from which the train is operated) as the lead car in the train, followed by two passenger coaches and a locomotive pushing the consist. The collision separated the left front corner of the cab car from the roof to its sill plate, and tore off much of the forward left side of the car body. Three crewmembers and eight passengers were fatally injured, and 13 other occupants of the MARC train sustained injuries. (FRA Accident Investigation Report (Report) B–3–96.)
- On February 9, 1996, a near-head-on collision occurred between New Jersey Transit Rail Operations, Inc., trains 1254 and 1107 on the borderline of Secaucus and Jersey City, New Jersey. Two crewmembers and one passenger were fatally injured, and 35 other people sustained injuries. The passenger fatality and most of the nonfatal injuries to passengers occurred on train 1254, which was operating with the cab car forward, followed by four passenger coaches and a locomotive pushing the consist. (FRA Report B–2–96.)
- On January 18, 1993, Northern Indiana Commuter Transportation District (NICTD) trains 7 and 12 collided corner-to-corner in Gary, Indiana. The left front corners and adjacent car body sidewall structures were destroyed on both of the lead cars in each train. Seven passengers died, and 95 people sustained injuries. (NTSB/Railroad Accident Report (RAR)–93/03.)

The exposure of passenger trains to hazards associated with sharing common rights-of-way with freight trains has been demonstrated in recent accidents, and a past disastrous accident.

- On February 15, 1995, an Amtrak train traveling at 58 mph struck a shifted load of steel ''I'' beams extending from a Union Pacific Railroad Company freight train stopped in a siding at Borah, Idaho. The Amtrak train's six passenger coaches were raked with a steel beam which penetrated the outer layer of the car bodies at various points. Although no passengers were injured, the Amtrak train's two locomotives were significantly damaged, and two crewmembers were injured. (FRA Report C–14–95.)
- On May 16, 1994, an Amtrak train derailed after striking an intermodal trailer which had fallen or was falling from a CSXT freight train travelling northbound on an adjacent track at Selma, North Carolina. The lead locomotive of the Amtrak train rolled over, and the assistant engineer was killed. The engineer sustained serious injuries, and 120 other occupants of the Amtrak train reported injuries. (NTSB/RAR–95/02.)
- On January 4, 1987, an Amtrak train collided with the rear of a Consolidated Rail Corporation (Conrail) train near Chase, Maryland, when it unexpectedly entered the track ahead of the Amtrak train, which had been travelling between 120 and 125 mph only a few seconds earlier. The Amtrak train's two locomotives and three front passenger cars were destroyed in the collision. The engineer and 15 passengers aboard the Amtrak train were fatally injured, and 174 other persons aboard the train were injured. (NTSB/RAR–88/01.)

The exposure of passenger trains to hazards associated with operating over frequent highway-rail grade crossings, used by heavy highway vehicles, has also been demonstrated in numerous accidents.

- On January 16, 1996, a Massachusetts Bay Transportation Authority (MBTA) train being operated by Amtrak struck a loaded tractor-trailer which had become lodged in a grade crossing in Wakefield, Massachusetts. Twenty-two passengers were taken to hospitals by ambulance or air. (FRA Report C–4–96.)
- On October 3, 1995, a Metro-North Commuter Railroad Company (Metro-North) train with a cab car in the lead struck a loaded tractor-trailer which had become lodged in a grade crossing near Milford, Connecticut. Two crewmembers and 24 passengers were injured. (FRA Report C–60–95.)
- On September 21, 1995, an Amtrak train traveling at 81 mph struck a loaded tractor-trailer at a highway-rail grade crossing near Indiantown, Florida. The assistant engineer was killed, and five other persons onboard the train were injured. (FRA Report C–56–95.)
- On November 30, 1993, an Amtrak train derailed after striking an 82-ton turbine being transported by a 184-foot long vehicle which was fouling a grade crossing near Intercession City, Florida. Fifty-eight of the train's passengers and crewmembers were injured. (NTSB Highway Accident Report 95/01.)

In addition to collisions involving passenger trains striking highway vehicles, highway vehicles may also strike passenger trains. According to FRA's Rail-Highway Grade Crossing Accident/Incident database, 13.8% of all highway-rail grade crossing collisions involving passenger trains from 1986 through 1995 occurred when the highway vehicle struck the passenger train. This accounts for 388 such occurrences out of 2,820 highway-rail grade crossing collisions involving passenger trains in this period. In commenting on the ANPRM, the Washington State Department of Transportation (WSDOT) had asked that FRA clarify the statement that 25 percent of all highway-rail grade crossing accidents involve a highway vehicle striking the side of a train. *See* 61 FR 30692. Though this higher figure does include accidents involving both freight and passenger trains, the potential for a highway vehicle to strike a passenger train is real.

The WSDOT also requested that FRA document how many ''heavy'' highway vehicles were involved in highway-rail grade crossing accidents in which highway vehicles struck passenger trains. Over the same ten-year period from 1986 through 1995, 52 of the 388 occurrences in which a highway vehicle

struck a passenger train involved a heavy highway vehicle. For purposes of this analysis, FRA considered the number of heavy highway vehicles which struck passenger trains to consist of all those vehicles identified as a ''Truck-Trailer'' (12) and one-half the number of those vehicles identified as a ''Truck'' (79), as specified according to Form FRA F 6180.57—Rail-Highway Grade Crossing Accident/Incident Report.

Passenger trains are also vulnerable to accidents caused by defective railroad track structure and vehicle interaction with the rail structure.

- On August 3, 1994, an Amtrak train derailed while travelling at approximately 79 mph on Conrail trackage near Batavia, New York, because of the dynamic interaction between a material handling car and a flattened rail head. Five of the derailed passenger cars descended a railroad embankment and came to rest on their sides. One-hundred-and-eight passengers and ten crewmembers were injured. (NTSB/RAR–96/02.)
- On July 31, 1991, an Amtrak train derailed while travelling at 80 mph over CSXT trackage in Lugoff, South Carolina, when a switch point leading to a parallel auxiliary track unexpectedly opened under the Amtrak train. The derailed passenger cars collided with the first of nine hopper cars stored on the auxiliary track. The collision caused the wheel set from the first hopper car to penetrate the last passenger car. Eight passengers were fatally injured, and 12 passengers sustained serious injuries. (NTSB/RAR–93/02.)

Moreover, passenger trains are vulnerable to accidents caused by vandalism and sabotage.

- On October 9, 1995, an Amtrak train derailed near Hyder, Arizona, while operating at 50 mph on Southern Pacific Transportation Company trackage because the railroad track structure had been sabotaged. The derailment killed an Amtrak employee who occupied a passenger car which had rolled over onto its side. Seventy-eight passengers were also injured. (FRA Report C–62–95.)
- On May 21, 1993, an Amtrak train traveling at approximately 45 mph derailed after striking two pieces of steel pipe which had been lodged between the rails of a turnout near Opa-Locka, Florida. Six of the train's passengers and crewmembers were injured. (FRA Report C–34–93.)
- On August 12, 1992, an Amtrak train traveling at 79 mph derailed at Newport News, VA, after being unexpectedly diverted into a railroad siding because of a vandalized track switch. Seventy of the train's passengers and crewmembers were injured. (FRA Report C–52–92.)

Regardless of the cause of an accident, the occupants of a passenger train may risk harm caused by the crushing of the occupant compartment, in which the occupants themselves are crushed, and local penetration into the occupant compartment, where an object intrudes into the occupant compartment and directly strikes an occupant, as demonstrated in the Amtrak accident in Lugoff, South Carolina. Passenger train occupants are also vulnerable to harm from collisions within the train's interior, including loose objects inside the train, such as baggage. For example, the NTSB determined that at least two passengers in a lounge car were injured when they were struck by displaced pedestal seats as a result of the Intercession City, Florida, grade crossing collision on November 30, 1993. The seat columns on four pedestal seats had separated from their floor attachments, allowing them to be projected forward.

A variety of threats to passengers are also posed by fire, broken glazing, electrical shock, and submergence. These dangers may arise following a train derailment or collision, with potentially catastrophic results.

- On September 22, 1993, an accident occurred when an Amtrak train travelling at approximately 72 mph derailed after striking a girder that had been displaced when a towboat, pushing six barges, struck a railroad bridge near Mobile, Alabama. The train's three locomotives, the baggage and dormitory cars, and two of its six passenger cars fell into the water. Forty-two passengers and five crewmembers were killed. All passengers died from asphyxia due to drowning, and the train's three locomotive engineers died from asphyxia and blunt force trauma while inside the lead locomotive that became filled with mud. Two other employees died from smoke inhalation inside the dormitory coach car which had caught on fire. (NTSB Railroad-Marine Accident Report 94/01.)

Further, in the 1996 Silver Spring, Maryland, train collision between the MARC and Amtrak trains, fire erupted after the fuel tank of one of the Amtrak locomotives was breached. Fuel oil spilled into the MARC train's cab car through the openings in the torn car body. The forward section of the cab car was incinerated.

Some dangers to passenger train occupants, such as fire and smoke, may also arise independently without being associated with a train collision or derailment.

- On June 23, 1982, a fire started onboard an Amtrak passenger train in a sleeping car travelling en route to Los Angeles, California. As a result of the fire and smoke, two passengers died, two passengers were seriously injured, and 59 other occupants of the train were treated for smoke inhalation. (NTSB/RAR–83/03.)

Development of Passenger Train Safety Program

This rulemaking is part of several related and complementary efforts by FRA that will contribute to rail passenger safety. FRA has proposed regulations governing emergency preparedness and emergency response procedures for rail passenger service in a separate rulemaking proceeding, designated as FRA No. PTEP–1. *See* 62 FR 8330, Feb. 24, 1997. In addition, FRA has formed a separate working group (the Passenger Train Emergency Preparedness Working Group) to assist FRA in the development of such regulations. This related proceeding is also addressing some of the issues FRA identified in the ANPRM on passenger equipment safety. Persons wishing to receive more information regarding this other rulemaking should contact Mr. Edward R. English, Director, Office of Safety Assurance and Compliance, FRA, 400 Seventh Street, S.W., Washington, D.C. 20590 (telephone number: 202–632–3349), or David H. Kasminoff, Esq., Trial Attorney, Office of Chief Counsel, FRA, 400 Seventh Street, S.W., Washington, D.C. 20590 (telephone: 202–632–3191).

Further, in response to the New Jersey Transit and MARC train accidents in early 1996, FRA issued Emergency Order No. 20 (Notice No. 1) on February 20, 1996, requiring prompt action to immediately enhance passenger train operating rules and emergency egress and to develop an interim system safety plan addressing the safety of operations that permit passengers to occupy the leading car in a train. 61 FR 6876, Feb. 22, 1996. Both the New Jersey Transit and MARC train accidents involved operations where a cab car occupied the lead position in a passenger train. The Emergency Order explained that in collisions involving the front of a passenger train, operating with a cab car in the forward position or a multiple unit (MU) locomotive, *i.e.*, a self-propelled locomotive with passenger seating, presents an increased risk of severe personal injury or death as compared with locomotive-hauled service when the locomotive occupies the lead position in the train and thereby acts as a buffer for the trailing passenger cars. This risk is of particular

concern where operations are conducted at relatively higher speeds, where there is a mix of various types of trains, and where there are numerous highway-rail crossings over which large motor vehicles are operated. Accordingly, the Emergency Order required in particular that ''railroads operating scheduled intercity or commuter rail service * * * conduct an analysis of their operations and file with FRA an interim safety plan indicating the manner in which risk of a collision involving a cab car is addressed.'' 61 FR 6879.

The Emergency Order also noted that there is a need to ensure that emergency exits are clearly marked and in operable condition on all passenger lines, regardless of the equipment or train control system used. Although FRA Safety Glazing Standards, 49 CFR Part 223, require that passenger cars have a minimum of four emergency window exits ''designed to permit rapid and easy removal during a crisis situation,'' the Silver Spring accident raised concerns that at least some of the occupants of the MARC train attempted unsuccessfully to exit through the windows. The Emergency Order requires ''that any emergency windows that are not already legibly marked as such on the inside and outside be so marked, and that a representative sample of all such windows be examined to ensure operability.'' 61 FR 6880. On February 29, 1996, FRA issued Notice No. 2 to Emergency Order No. 20 to refine three aspects of the original order, including providing more detailed guidance on the emergency egress sampling provision. 61 FR 8703, Mar. 5, 1996.

In addition, FRA submitted a report to Congress on locomotive crashworthiness and working conditions on September 18, 1996, and subsequently referred the issues raised in the report to the Railroad Safety Advisory Committee (RSAC). FRA established RSAC in March of 1996, to provide FRA with advice and recommendations on railroad safety matters. *See* 61 FR 9740, Mar. 11, 1996. RSAC consists of 48 individual representatives, drawn from 27 organizations representing various rail industry perspectives, and two associate nonvoting representatives from the agencies with railroad safety regulatory responsibility in Canada and Mexico. RSAC will make recommendations as to the best way to address the findings of the report to Congress, including voluntary initiatives, and regulatory standards where appropriate. As a result, FRA may initiate a separate rulemaking proposing equipment safety requirements for both conventional freight and passenger locomotives.

In the context of improving railroad communications, RSAC has established a working group to specifically address communication facilities and procedures, with a strong emphasis on passenger train emergency requirements. FRA expects that group will report recommendations to RSAC early in 1997. FRA anticipates that those recommendations will address the issue of whether there should be redundant communications capability on all passenger trains.

Scope of the Proposed Rule

Through this Notice, FRA proposes to establish a comprehensive set of necessary safety regulations for railroad passenger equipment. These safety standards will improve the safety of rail passenger service.

In commenting on the ANPRM, the General Railway Signal Corporation (GRS) expressed concern that FRA has focused on equipment crashworthiness without sufficiently addressing crash avoidance. GRS noted that the underlying systems which can provide crash avoidance and the related systems safety elements involving a vitally integrated crash avoidance control system include much more than the elements onboard a train.

As explained in the ANPRM (61 FR 30683), and as is evident in Emergency Order No. 20, FRA recognizes that rail passenger safety does involve the safety of the railroad system as a whole, including the track structure, signal and train control systems, operating procedures, and station- and platform-to-train interface design—in addition to passenger equipment safety. To that end, FRA has active rulemaking and research projects in a variety of contexts that address non-equipment aspects of passenger railroad safety, including signal and train control systems. Nevertheless, this proposed rule is designed to address the specific statutory mandate that minimum safety standards be prescribed for the safety of cars used to transport railroad passengers. Signal and train control systems are not the focus of this rulemaking.

FRA received comments from the SBA and on behalf of the Minnesota Transportation Museum, Inc., about this rulemaking's effect on tourist, scenic, historic, and excursion railroads. The proposed rule does not apply to these railroads. Instead, the proposed rule applies to railroads that provide intercity passenger and commuter service. A joint FRA/industry working group formed under RSAC is currently developing recommendations regarding the applicability of FRA regulations, including this one, to tourist, scenic, historic, and excursion railroads. After appropriate consultation with the excursion railroad associations takes place, passenger equipment safety requirements for these operations may be proposed by FRA that are different from those affecting other types of passenger train operations. Any such requirements proposed by FRA will be part of a separate rulemaking proceeding.

Approach

The proposed regulations are principally designed to apply to two groups of equipment. The first group is identified as Tier I equipment and consists of railroad passenger equipment operated at speeds not exceeding 125 mph. The second group is identified as Tier II equipment and consists of railroad passenger equipment operated at speeds greater than 125 mph but not exceeding 150 mph. FRA is not proposing a rule of general applicability for railroad passenger equipment operated at speeds exceeding 150 mph. FRA believes that the safety of such passenger equipment must be addressed in a rule of a particular applicability for an individual railroad.

The speed break points between Tier I and Tier II equipment have been chosen because most of the nation's intercity passenger and commuter rail equipment has demonstrated an ability to operate safely at speeds up to 125 mph. Nevertheless, FRA recognizes that most of this same equipment is currently operated only at speeds of 110 mph or less. As a result, the proposed rule contains particular suspension system safety requirements for passenger equipment operating at speeds above 110 mph but not exceeding 125 mph, near the transition range from Tier I to Tier II requirements.

Pursuant to 49 U.S.C. 20133(a), FRA may apply some or all of the proposed standards to passenger cars existing at the time the regulations are published, as well as to new cars, but FRA must explain the basis for applying any such standards to existing cars. FRA believes that passenger railroad equipment operating in permanent service in the United States has established a good safety record, proving its compatibility with the operating environment. Moreover, FRA seeks to maximize the benefits resulting from the passenger railroad industry's investment in any safety requirements which FRA may impose through this rule. Accordingly, to be cost effective, most of the proposed requirements would apply only to new or rebuilt equipment.

However, certain features routinely incorporated in existing designs would be required at an earlier date than the more innovative features proposed by this rule. Further, where appropriate, rebuilt equipment would be required to comply with specific requirements.

FRA intends that the rules proposed in this NPRM lead to the issuance of initial passenger equipment safety regulations, which are required by statute to be issued by November 2, 1997. *See* 49 U.S.C. 20133(b)(1). FRA will propose additional rules for passenger equipment in a second NPRM principally when the results of further research are available. FRA intends that the second NPRM lead to the issuance of final regulations by November 2, 1999, thereby completing the rulemaking within the five-year period required by law. *See* 49 U.S.C. 20133(b)(2). To that end, FRA convened a meeting of the Working Group on December 10–11, 1996, at the Volpe Center in Cambridge, Massachusetts, to determine and set priorities for the research necessary to address unresolved safety issues identified in prior Working Group meetings. Moreover, FRA hopes that the establishment of final regulations in 1999 will be furthered by APTA's own initiative to develop and maintain recommended industry standards for rail passenger equipment. APTA's effort is being carried out through the Passenger Rail Equipment Safety Standards (PRESS) Task Force, and APTA has invited FRA, FTA, the NTSB, equipment manufacturers, engineering and consulting firms, rail labor, and others with an interest in rail passenger equipment to work with it in developing and effectuating the recommended standards. This represents a substantial and continuing investment by member commuter authorities in the safety of rail passenger service.

System Safety

FRA believes that passenger railroads should carefully evaluate their operations with a view toward enhancing the safety of those operations. The importance of formal safety planning has been recognized in Emergency Order No. 20 and the proposed rule on passenger train emergency preparedness. As noted, Emergency Order No. 20, Notice No. 1, required that ''railroads operating scheduled intercity or commuter rail service . . . conduct an analysis of their operations and file with FRA an interim safety plan indicating the manner in which risk of a collision involving a cab car is addressed.'' 61 FR 6879.

In a letter to FRA dated June 24, 1996, Mr. Donald N. Nelson, President of Metro-North and Chairperson of APTA's Commuter Railroad Committee, announced that commuter railroads are committed to seeking additional opportunities to ensure the safety of their operations beyond efforts such as those made to comply with the interim system safety plan requirements of Emergency Order No. 20. Mr. Nelson explained in particular that commuter railroads will examine and ensure the safety of their operations by adopting a comprehensive system safety plan that:

(a) Defines the overall safety effort, how it is to be implemented and the staff required to maintain it;

(b) Establishes the safety interface within the railroad, as well as with its key outside agencies;

(c) Clearly indicates Senior Management support for implementing the safety plan and the railroad's overall commitment to safety;

(d) Establishes the safety philosophy of the organization and provides the means for implementation;

(e) Defines the authority and responsibilities of the safety organization and delineates the safety related authority and responsibilities of other departments; and

(f) Incorporates safety goals and objectives into the overall corporate strategic plan.

(APTA's Commuter Railroad Committee letter at pages 1 and 2.) Further, the system safety plan is intended to be updated through periodic safety reviews of all operations.

In a letter to FRA dated October 21, 1996, Mr. Donald N. Nelson submitted for FRA's review APTA's ''Manual for the Development of a System Safety Plan for Commuter Railroads'' (APTA Manual). The APTA Manual is intended to assist commuter railroads in adopting a comprehensive system safety plan by September 1, 1997. In addition, Amtrak recently began a corporate system safety program initiative to make system safety formally an integral part of Amtrak's operations. The value of the system safety process is rapidly being recognized and accepted by the passenger railroad industry.

The System Safety Society (the ''Society''), which provided detailed comments in response to the ANPRM, observed that the use of the systems approach to safety is very actively followed in many other industries. The Society noted that the implementation of system safety plans has been observed to improve safety by reducing accidents and incidents. Further, the Society explained that safety plans are usually updated annually to maintain their utility because of technological improvements and other changed circumstances, including changes in the operating environment, rules and regulations.

The proposed rule contains system safety requirements to be applied to all intercity passenger and commuter rail equipment. Although FRA initially considered addressing system safety requirements for Tier I and Tier II equipment separately, FRA decided to propose system safety requirements which can be applied generally to all types of passenger equipment. Each individual railroad would be required to develop a system safety plan and a system safety program tailored to its specific operation, including train speed. The plan required by this part would be developed as part of a comprehensive system safety process to which commuter railroads are already committed.

Through the system safety process, each railroad would be required to identify, evaluate, and seek to eliminate or reduce the hazards associated with the use of passenger equipment over the railroad system. In particular, the proposed rule would require that each intercity passenger and commuter railroad prepare a system safety plan addressing, at a minimum:

- Fire protection;
- Software safety;
- Equipment inspection, testing, and maintenance;
- Employee training and qualifications; and
- Pre-revenue service acceptance testing of equipment.

However, because FRA is also proposing a comprehensive set of mandatory, equipment safety standards in this rule, FRA is generally not proposing to enforce every element of a railroad's system safety plan. The section-by-section analysis identifies those portions of the system safety plan that will be enforced by FRA. Commenters are requested to address whether FRA should mandate the contents of system safety plans, whether the areas identified by FRA are appropriate, whether additional areas should be added, and whether FRA should enforce other portions of the system safety plans and, if so, which portions. Should the proposed rule require that system safety plans be comprehensive and address the entire railroad system in which the equipment operates? Should the emergency preparedness planning requirements contained in proposed 49 CFR part 239 (See the Passenger Train Emergency Preparedness rulemaking,

designated as FRA No. PTEP–1 (62 FR 8330, Feb. 24, 1997)) be expressly integrated with the system safety planning requirements contained in this proposed part (49 CFR part 238)?

APTA, citing to the fact that the commuter railroads have voluntarily agreed to adopt system safety plans, has objected to FRA issuing any regulations governing such plans. Commenters are requested to address APTA's suggestion that the commuter railroads be allowed to regulate themselves in this area. FRA understands that APTA's system safety approach will be more comprehensive than what FRA is proposing and address each commuter railroad's system more as an integrated whole, not focused principally on rail equipment. FRA will carefully consider the comments received in deciding what approach to take in the final rule with respect to system safety plans.

Passenger railroads should seek to employ all means necessary to reduce the risks associated with the use of passenger equipment over their systems such as by improving the crashworthiness of their equipment or by imposing operational limitations on its use. Further, because many passenger railroads operate at least in part as a tenant on the right-of-way of another railroad and may not in themselves be able to control some of the major system hazards, as demonstrated when an intermodal trailer from a CSXT freight train struck an Amtrak train operating on an adjacent track in Selma, North Carolina, all railroads are encouraged to exploit ways to reduce the risks associated with rail travel to their employees, passengers, and the general public.

Emergency Egress and Access

During the NTSB's investigation of the February 16, 1996, collision between the MARC and Amtrak trains in Silver Spring, Maryland, that agency identified unsafe conditions on MARC's rail cars that had been manufactured by Sumitomo. Concerned that the unsafe conditions identified on these rail cars may exist on other commuter lines subject to FRA oversight, on March 12, 1996, the NTSB recommended that FRA:

> Inspect all commuter rail equipment to determine whether it has: (1) easily accessible interior emergency quick-release mechanisms adjacent to exterior passageway doors; (2) removable windows or kick panels in interior and exterior passageway doors; and (3) prominently displayed retroreflective signage marking all interior and exterior emergency exits. If any commuter equipment lacks one or more or these features, take appropriate emergency measures to ensure corrective action until these measures are incorporated into minimum passenger car safety standards. (Class I, Urgent Action) (R–96–7)

(In a letter to FRA dated June 24, 1996, the NTSB announced that it has added ''Safety of Passengers in Railroad Passenger Cars'' to its list of ''Most Wanted'' transportation safety improvements.)

In the discussion accompanying the safety recommendation, the NTSB expressed concern that emergency quick-release mechanisms for the exterior side doors on MARC's Sumitomo rail cars are located in a secured cabinet some distance from the doors that they control, and the emergency controls for each door are not readily accessible and identifiable. Each cabinet door was secured by two fasteners, requiring a screwdriver or coin to open. The NTSB believes that the emergency quick-release mechanisms for exterior doors on MARC rail cars should be well marked and relocated, so that they are immediately adjacent to the door which they control and readily accessible for emergency escape.

Access to Emergency Door-Release for Power-0perated Doors

In response to the NTSB's recommendation, FRA inspected a total of 1,250 pieces of equipment in use on 16 commuter organizations. In addition to MARC rail cars, FRA found that some commuter railroads operate cars with power doors equipped with emergency door-release levers located inside cabinets requiring special tools to enter. In large part, these railroads have committed to the voluntary elimination of latches requiring tools or other implements to access the emergency-release levers on power-operated doors.

FRA convened a joint meeting of the Passenger Equipment Safety Standards Working Group and the Passenger Train Emergency Preparedness Working Group on March 26, 1996, to discuss the NTSB's recommendations and incorporate the Safety Board's findings, as appropriate, into each working group's rulemaking. In accordance with the consensus of the working groups, FRA is proposing in §§ 238.237 and 238.441 of the rule that train passengers and crewmembers be able to access door-release mechanisms without the use of any tool or other implement.

Relocation of Emergency Door-Release

NTSB advisors to the Working Group clarified that the recommendation to relocate emergency door-release mechanisms refers to exterior side doors located in end vestibules partitioned from the passenger compartment of the rail vehicle. If emergency door-release mechanisms are located inside the passenger compartments of such vehicles, exiting the vehicles in an emergency through side doors in the vestibules may be complicated as passengers try to locate the mechanisms and move between the vestibule and passenger compartment areas.

In response to the NTSB's safety recommendation, passenger railroads that operate rail equipment with end vestibules have agreed to relocate emergency door-release mechanisms so that they are located adjacent to the doors which they control. However, agreement could not be reached on a time-table for retrofitting existing equipment. APTA has proposed that the retrofit be required on all such passenger equipment when it is overhauled in the course of each railroad's equipment overhaul cycle. APTA anticipates that under this process retrofitting the entire fleet of affected equipment will be accomplished within 10 to 15 years.

FRA believes that the retrofit must be accomplished sooner to ensure the safety of passenger train occupants. Consequently, FRA is proposing in § 238.237 that for equipment operated at speeds not exceeding 125 mph (Tier I equipment), within two years of the effective date of the final rule each powered, exterior side door in a vestibule that is partitioned from the passenger compartment of a passenger car be equipped with a manual override that is: (1) capable of opening the door without power from inside the car; (2) located adjacent to the door which it controls; and (3) designed and maintained so that a person may access the override device from inside the car without requiring the use of any tool or other implement.

FRA expects that railroads will expedite this retrofit program and believes that this retrofit can be completed well in advance of the 2-year deadline. APTA maintains that the supply industry cannot provide the necessary materials to complete the retrofit in such time without unreasonable increases in costs, and believes that a 3 to 5 year time frame is needed. (Commenters are requested to address whether a shorter or longer time period should be established and, if so, provide the rationale for the time period that the commenter recommends. Railroads are requested to identify the number of cars that are not yet retrofitted.) Further, before any equipment may be introduced for service at speeds exceeding 125 mph but not exceeding 150 mph (Tier II

equipment), FRA is proposing in § 238.441 that each powered, exterior side door on a passenger car be equipped with a manual override meeting the above and additional requirements.

FRA believes that the cost of meeting the retrofit requirement will be $3.7 million dollars, and recognizes that it is not clear whether the occupants of the MARC train in the Silver Spring, Maryland, accident could have opened the vestibule exterior side doors after the collision, assuming that the emergency-release had been employed. The NTSB did note that the left and right rear exterior side doors of the first car and the front interior end door and the right front exterior door of the second car on the MARC train were jammed. However, FRA believes it must institute the retrofit requirement to decrease the risk that passengers cannot rapidly exit a train in a life-threatening situation.

FRA recognizes that passenger railroads have located door-release mechanisms away from the doors which they control to discourage passengers from exiting trains in non-emergency situations. When no emergency is present, passengers exiting trains along the railroad right-of-way unnecessarily risk exposure to oncoming trains, electrical hazards, and other dangerous conditions. In consequence, the proposed rule permits railroads to protect emergency door-release mechanisms from casual or inadvertent use with a cover or a screen. However, the cover or screen must be capable of removal by a 5th-percentile female without the use of any tool or other implement. If the method of removing the protective cover or screen entails breaking or shattering it, the cover or screen shall be scored, perforated, or otherwise weakened so that a 5th-percentile female can penetrate the cover or screen with a single blow of her fist without injury to her hand.

Additional Egress Issues

The NTSB noted that none of the car doors on the MARC train involved in the Silver Spring, Maryland, accident had removable windows or pop-out emergency escape panels (''kick panels'') for use in an emergency. In addition, the NTSB stated that several train passengers were unaware of the locations of emergency exits, and none knew how to operate them. The NTSB found that the interior emergency window decals were not prominently displayed and that one car had no interior emergency window decals. Also, the exterior emergency decals were often faded or obliterated, and the information on them, when legible, directed emergency responders to another sign at the end of the car for instructions on how to open emergency exits.

Through the issuance of Emergency Order No. 20, FRA has addressed on an interim basis the inspection of required emergency exits, and emergency exit signage and marking. Further, FRA is proposing requirements concerning the marking of emergency exits, as well as instructions for their use, in the related rulemaking on passenger train emergency preparedness. FRA shares the NTSB's concern about passenger egress in an emergency; however, FRA believes that the NTSB's suggestion to install kick panels is best limited to interior doors to ensure passage through a train in an emergency—and not applied to exterior doors.

To the best of FRA's knowledge, the concept of kick panels has not been utilized in North American rail equipment. Installing kick panels below the window levels in exterior doors was evaluated by FRA, with concurrence from the joint working groups, as unacceptable for safety reasons. Because passenger railroads have encountered recurring situations in which passengers have inappropriately exited moving trains, leading to death or serious injury, introducing kick panels in exterior doors would create an unacceptable risk of inadvertent use, particularly by children. Penetration of occupied areas by objects from the outside is also a potential concern.

Use of kick panels to open passageways through a train has merit. If panels can be made sufficiently large without decreasing the functionality of doors in normal operation, such a feature may facilitate evacuation through the length of the train if exterior side doors are jammed. Evacuation throughout the length of the train is often the safest route of egress in situations such as fires, derailments in multiple track territory, and incidents in third-rail powered commuter service. Accordingly, FRA is proposing in § 238.441 of the rule that Tier II passenger car end doors be equipped with a kick-out panel, pop-out window or other similar means of egress in the event the doors will not open.

Unlike a Tier II passenger train which should operate as a fixed unit, the interchangeable use of some cab cars and MU locomotives as leading and trailing units on a Tier I passenger train will complicate analyzing the efficacy of installing such panels on Tier I equipment. It would be unacceptable to have a removable panel at the point of a train where objects or fluids might enter the vehicle as a result of a highway-rail grade crossing accident or other collision. As a result, FRA will further examine the concerns involving the use of kick panels on Tier I equipment in the second phase of this rulemaking.

Additional emergency egress and access topics addressed in this proposed rule are discussed below in the Emergency Systems section of this preamble. Emergency egress and access topics are also addressed in the related rulemaking on passenger train emergency preparedness. *See* 62 FR 8330, Feb. 24, 1997.

Power Brake Inspection and Testing

In 1992, Congress amended the Federal rail safety laws by adding certain statutory mandates related to power brake safety. These amendments specifically address the revision of the power brake regulations and state in pertinent part:

> (r) POWER BRAKE SAFETY.—(1) The Secretary shall conduct a review of the Department of Transportation's rules with respect to railroad power brakes, and not later than December 31, 1993, shall revise such rules based on such safety data as may be presented during that review.
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Pub. L. No. 102–365, § 7; codified at 49 U.S.C. 20141, superseding 45 U.S.C. 431(r).

In response to the statutory mandate, various recommendations to improve power brake safety, and due to its own determination that the power brake regulations were in need of revision, FRA published an ANPRM on December 31, 1992, concerning railroad power brake safety. *See* 57 FR 62546. The ANPRM provided background information and presented questions on various subjects related to intercity passenger and commuter train operations, including: training of testing and inspection personnel; electronic braking systems; cleaning, oiling, testing, and stenciling (COT&S) requirements; performance of brake inspections; and high speed passenger train brakes. Following publication of the ANPRM, FRA conducted a series of public workshops. The ANPRM and the public workshops were intended as fact-finding tools to elicit views of those persons outside FRA charged with ensuring compliance with the power brake regulations on a day-to-day basis.

Furthermore, on July 26, 1993, the NTSB made the following recommendation to FRA: ''Amend the power brake regulations, 49 Code of Federal Regulations 232.12, to provide appropriate guidelines for inspecting brake equipment on modern passenger

cars.'' (R–93–16). The recommendation arose out of the NTSB's investigation of the December 17, 1991, derailment of an Amtrak passenger train in Palatka, Florida. The derailed equipment struck two homes and blocked a street north of the Palatka station. The derailment resulted in eleven passengers sustaining serious injuries and 41 others receiving minor injuries. In addition, five members of the operating crew and four onboard service personnel received minor injuries. By letter dated September 16, 1993, FRA told the NTSB that it was in the process of reviewing and rewriting the power brake regulations and would consider the NTSB's recommendation during the process.

Based on comments and information received, FRA published an NPRM in 1994 regarding revision of the power brake regulations which contained specific requirements related to intercity passenger and commuter train operations. These specific requirements included: general design requirements; movement of defective equipment; employee qualifications; inspection and testing requirements; single car testing requirements and periodic maintenance; operating requirements; and requirements for the introduction of new train brake system technology. *See* 59 FR 47722–47753, September, 16, 1994.

Following publication of the 1994 NPRM (59 FR 47676), FRA held a series of public hearings in 1994 to allow interested parties the opportunity to comment on specific issues addressed in the 1994 NPRM. Public hearings were held in Chicago, Illinois, on November 1–2; in Newark, New Jersey, on November 4; in Sacramento, California, on November 9; and in Washington, D.C. on December 13–14, 1994. These hearings were attended by numerous railroads; organizations representing railroads; labor organizations; rail shippers; and State governmental agencies. Due to the strong objections raised by a large number of commenters, FRA announced by notice published on January 17, 1995, that it would defer action on the 1994 NPRM and permit the submission of additional comments prior to making a determination as to how it would proceed in this matter. *See* 60 FR 3375.

Based on these considerations and after review of all the comments submitted, FRA determined that in order to limit the number of issues to be examined and developed in any one proceeding it would proceed with the revision of the power brake regulations via three separate processes. In light of the testimony and comments received on the 1994 NPRM, emphasizing the differences between passenger and freight operations and the brake equipment utilized by the two, FRA decided to separate passenger equipment power brake standards from freight equipment power brake standards. As passenger equipment power brake standards are a logical subset of passenger equipment safety standards, FRA requested the Passenger Equipment Safety Standards Working Group to assist FRA in developing appropriate power brake standards for passenger equipment and then decided that they would be included in this NPRM. *See* 49 U.S.C. 20133(c). In addition, a second NPRM covering freight equipment power brake standards would be developed with the assistance of FRA's Railroad Safety Advisory Committee. *See* 61 FR 29164, June 7, 1996. Furthermore, in the interest of public safety and due to statutory as well as internal commitments, FRA determined that it would separate the issues related to two-way end-of-train-telemetry devices from both the passenger and freight issues. FRA convened a public regulatory conference and published a final rule on the subject on January 2, 1997. *See* 62 FR 278.

Beginning in December of 1995, the Passenger Equipment Safety Standards Working Group adopted the additional task of attempting to develop power brake standards applicable to intercity passenger and commuter train operations and equipment. The Working Group met on four separate occasions in the last six months, which consisted of ten days of meetings, with a good portion of these meetings being devoted to discussion of power brake issues. From the outset, a majority of the members, as well as FRA, believed that any requirements developed by the group regarding the inspection and testing of the brake equipment should not vary significantly from the current requirements and should be consistent with current industry practice.

FRA's accident/incident data related to intercity passenger and commuter train operations support the assumption that the current practices of these operations in the area of power brake inspection, testing, and maintenance are for the most part sufficient to ensure the safety of the public. Between January 1, 1990 and October 31, 1996, there were only five brake related accidents involving commuter and intercity passenger railroad equipment. No casualties resulted from any of these accidents and the total damage to railroad equipment totaled approximately $650,000, or $96,000 annually. In addition, between January 1, 1995 and October 31, 1996, FRA inspected approximately 13,000 commuter and intercity passenger rail units for compliance with 49 CFR part 232. The defect ratio for these units during this period was approximately 0.8 percent. Furthermore, during this same period FRA inspected approximately 6,300 locomotives for compliance with 49 CFR part 229. The brake defect ratio for these units was approximately 4.65 percent. Consequently, the defect ratio for brake related defects on locomotives and other passenger equipment during this period was approximately 2.08 percent.

The existing regulations covering the inspection and testing of the braking systems on passenger trains are contained in 49 CFR part 232. The current regulations do provide some requirements relevant to passenger train operations, including: initial terminal inspection and testing, intermediate inspections, running tests, and general maintenance requirements. *See* 49 CFR 232.12, 232.13(a), 232.16, and 232.17. However, most of the existing regulations are written to address freight train operations and do not sufficiently address the unique operating environment of commuter and intercity passenger train operations or the equipment currently being used in those operations. Therefore, it has been necessary for FRA to provide interpretations of some of the current regulations in order to address these unique concerns.

Currently, all non-MU (multiple unit) commuter trains that do not remain connected to a source of compressed air overnight and all MU commuter trains equipped with RT–5 or similar brake systems must receive an initial terminal inspection of the brake system pursuant to § 232.12(c)–(j) prior to the train's first departure on any given calendar day. All non-MU commuter trains that remain connected to a source of compressed air overnight are permitted to receive an initial terminal inspection of the brake system sometime during each 24-hour period in which they are used. Furthermore, all intercity passenger trains must receive an initial terminal inspection of the brake system at the point where they are originally made up and must receive an intermediate inspection in accordance with § 232.12(b) every 1,000 miles.

As noted previously, most of the members of the Working Group believed that any requirements developed by the group regarding the inspection and testing of the brake equipment should not vary significantly from the current requirements and should be consistent

with current industry practice. However, the Working Group was unable to reach consensus on power brake standards, despite the positing of multiple alternatives, use of a facilitator, and the foundation provided by the 1994 NPRM. The Working Group identified and discussed options with which the agency and labor can agree, and others with which FRA and the railroads can agree. However, bridging the gap between those various options proved elusive. Consequently, as the Working Group could not reach any type of consensus on the inspection and testing requirements, it was determined that FRA would address these issues unilaterally, based on the information and discussions provided by the Working Group and the information gathered from the 1994 NPRM. FRA is interested in receiving comments on the brake tests that it has developed given the differences in the positions of the various parties.

The Working Group discussed various options regarding the types of brake inspections that should be required as well as when and how these inspections should be performed. Labor representatives, particularly the BRC, insisted that a comprehensive power brake inspection (i.e., something similar to the initial terminal brake inspections currently required under § 232.12(c)–(j)) must be performed prior to a train's first run on a given calendar day. The BRC expressed concern that, as equipment lays over between the evening commuter cycle and the first trip of the morning, vandalism, weather changes, or other factors could affect the integrity of the air brake system. The BRC also believes that it is necessary for the first inspection of the day to determine whether the brake shoes and the disc pads actually apply as intended. The BRC further contends that in order to perform a comprehensive inspection equivalent to an initial terminal inspection the train must be walked or otherwise inspected on a car-to-car basis. In addition, the BRC contends that these principal inspections should be performed only by carmen or other qualified mechanical personnel as they are the only employees sufficiently trained to perform these inspections.

Representatives of intercity passenger and commuter railroads expressed the desire to have the flexibility to conduct a comprehensive in-depth inspection of the train brake system sometime during the day in which the equipment is utilized. These parties argued that safety would be better served by allowing the railroads the flexibility to conduct these inspections on a daily basis as it would allow the railroads to conduct the inspections at locations that are more conducive to permitting a full inspection of the equipment than many of the outlying locations where trains are stationed overnight and where the ability to observe all the equipment may be hampered. It is further contended that, if trains are required to received the equivalent of an initial terminal inspection at these outlying points, then many of these inspections may be performed by individuals not as fully qualified as a mechanical inspector. Whereas, if the railroads are allowed some flexibility in conducting these type of inspections, then the equipment can be moved to a location where a fully qualified mechanical inspector can perform a detailed brake inspection under optimum conditions, perhaps in conjunction with a daily mechanical inspection.

Several parties also pointed out that, with proper maintenance, ''tread brake units'' and other friction brake components, commonly used in commuter train operations, are highly reliable and that the non-functioning of any individual unit would in no way compromise the overall safety of the train. Furthermore, permitting the inspection of these types of brake components in the middle of the day, rather than at the beginning of the day, involves no greater safety risk to passengers because friction brake systems and their components degrade in performance based largely on use, and nothing short of a continuous brake inspection can guarantee 100-percent performance at all times. Railroad representatives suggested an inspection scheme that would permit an in-depth, comprehensive brake inspection to be performed sometime during the day in which the equipment is used with a brake inspection being performed prior to the first run of the day verifying the continuity of the trainline by performing a set and release on the rear car of the train. In addition, one commuter railroad also requested relief from performing Class I inspections on trains operated in weekend service due to the shortage of mechanical inspectors currently employed on those shifts.

Based on consideration of the discussions held in the Working Group meetings, outlined above, as well as information obtained in relation to the 1994 NPRM, FRA proposes to abandon the terminology related to the power brake inspection and testing requirements contained in the current regulations, which is generally based on the locations where the inspections and tests are performed (*i.e.*, initial terminal, intermediate locations). In its stead, FRA proposes to identify various classes of inspections based on the duties and type of inspection required, such as: Class I; Class IA; and Class II. This is similar to the approach taken by FRA in the 1994 NPRM. *See* 59 FR 47736–40. FRA believes that this type of classification system will avoid confusion with the power brake inspection and testing requirements applicable to freight operations and will avoid the connotations historically attached to the current terminology. FRA also believes this approach is better suited for providing operational flexibility to commuter operations while maintaining the safety provided by the current inspection and testing requirements. Although FRA proposes a change in the terminology used to describe the various power brake inspections and tests, the requirements of these inspections and tests will closely track the current requirements with some modifications made to address the unique operating environment of, and equipment operated in, commuter and intercity passenger train service. Members of the Working Group appeared receptive to this kind of classification system and discussed various options using some of this terminology. Consequently, FRA proposes four different types of brake inspections to be performed by commuter and intercity passenger railroads some time during the operation of the equipment. FRA proposes the terms ''Class I,'' ''Class IA,'' ''Class II,'' and ''running brake test'' to identify the four types of brake inspections required by this proposal.

FRA also proposes to divide passenger train operations into two distinct types for purposes of brake inspections and testing. FRA recognizes that there are major differences in the operations of commuter or short-distance intercity passenger trains, and long-distance intercity passenger trains. Commuter and short-distance intercity passenger trains tend to operate for fairly short distances between passenger stations and generally operate in relatively short turn-around service between two terminals several times in any given day. In contrast, long-distance intercity passenger trains tend to operate for long distances, with trips between the beginning terminal and ending terminal taking a day or more and traversing multiple states with relatively long distances between passenger stations. Consequently, FRA proposes to use and define the terms ''commuter train,'' ''short-distance intercity passenger train,'' and ''long-distance intercity passenger train'' in order to identify the inspection and

testing requirements associated with each. For the most part, commuter and short-distance intercity passenger trains are treated similarly, whereas, long-distance intercity passenger trains have slightly different proposed inspection and testing requirements. In addition, FRA proposes slightly different requirements with regard to the movement of defective equipment in long-distance intercity passenger trains (see the discussion below on the ''Movement of Equipment with Defective Brakes'').

APTA, in its comments on a draft of the NPRM, expressed opposition to the proposed Class IA brake test. APTA's position is that brake tests prior to a train's first departure in any day should be limited to a pre-departure set and release followed by a running test of the brakes. APTA also expresses the belief that the proposed NPRM Class I and Class II requirements go well beyond existing brake inspection processes and that which is required for safety, and that these requirements will increase costs dramatically.

A. Commuter and Short-Distance Intercity Passenger Trains Require a Class I Brake Test Sometime During a Day the Equipment Is Used

The proposed Class I brake test basically requires an inspection similar to an initial terminal inspection as currently described at § 232.12(c)–(j), but is somewhat more extensive and specifically aimed at the types of equipment being used in commuter and intercity passenger train service. A Class I brake test would require an inspection of the application and release of the friction brakes on each side of each car as well as an inspection of the brake shoes, pads, discs, rigging, angle cocks, piston travel, and brake indicators if the equipment is so equipped. The Class I brake test would also require testing of the communication signal system and the emergency braking control devices. In addition, all supplemental braking systems would be required to be inspected and be working. In recognition of the advanced technology and various designs used in many of these operations, which make observation of the piston travel virtually impossible, FRA proposes to permit the inspection of the piston travel to be conducted either through direct observation or by observation of a brake actuator or the clearance between the brake shoe and the wheel. Furthermore, FRA proposes to require a brake pipe leakage test only when leakage will affect service performance.

Although FRA agrees with the position advanced by many labor representatives that some sort of car-to-car inspection must be made of the brake equipment prior to the first run of the day, FRA does not agree that it is necessary to perform a full Class I brake test before the first run in order to ensure the proper functioning of the brake equipment. As FRA proposes that Class I brake tests be a comprehensive inspection of the braking system, including the proper operation of supplemental braking systems, FRA believes that commuter and short-distance intercity passenger train operations must be permitted some flexibility in conducting these inspections. Consequently, FRA proposes to require that commuter and short-distance intercity passenger train operations perform a Class I brake test sometime during the calendar day in which the equipment is used. FRA believes that the flexibility permitted by this proposed requirement will allow these railroads to move equipment to locations that are most conducive to the inspection of the brake equipment and would allow these railroads to combine the daily mechanical inspections with this brake inspection for added efficiency.

Furthermore, as FRA intends for these Class I brake inspections to be in-depth inspections of the entire braking system which most likely will be performed only one time in any given day in which the equipment is used, FRA believes that these inspections must be performed by individuals possessing not only the knowledge to identify and detect a defective condition in all of the brake equipment required to be inspected but also the knowledge to recognize the interrelational workings of the equipment and the ability to ''troubleshoot'' and repair the equipment. Therefore, FRA proposes that only qualified mechanical inspectors be permitted to perform Class I brake tests.

Currently, initial terminal air brake inspections are conducted prior to the first run of the day on 554 commuter train sets by mechanical inspectors and on 168 commuter train sets by train crews or other personnel who could not be fully qualified as mechanical inspectors. Typically, commuter and short-distance intercity passenger trains receive more than one initial terminal test each day, even if this is not required due to the equipment being left ''off air.'' *See* 49 CFR 232.12(a). Often these additional tests are conducted sometime during the middle of the day by train crews or mechanical employees. Although most commuter and short-distance intercity operations voluntarily perform an initial terminal brake inspection with mechanical employees some time during the day, there is no requirement to do so. In addition, there is a certain percentage of equipment where the principal brake inspections are currently being performed strictly by train crews rather than by mechanical employees. Consequently, FRA believes that the proposed requirement incorporates the current best practices of the industry and will, at a minimum, ensure that the braking systems on all commuter and short-distance intercity equipment will be inspected at least once each day by a fully qualified mechanical inspector.

FRA has not proposed any special provisions for weekend operations as suggested by some members of the Working Group. FRA recognizes this is a difficult issue. Existing operations generally involve using particular sets of equipment on only one day during the weekend to avoid the need to refuel. On the one hand, there is no specific data suggesting that existing weekend operations involving inspections exclusively by train crew members have created a safety hazard. Yet, the rationale for requiring daily attention by mechanical forces, a proposition generally accepted by Working Group members, would appear to apply equally to weekend periods. FRA believes that adjustments might be made to weekend operations that might avoid significant new expense while providing expert attention to inspection of the equipment. Accordingly, FRA seeks additional information on the costs and benefits of requiring that Class I brake inspections and daily mechanical inspections be conducted by qualified mechanical inspectors, as well as any suggestions for alternative means of addressing this issue.

B. Commuter and Short-Distance Intercity Passenger Trains Require at Least a Class IA Brake Test Prior to the Train's First Departure in Any Given Day

Although FRA agrees with the position advanced by many labor representatives that some sort of car-to-car inspection must be made of the brake equipment prior to the first run of the day, FRA does not agree that it is necessary to perform a full Class I brake test in order to ensure the proper functioning of the brake equipment in all situations. However, contrary to the position espoused by APTA, FRA believes that something more than just a determination that the brakes on the rear car set and release is necessary.

Currently, the quality of initial terminal tests performed by train crews is likely adequate to determine that

brakes apply on each car. However, most commuter equipment utilizes ''tread brake units'' in lieu of cylinders and brake rigging of the kind prevalent on freight and some intercity passenger cars. It is undoubtedly the case that train crew members do not verify application of the brakes by tapping brake shoes while the brakes are applied, the only effective means of determining that adequate force is being applied. This is one reason why the subject railroads typically conduct redundant initial terminal tests at other times during the day. Further, train crews are not asked to inspect for wheel defects and other unsafe conditions, nor should they be asked to do so, given the conditions under which they are asked to inspect and the training they receive.

FRA proposes that, at a minimum, a Class IA brake test be performed prior to a commuter or short-distance intercity passenger train's first departure on any given day. FRA believes that the proposed Class IA brake is sufficiently detailed to ensure the proper functioning of the brake system yet not so intensive that it requires individuals to perform an inspection for which they are not qualified.

The proposed Class IA brake test is somewhat less comprehensive than a Class I brake test but includes a detailed inspection of the brake system to verify the continuity of the brake system and the proper functioning of the brake valves on each car. A Class IA brake test would be similar to the intermediate brake inspection currently required for freight trains prescribed at § 232.13(d)(1). A Class IA brake test would generally require a walking inspection of the set and release of the brakes on each car; however, the proposal would allow brake indicators to be used to verify the set and release if the railroad determines that operating conditions pose a safety hazard to an inspector walking along the train. The Class IA brake test would also require a leakage test if leakage affects service performance, as well as an inspection of: angle cocks; piston travel, if determinable; brake indicators; emergency brake control devices; and communication of brake pipe pressure changes at the rear of train to the controlling locomotive. FRA believes that a qualified mechanical inspector or a properly trained and qualified train crew member could perform a Class IA brake test.

C. Long-distance Intercity Passenger Trains Require a Class I Brake Test Prior to Departure From an Originating Terminal and Once Each Calendar Day the Equipment Is Used or Every 1,500 Miles, Whichever Occurs First

As noted above, FRA recognizes the differences between commuter or short-distance intercity operations and long-distance intercity passenger train operations. Long-distance intercity passenger trains do not operate in shorter turn around service over the same sections of track on a daily basis for the purpose of transporting passengers from major centers of employment. Instead, these trains tend to operate for extended periods of time, over long distances with greater distances between passenger stations and terminals. Further, these trains may operate well over 1,000 miles in any 24 hour period. Thus, the opportunity for conducting inspections on these trains is somewhat diminished. Therefore, FRA believes that a thorough inspection of the braking system on these types of operations must be conducted prior to the train's departure from an initial starting terminal. Consequently, FRA will not permit the use of Class IA brake tests for these trains and proposes to require that a Class I brake inspection be performed on long-distance intercity passenger trains prior to departure from an initial terminal. FRA does not believe there would be any significant burden placed on these operations as the current regulations require that an initial terminal inspection be performed at these locations. Furthermore, virtually all of the initial terminal inspections currently conducted on these types of trains are performed by individuals who would be considered qualified mechanical employees under this proposal.

FRA also recognizes that these long-distance intercity passenger trains could conceivably travel over 3,000 miles if Class I inspections were required only once every 24 hours the equipment is in service as proposed for commuter and short-distance intercity passenger trains. Thus, FRA believes that some outside mileage limit must be placed on these trains between brake inspections. Currently, a passenger train is permitted to travel no further than 1,000 miles from its initial terminal, at which point it must receive an intermediate inspection of brakes that includes application of the brakes and the inspection of the brake rigging to ensure it is properly secured. *See* 49 CFR 232.12(b). However, in recognition of the improved technology used in passenger train brake systems combined with the comprehensive nature of the proposed Class I brake tests and mechanical safety inspections both being performed by qualified mechanical inspectors, FRA proposes to permit long-distance passenger trains to travel up to 1,500 miles between Class I brake tests. Consequently, FRA proposes to eliminate the 1,000-mile inspection for these trains and proposes to require that the proposed Class I brake test be performed once every calendar day that the equipment is used or every 1,500 miles, which every occurs first.

D. The Brake Inspection and Testing Intervals for Long-distance Intercity Passenger Trains Apply to All Tier II Equipment Regardless of Whether the Equipment is Used in Short- or Long-distance Intercity Trains

FRA also proposes to apply the brake inspection and testing intervals proposed for long-distance passenger trains to all Tier II equipment (i.e., equipment operating at speeds greater than 125 mph but not exceeding 150 mph) regardless of whether it is used in short- or long-distance intercity trains. As FRA proposes to permit operators of Tier II equipment to develop inspection and testing criteria and procedures, these operations will be required to develop a brake test that is equivalent to a Class I brake test for Tier II equipment. Due to the speeds at which this equipment will be allowed to operate, FRA believes it is a necessity that an equivalent Class I brake test be performed on Tier II equipment before it departs from its initial terminal. Likewise, FRA proposes to require that the equivalent Class I brake test be performed every calendar day in which the equipment is used or every 1,500 miles, whichever comes first.

E. Class II Brake Test Required Where Minor Changes to a Train Consist Occur

In addition to the proposed Class I and Class IA brake tests, FRA also proposes a Class II brake test. The proposed Class II brake test is an inspection intended to verify the continuity of the train brake system and is similar to the intermediate terminal inspection currently prescribed at § 232.13(a). A Class II brake test would basically require a set and release of the brakes on the rear car. The proposed Class II test would be required in those circumstances where minor changes to a train consist occur. These include the change of a control stand, the removal of cars from the consist, the addition of previously tested cars, and the situations in which an operator first takes control of the train.

F. Running Brake Tests

FRA also proposes to require a running brake test as soon as conditions safely permit it to be conducted after a train receives a Class I, Class IA, or Class II brake test. FRA believes that this test should be conducted in accordance with each railroad's operating rules. The ''running brake test'' requirement is similar to the ''running test'' requirements currently contained at § 232.16.

Movement of Equipment With Defective Brakes

The current regulations do not contain requirements pertaining to the movement of equipment with defective power brakes. The movement of equipment with these types of defects is currently controlled by a specific statutory provision originally enacted in 1910, which states:

> (a) GENERAL.—A vehicle that is equipped in compliance with this chapter whose equipment becomes defective or insecure nevertheless may be moved when necessary to make repairs, without a penalty being imposed under section 21302 of this title, from the place at which the defect or insecurity was first discovered to the *nearest available place at which the repairs can be made*—
>
> (1) On the railroad line on which the defect or insecurity was discovered; or
>
> (2) At the option of a connecting railroad carrier, on the railroad line of the connecting carrier, if not further than the place of repair described in clause (1) of this subsection.

49 U.S.C. 20303(a) (emphasis added).

Although there is no limit contained in 49 U.S.C. 20303 as to the number of cars with defective equipment that may be hauled in a train, FRA has a longstanding interpretation which requires that, at a minimum, 85 percent of the cars in a train have operative brakes. FRA bases this interpretation on another statutory requirement which permits a railroad to use a train only if ''at least 50 percent of the vehicles in the train are equipped with power or train brakes and the engineer is using the power or train brakes on those vehicles and on all other vehicles equipped with them that are associated with those vehicles in a train.'' 49 U.S.C. 20302(a)(5)(B). As originally enacted in 1903, section 20302 also granted the Interstate Commerce Commission (ICC) the authority to increase this percentage, and in 1910 the ICC issued an order increasing the minimum percentage to 85 percent. See 49 CFR 232.1, which codified the ICC order.

As virtually all freight cars are presently equipped with power brakes and are operated on an associated trainline, the statutory requirement is in essence a requirement that 100 percent of the cars in a train have operative power brakes, unless being hauled for repairs pursuant to 49 U.S.C. 20303. Consequently, FRA currently requires that equipment with defective or inoperative air brakes makeup no more than 15 percent of the train and that, if it is necessary to move the equipment from where the railroad first discovered it to be defective, the defective equipment be moved no further than the nearest place on the railroad's line where the necessary repairs can be made or, at the option of the receiving carrier, to a repair point that is no further than the repoint on the delivering line.

The requirements regarding the movement of equipment with defective or insecure brakes noted above can and do create safety hazards as well as operational difficulties in the area of commuter and intercity passenger railroad operations. As the provisions regarding the movement of defective brake equipment were written almost a century ago, they do not address the realities of these types of operations in today's world. Strict application of the requirements has the potential of causing major disruptions of service which result in the creation of serious safety and security problems. For example, requiring repairs to be made at the nearest location where the necessary repairs can be made could result in passengers being discharged between stations where adequate facilities for their safety are not available or in the overcrowding of station platforms and trailing trains due to discharging passengers from a defective train at a location other than the passenger's destination. In addition, strict application of the statutory requirements could result in the moving of trains with defective brake equipment against the current of traffic during busy commuting hours. Irregular movements of this type increase the risk of collisions on the railroad. Furthermore, many of today's commuter train operations often utilize six cars or less in trains and in many instances operate just two-car trains. Consequently, the necessity to cut out the brakes on one car can easily result in noncompliance with the 85-percent requirement for hauling the car for repairs, thus prohibiting the train's movement and resulting in the same type of safety problems noted above.

FRA has attempted to recognize the nature of commuter and intercity passenger operations and the importance of addressing the safety of passengers, as well as avoiding disruption of this service, when applying the requirements regarding the movement of equipment with defective brakes on a day-to-day basis. In addition, the representatives of commuter and intercity passenger train operations participating in this proceeding have requested that the regulations be brought up to date, recognizing that brakes will have to be cut out en route from time to time (e.g., because of damage from debris placed on the track structure or because of sticking brakes) and that contemporary braking systems and established stopping distances provide a very considerable margin of safety. Furthermore, speed restrictions can readily be used to compensate for the loss of brakes on a minority of cars. FRA believes that affirmatively recognizing appropriate movement restrictions would actually enhance safety, since compliance with the existing restrictions is potentially unsafe.

Representatives from APTA proposed a method of updating the current requirements regarding the movement of commuter passenger equipment with defective brakes to bring them more in line with the realities of today's operations. The Working Group discussed the proposal at length, making various revisions. Although the Working Group did not reach consensus on the issue, FRA believes that the proposed requirements are within the scope of options discussed by the group. FRA believes that the proposed restrictions are very conservative and effectively ensure a high level of safety in light of the reliability of braking systems currently used in commuter and intercity passenger train operations.

FRA recognizes that some of the proposed restrictions are not in accord with the requirement contained in 49 U.S.C. 20303(a) that cars with defective or insecure brakes be moved to the ''nearest'' location where the necessary repairs can be made. However, FRA does have authority under 49 U.S.C. 20306, entitled ''Exemption for technological improvements,'' to establish the proposed restrictions. Section 20306 provides:

> [T]he Secretary of Transportation may exempt from the requirements of this chapter railroad equipment or equipment that will be operated on rails, when those requirements preclude the development or implementation of more efficient railroad transportation equipment or other transportation innovations under existing law.

This provision was originally enacted as a part of the Rock Island Railroad Transition and Employee Assistance Act to authorize the use of RoadRailer® trailers as freight cars. *See* Pub. L. 96–

254 (May 30, 1980). Although it could be argued that the purpose of the provision is too narrow to comprehend the instant application, FRA believes that the use of the provision as contemplated in this proposal is consistent with the authority granted the Secretary of Transportation in 49 U.S.C. 20306. As noted previously, the statutory requirements regarding the movement of equipment with defective brake equipment were written nearly a century ago and, in FRA's opinion, were focused generally on the operation of freight equipment and did not contemplate the types of commuter and intercity passenger train operations currently prevalent throughout the nation. Since the original enactment in 1910 of the provisions now codified at 49 U.S.C. 20303(a), there have been substantial changes both in the nature of the operations of passenger trains as well as in the technology used in those operations.

Contemporary passenger equipment incorporates various types of advanced braking systems; in some cases these include electrical activation of brakes on each car (with pneumatic application through the train line available as a backup). Dynamic brakes are also typically employed to limit thermal stresses on friction surfaces and to limit the wear and tear on the brake equipment. Furthermore, the brake valves and brake components used today are far more reliable than was the case several decades ago. In addition to these technological advances, the brake equipment used in commuter and intercity passenger train operations incorporate advanced technologies not found with any regularity in freight operations. These include:

- The use of brake cylinder pressure indicators which provide a reliable indication of the application and release of the brakes.
- The use of disc brakes which provide shorter stopping distances and decrease the risk of thermal damage to wheels.
- The ability to effectuate a graduated release of the brakes due to a design feature of the brake equipment which permits more flexibility and more forgiving train control.
- The ability to cut out brakes on a per-axle or per-truck basis rather than a per car basis, thus permitting greater use of those brakes that are operable.
- The use of a pressure-maintaining feature on each car which continuously maintains the air pressure in the brake system, thereby compensating for any leakage in the trainline and preventing a total loss of air in the brake system.
- The use of a separate trainline from the locomotive main reservoir to continuously charge supply reservoirs independent of the brake pipe train line.
- Brake ratios that are 2½ times greater than the brake ratios of loaded freight cars.

Although some of the technologies noted above have existed for several decades, most of the technologies were not in wide spread use until after 1980. Furthermore, most of the noted technological advances just started to be integrated into one efficient and reliable braking system within the last decade. In addition to the technological advances, commuter and intercity passenger train operations have experienced considerable growth in the last 15 years necessitating the need to provide more reliable and efficient service to the riding public. Since 1980, the number of commuter operations providing rail service has almost doubled and the number of daily passengers serviced by passenger operations has more than doubled over the same time period. Furthermore, commuter and intercity passenger train operations conduct more frequent single car tests, COT&S, and maintenance of the braking systems than is generally the practice in the freight industry. Consequently, the technology incorporated into the brake equipment used in today's commuter and intercity passenger train operations has increased the reliability of the braking system and permits the safe operation of the equipment for extended distances even though a portion of the braking system may be inoperative or defective.

In the face of these technological advances, FRA believes it is appropriate to utilize the authority granted by 49 U.S.C. 20306 and exempt commuter and intercity passenger train operations from the specific restriction contained in 49 U.S.C. 20303(a) requiring the movement of equipment with defective or insecure brakes to the nearest location where the necessary repairs could be made and proposes various restrictions on the movement of this type of equipment which FRA believes are more conducive to safe operations.

In utilizing the authority granted pursuant to 49 U.S.C. 20306, the Secretary is required to make ''findings based on evidence developed at a hearing,'' unless there is ''an agreement between national railroad labor representatives and the developer of the new equipment or technology.'' FRA is confident that, after notice and opportunity for public comment, oral and written, the record will support a finding that the proposed provisions are ''in the public interest and consistent with railroad safety,'' the basic test for waiving safety requirements issued under other, general provisions of the code. *See* 49 U.S.C. 20103(d). It should be noted that the exemption granted to these operations does not include an exemption from 49 U.S.C. 20303(c), which contains the liability provisions attendant with the movement equipment with defective or insecure safety appliances, including power brakes. Consequently, the liability provisions contained in 49 U.S.C. 20303(c) will be applicable to a railroad when hauling equipment with defective or insecure power brakes pursuant to the requirements proposed by FRA in this notice.

FRA also proposes to exempt commuter and intercity passenger train operations from its longstanding interpretation, based on 49 U.S.C. 20302(a)(5)(B) and 49 CFR 232.1 noted above, prohibiting the movement of a train if more than 15 percent of the cars in the train have defective, insecure, or inoperative brakes. As discussed previously, such a limitation is overly burdensome and has the potential of creating safety hazards due to the short length of the trains commonly operated in commuter and intercity passenger service.

Based on the preceding discussions, FRA proposes various restrictions on the movement of vehicles with defective brake equipment which allow commuter and intercity passenger train operations to take advantage of the efficiencies created due to the advanced braking systems these operations employ as well as the improvements made in brake equipment over the years, while ensuring if not enhancing the safety of the traveling public. FRA proposes to permit trains to be operated with up to 50 percent inoperative brakes to the next forward passenger station or terminal based on the percentage of operative brakes, which may result in movements past locations where the necessary repairs could be made. However, to ensure the safety of these trains with lower percentages of operative brakes, FRA also proposes various speed restrictions and other operating restrictions, based on the percentage of operative brakes. FRA believes that the proposed speed restrictions are very conservative and ensure a high level of safety. In fact, test data establish that with the proposed speed restrictions the stopping distances of those trains with lower percentages of operative brakes are shorter than if the trains were operating at normal speed and had 100 percent operative brakes. Consequently, FRA believes that the proposed approach to the movement of

equipment with defective brakes not only enhances the overall safety of train operations but benefits both the railroads, by providing operational flexibility, and the traveling public, by permitting them to get to their destinations in a more expedient and safe fashion. (The proposed restrictions on the movement of equipment with defective brakes are discussed in detail in the section-by-section analysis below.)

Although FRA proposes to exempt all commuter and passenger operations from the specific statutory requirement contained in 49 U.S.C. 20303(a), it should be noted that in reality the exemption being proposed is fairly limited. In FRA's view, many of the proposed methods for moving defective equipment are consistent, if not in accordance, with the current statutory requirement. For example, FRA proposes to permit a passenger train with 50–75 percent operative brakes to be moved at reduced speed to the next forward passenger station. Although the percentage of operative brakes is lower than currently permitted by FRA's longstanding agency interpretation (which FRA believes is fully compensated for by the proposed speed restrictions), FRA believes that the movement of the defective equipment to the next passenger station is in accordance with the statutory requirement as the safety of the passengers must be considered in determining the nearest location where necessary repairs can be made. In addition, permitting passenger trains to continue to the next forward location where the necessary repairs can be performed is also consistent with the statutory requirement as such movement is necessary to ensure the safety of the traveling public by protecting them from the hazards incident to performing movements against the current of traffic. Furthermore, the proposed movement provisions related to long-distance intercity passenger trains and long-distance Tier II equipment are consistent with the current statutory requirements as the proposal permits the movement of defective brake equipment on these trains only to the next passenger station or the next repair location, with various speed restrictions depending on the percentage of operative brakes. Due to the unique technologies used on the brake systems of these operations and the unique operating environments, the facilities and personnel necessary to conduct proper repairs on this equipment are somewhat specialized and limited. Thus, FRA proposes to require the operators of these trains to designate the locations where repairs will be made to the equipment.

Some of the members of the Working Group, particularly those representing labor organizations, expressed concern that any alteration of the movement for repair provisions made in the context of commuter and intercity passenger train operations may have a spillover effect into the freight industry. FRA wishes to make clear that it has no intention, at this time, of exempting freight operations from the requirements relating to the movement of defective equipment contained in 49 U.S.C. 20303. As noted above, many of the advanced brake system technologies currently used in passenger service are not used in the freight context. Furthermore, even if freight operations were to make similar advances in the braking equipment they employ, this development on the freight side may not create the efficiencies created in the passenger train context since the operating environments of freight trains and passenger trains differ significantly. Finally, the special safety considerations relative to passengers are not present in freight operations.

Structural Standards

To help ensure the survivability of a passenger train accident, FRA is proposing comprehensive, minimum safety standards for the structural design of rail passenger equipment. Under current regulations, MU locomotives must comply with minimum structural design requirements, *see* 49 CFR 229.141; however, no comparable set of Federal structural design requirements apply to other forms of passenger equipment. Moreover, FRA believes that existing structural design requirements for MU locomotives should be revised, particularly those concerning MU locomotives operating in trains having a total empty weight of less than 600,000 pounds, *see* § 229.141(b), because train operation has significantly changed since these requirements were first promulgated.

The requirements contained in the proposed rule for the structural design of Tier I and Tier II equipment are specified below in the section-by-section analysis. These requirements include safety standards for the following:

- Anti-climbers—to prevent vehicles in a passenger train from overriding or telescoping into one another;
- Collision posts—to protect against the crushing of a passenger vehicle's occupied areas in the event of a collision or derailment;
- Corner posts—to protect passenger vehicles in corner-to-corner collisions and impacts with objects intruding upon the clearance envelope;
- Rollover strength—to prevent significant deformation of the normally occupied spaces of a vehicle in the event it rolls onto its side or roof;
- Side impact strength—to resist penetration of a passenger vehicle's side structure from a side collision with an object such as a highway vehicle or a freight car; and
- Truck to car body attachment—to prevent separation of trucks from car bodies during collisions or derailments.

Corner Posts

Requirements concerning corner posts on rail passenger equipment have been the subject of an NTSB safety recommendation. Following the January 18, 1993, NICTD corner-to-corner train collision in Gary, Indiana, the NTSB expressed concern about the adequacy of the corner post structure in self-propelled passenger cars (MU locomotives) that allows significant inward car body intrusion and subsequent serious injuries and fatalities in a corner-to-corner collision. The NTSB noted that, while MU locomotives must comply with Federal structural design requirements which include providing for the protection of vulnerable areas of the car body in a head-on collision, Federal regulations do not address structural requirements for corner posts which protect the car body in a corner-to-corner collision. Based on its investigation, the NTSB recommended that FRA:

> In cooperation with the Federal Transit Administration and the American Public Transit Association, study the feasibility of providing car body corner post structures on all self-propelled passenger cars and control cab locomotives to afford occupant protection during corner collisions. If feasible, amend the locomotive safety standards accordingly. (Class II, Priority Action) (R–93–24)

The Working Group has recommended that minimum corner post structural design requirements be proposed for both locomotives and rail cars designed to carry passengers, regardless whether the rail cars are self-propelled or have control compartments. FRA is proposing such a requirement in this rule and thereby extending the scope of the NTSB's safety recommendation, which is expressly limited to self-propelled rail cars. This action recognizes passenger exposure in accidents such as the one in Lugoff, South Carolina, on July 31, 1991. There, eight passengers were killed following incursion of a freight car into

the side of two Amtrak coaches beginning at the corner of each car.

For cab cars, material improvements in actual end structure design with respect to corner posts must await completion of further research. Research completed to date indicates that improvements in strength alone will not prevent casualties in accidents at higher closing speeds such as those in the Silver Spring, Maryland, and Secaucus, New Jersey, accidents.

Fuel Tank Standards

Locomotive fuel tanks are vulnerable to damage from collisions, derailments, and debris on the roadbed due to their location on the underframe and between the trucks of locomotives. Damage to the tank frequently results in spilled fuel, creating the safety problem of an increased risk of fire and the environmental problem of cleanup and restoration of the spill site. Although 49 CFR 229.71 does require a minimum clearance of 2.5 inches between the top of the rail and the lowest point on a part or appliance of a locomotive, which includes fuel tanks, FRA regulations do not address the safety of fuel tanks in particular.

In 1992, the NTSB issued a report identifying concerns regarding safety problems caused by diesel fuel spills from ruptured or punctured locomotive fuel tanks. Entitled ''Locomotive Fuel Tank Integrity Safety Study,'' the NTSB report cited in particular a collision involving an Amtrak train and an MBTA commuter train on December 12, 1990, as both trains were entering a station in Boston, Massachusetts. (NTSB Safety Study-92/04.) Fuel spilled from a tank which had separated from an Amtrak locomotive during the collision. The fuel ignited. Smoke and fumes from the burning diesel fuel filled the tunnel, increasing the hazard level in the post-crash phase of the accident, and hindering emergency response activity. As a result of the safety study, the NTSB made several safety recommendations to FRA, including in particular that FRA:

Conduct, in conjunction with the Association of American Railroads, General Electric, and the Electro-Motive Division of General Motors, research to determine if the locomotive fuel tank can be improved to withstand forces encountered in the more severe locomotive derailment accidents or if fuel containment can be improved to reduce the rate of fuel leakage and fuel ignition. Consideration should be given to crash or simulated testing and evaluation of recent and proposed design modifications to the locomotive fuel tank, including increasing the structural strength of end and side wall plates, raising the tank higher above the rail, and using internal tank bladders and foam inserts. (Class II, Priority Action) (R–92–10)

Establish, if warranted, minimum performance standards for locomotive fuel tanks based on the research called for in recommendation R–92–10. (Class III, Longer Term Action) (R–92–11)

The NTSB reiterated Safety Recommendation R–92–10 in a letter to FRA dated August 28, 1997, conveying the NTSB's final safety recommendations arising from the February 16, 1996, collision between a MARC commuter train and an Amtrak passenger train. During the collision, the fuel tank on the lead Amtrak locomotive ruptured catastrophically. The fuel sprayed into the exposed interior of the MARC cab control car and ignited, engulfing the car. (Letter at 12.)

As explained in FRA's report to Congress on locomotive crashworthiness and working conditions, FRA believes that fuel tank design has a direct impact on safety. Minimum performance standards for locomotive fuel tanks should be included in Federal safety regulations. Accordingly, FRA is proposing that AAR Recommended Practice RP–506 be incorporated into § 238.223 of the proposed rule for external fuel tanks on Tier I passenger locomotives. FRA believes that RP–506 represents a good interim safety standard for Tier I passenger locomotives. Further, FRA is proposing more demanding fuel tank safety standards for Tier II passenger equipment in § 238.423 of the proposed rule. Additionally, it is anticipated that RSAC will address the safety of locomotive fuel tanks used on freight equipment, thereby furthering the safety of rail passenger trains which operate commingled with freight trains.

FRA invites comments whether the proposed rule should also require that locomotive fuel tanks be compartmentalized. The Working Group specifically discussed requiring whether the interior of fuel tanks be divided into a minimum of four separate compartments so that a penetration in the exterior skin of any one compartment results in loss of fuel only from that compartment. The Working Group recommended that such a requirement be addressed in the second phase of the rulemaking, to allow for additional research to remedy fuel feeding disruptions that may result from the compartmentalization of fuel tanks. Commenters are therefore requested to provide the results of specific research and operating experience showing how compartmentalization can be practically accomplished. Commenters are also asked to explain why the issue of compartmentalization should or should not be addressed in the final rule of this first phase of the rulemaking.

Rim-Stamped Straight-Plate Wheels

On January 13, 1994, a Ringling Bros. and Barnum & Bailey Circus (Ringling Bros.) train operating on CSXT trackage derailed while passing through Lakeland, Florida. Two circus employees were killed, and 15 received minor injuries. The NTSB determined that the probable cause of the accident was the fatigue failure of a thermally damaged straight-plate wheel due to fatigue cracking that initiated at a stress raiser associated with a stamped character on the wheel rim. (NTSB/RAR–95/01.)

Noting that tread braking is a significant source of wheel overheating and thermal damage; straight-plate wheels are vulnerable to thermal damage; and rim stamping provides a stress concentration for crack initiation, the NTSB recommends as a result of its investigation that FRA ''[p]rohibit the replacement of wheels on any tread-braked passenger railroad car with rim-stamped straight-plate wheels.'' (Class II, Priority Action) (R–95–1).

FRA agrees that rim stamping of straight-plate wheels can lead to wheel failure when subjected to heat from tread braking. Rim-stamping was banned by the AAR in 1978, and FRA does not believe that rim-stamped straight-plate wheels are in use on Amtrak or the nation's commuter railroads. Nevertheless, in the event such wheels are in fact in use, FRA proposes to prohibit the use of rim-stamped straight-plate wheels on all equipment, whether tread-braked or not, used in intercity passenger or commuter service as of January 1, 1998. In a letter to the NTSB dated February 21, 1995, Ringling Bros. itself announced that it has removed all rim-stamped straight-plate wheels on tread-braked passenger cars from its circus trains. (Appendix D, NTSB/RAR–95/01.)

At this time, FRA is not proposing to prohibit the use of rim-stamped straight-plate wheels on private passenger cars hauled in intercity passenger or commuter trains. Private passenger cars are generally not highly utilized in comparison to intercity passenger or commuter equipment. According to a comment received from the AAPRCO, the average private car, qualified to operate on Amtrak, probably operates less than 4,000 miles per year, and a few may exceed 50,000 miles per year. Further, in a letter to the NTSB dated December 2, 1994, Amtrak stated that it only operates private cars that are registered with Amtrak and are subject to a regular inspection by Amtrak-approved inspectors. Amtrak observed that it ''has not experienced any

problems on the private cars that operate on Amtrak trains with wheels that are rim-stamped.'' (Appendix E, NTSB/RAR–95/01.)

However, FRA is requiring that rim-stamped straight-plate wheels not be used as a replacement wheelset on a private car. As part of this rulemaking, FRA may further address the use of rim-stamped straight-plate wheels on private cars hauled in intercity passenger or commuter trains.

Fire Safety

In 1984, FRA published guidelines recommending testing methods and performance criteria for the flammability, smoke emission, and fire endurance characteristics for categories and functions of materials to be used in the construction of new or rebuilt rail passenger equipment. *See* 49 FR 33076, Aug. 20, 1984; 49 FR 44582, Nov. 7, 1984. The guidelines mirrored fire safety guidelines developed by the Urban Mass Transit Administration (UMTA) of DOT (now the Federal Transit Administration).

The intent of the guidelines is to prevent fire ignition and to maximize the time available for passenger evacuation if fire does occur. FRA later reissued the guidelines in 1989 to update the recommended testing methods. *See* 54 FR 1837, Jan. 17, 1989. Testing methods cited in the current FRA guidelines include those of the American Society of Testing and Materials (ASTM) and the Federal Aviation Administration (FAA). In particular, the ASTM and FAA testing methods provide a useful screening device to identify materials that are especially hazardous.

FRA sought comments in the ANPRM on the need for more thorough guidelines or Federal regulations concerning fire safety (61 FR 30696). FRA noted that fire resistance, detection, and suppression technologies have all advanced since the guidelines were first published. In addition, FRA explained that a trend toward a systems approach to fire safety is evident in most countries with modern rail systems. In response, the National Fire Protection Association (NFPA) commented that perhaps more thorough guidelines are needed, or at least should be evaluated. A private citizen also responded that, at a minimum, guidelines which are more in depth and ''well thought out''—based on current system safety procedures and available fire safety engineering techniques—are needed to address the fire safety concerns FRA raised in the ANPRM. The commenter noted in particular that Federal maintenance standards related to fire safety are necessary to ensure that materials carefully qualified for use in rail passenger vehicles because of their fire safety characteristics are not replaced with either substandard materials or materials whose origin and fire performance cannot be determined.

The proposed rule addresses fire safety by making FRA's fire safety guidelines mandatory for the construction of new passenger equipment as well as the refurbishing of existing equipment. In addition, the proposed rule would require that fire safety be furthered through a fire protection plan and program carried out by each operating railroad. This effort would include conducting a fire safety analysis of existing passenger equipment and taking appropriate action to reduce the risk of personal injuries. In the second phase of this rulemaking, FRA anticipates improving upon the safety standards contained in the existing fire safety guidelines through ongoing research.

Currently, the National Institute of Standards and Technology (NIST) is conducting research under the direction of FRA and the Volpe Center involving the fire safety of rail passenger vehicles. The NIST project, scheduled for completion in 1998, will investigate the use of alternative fire testing methods and computer hazard assessment models to identify and evaluate approaches to passenger train fire safety. The evaluation will examine the effects and tradeoffs of passenger car and system design (including materials), fire detection and suppression systems, and passenger egress time. A peer review committee has been established to provide project guidance and review interim results and reports. The committee includes representatives from FRA, the Volpe Center, the NFPA, builders of rail passenger vehicles, producers of materials, Amtrak and commuter railroads, and testing laboratories.

In the first phase of the NIST project, selected materials which satisfy the testing methods referenced in FRA's fire safety guidelines will be evaluated using a different testing instrument, the ASTM 1354 Cone Calorimeter. The Cone Calorimeter provides a measurement of heat release rate (the amount of energy that a material produces while burning), specimen mass loss, smoke production, and combustion gases. For a given confined space such as a rail car interior, the air temperature and risk of harm to passengers are increased as the heat release rate increases. As a result, even if passengers do not come in direct contact with a fire, they may likely be injured from the high temperatures, high heat fluxes, and large amounts of toxic gases emitted by materials involved in the fire.

The NIST testing will help develop performance criteria for materials using the Cone Calorimeter in a context similar to that provided in the FRA fire safety guidelines. In addition, unlike data derived from the testing methods referenced in the current FRA guidelines, heat release rate and other measurements obtained from the Cone Calorimeter can be used in a fire modeling methodology to evaluate the contribution of materials to the overall fire safety of a passenger train. Data gathered from the NIST testing will be used in the second phase of the project to perform a fire hazard analysis of selected passenger train fire scenarios. The analysis will employ computer modeling to assess the impact on passenger train fire safety for a range of construction materials and system design. In the final phase of the project, selected real-scale proof testing of assemblies representing rail passenger equipment will be performed to verify the bench-scale (small-scale) criteria and hazard analysis studies in actual end use configurations. This research effort thus follows upon FRA-sponsored studies by the National Bureau of Standards in 1984 and the NIST in 1993 which noted among their findings that the performance of individual components of a rail passenger car in a real-world fire environment may be different from that experienced in bench-scale tests due to vehicle geometry and materials interaction.[2]

The NFPA publishes a standard (NFPA 130) covering fire protection requirements for fixed guideway transit systems and for life safety from fire in transit stations, trainways, vehicles, and outdoor maintenance and storage areas. (A copy of the 1995 edition of this standard has been placed in the public docket for this rulemaking.) However, this standard does not apply to passenger railroad systems including those that provide commuter service (NFPA 130 1–1.2). An APTA representative on the Working Group who is also an NFPA member has initiated an NFPA-sponsored task force to revise the scope of NFPA 130 to cover all passenger rail transportation systems, including intercity and

[2] ''Fire Tests of Amtrak Passenger Rail Vehicle Interiors.'' (NBS Technical Note 1193, May 1984); ''Fire Safety of Passenger Trains: A Review of U.S. and Foreign Approaches.'' (DOT/FRA/ORD–93/23–DOT–VNTSC–FRA–93–26, December, 1993). The 1993 report is available to the public through the National Technical Information Service, Springfield, VA 22161. A copy of both reports have been placed in the public docket for this rulemaking.

commuter rail, and revise other provisions as necessary. (Copies of the correspondence concerning the establishment of this task force have also been placed in the public docket.) FRA and the Working Group will evaluate the results of this effort for application to this rulemaking.

Safety Glazing Standards

Existing regulations found in 49 CFR part 223 provide minimum requirements for glazing materials in order to protect railroad passengers and employees from injury as a result of objects striking the windows of locomotives, cabooses, and passenger cars. Noting some possible concerns with these requirements, FRA sought comment on whether these standards should be revised and requested information on any glazing-related injuries to passenger train occupants (61 FR 30696).

The Sierracin/Sylmar Corporation (Sierracin) commented that rail glazing meeting much higher impact and ballistic requirements is currently available, economically viable, and in fact in use by a few rail agencies (mass transit and commuter rail) here in the United States. Among its observations in particular, Sierracin noted that the strength of the glazing frame could quite easily be tested. Further, it explained that from its experience as a glazing manufacturer it is aware of very few ballistic attacks on trains, and such attacks have been limited to the side windows of locomotives or coach cars or both—not to end-facing windows. In addition, Sierracin pointed out that since the impact energy of an object is a function of velocity, an object's destructive capability increases as the speed of the surface it impacts increases.

FRA believes that existing safety glazing requirements have largely proven effective in passenger service at speeds up to 125 mph. In fact, FRA is concerned that less stringent requirements would create vulnerability to objects thrown at trains as well as the risk of ejection of passengers during train derailments. Because the safety glazing standards do not address the performance of the frame which attaches the glazing to the car body, FRA is proposing frame performance requirements for all passenger equipment. Moreover, FRA believes that more stringent glazing requirements are necessary or passenger equipment operating at speeds greater than 125 mph because of the increased destructive potential of an object impacting equipment operating at such speeds. Additionally, improved marking and periodic inspection of emergency windows are being addressed in FRA's emergency preparedness rulemaking.

Train Interior Safety Features

A review of the accident/incident data, related to fatalities and injuries on passenger trains for the period of 1972 to 1973, indicates that collapse of the equipment structure and the loss of sufficient space for the passengers to ride out the collision is the principal cause of fatality in train accidents, resulting in approximately 63 percent of the fatalities and 27 percent of the serious injuries. Fire and post-collision conditions result in 30 percent of the fatalities and 16 percent of the serious injuries. Thus, collapse of the equipment structure, fire, and post-collision conditions account for 93 percent of the fatalities and 43 percent of the serious injuries. To address these major causes of fatalities and injuries, FRA is proposing comprehensive requirements related to structural design, fire protection, and emergency exits. As discussed above, FRA believes these proposed requirements will aid in reducing the number of fatalities and injuries by minimizing the collapse of equipment, reducing the likelihood of fire, and ensuring accessible and operable emergency exits.

Prior research also indicates, however, that passengers striking interior objects in trains, principally during collisions and derailments, accounts for 57 percent of the serious injuries and 7 percent of the fatalities occurring on passenger trains. [3] Therefore, as an initial measure to reduce these numbers, FRA proposals include requiring that:

- Passenger seats and other interior fittings be securely attached to the car body;
- Interior fittings in a passenger car be recessed or flush-mounted;
- Overhead storage racks provide restraint for stowed articles; and
- Sharp edges be padded or otherwise avoided.

Overall, FRA's proposed requirements rely on ''compartmentalization'' or ''passive restraints'' (i.e., requiring no action to be taken on the part of the occupant) as a passenger protection strategy. The proposed requirements are based on the current available research, discussed in detail below, which indicates that during a collision the interior environment of a passenger coach is substantially less hostile than the interiors of automobiles and aircraft. In fact, current research indicates that the interior of a typical intercity passenger coach without active restraints provides a level of protection to the occupants that is at least as high as that provided to automobile and transport aircraft passengers with active restraints.

Some research indicates that there may be a potential for even a greater level of passenger protection if lap belts and shoulder harnesses are utilized on passenger trains. In fact, FRA is proposing that lap belts and shoulder harnesses be required in the cab of a Tier II train, as recommended by the Tier II Equipment Subgroup. Due to the high strength of the cab and its forward location near the expected point of impact in many different collision scenarios, decelerations experienced by crewmembers in the cab of Tier II trains may be high. Accordingly, members of the subgroup believed that restraints for the crewmembers could provide a significant benefit. FRA requests information and comment from interested parties as to whether there is any existing research or experience which would justify proposing active seat restraints in the current stage of this rulemaking. However, FRA believes more research is necessary in this area in order to determine the feasibility and effectiveness of such active restraints as well as the impact on seat design and strength. Although FRA currently proposes a passenger protection strategy based on compartmentalization, FRA will be undertaking an aggressive research and testing program to determine the feasibility and effectiveness of active restraints such as lap belts and shoulder harnesses. If this research indicates that these types of active restraints are a viable and feasible means of providing additional protection to the riding public, then FRA will propose the use of such restraints in the second NPRM on passenger equipment scheduled for development in 1998.

Discussion

The principal means of protecting occupants during accidents include ''friendly'' (''delethalized'') interior arrangements and occupant restraints, such as lap belts, shoulder harnesses and airbags. Occupant protection devices which require some action on the part of the occupant, such as buckling a seatbelt, are termed ''active devices,'' while protection devices which require no action, such as automobile door-mounted shoulder harnesses and airbags, are termed ''passive devices.'' Both active and passive occupant protection strategies

[3] Rail Safety/Equipment Crashworthiness,'' M.J. Reiley, R.H. Jines, & A.E. Tanner. (FRA/ORD–77/73, Vol. I, July 1978).''

act to limit the decelerations and to distribute the loads imparted to occupants during an accident. Typical passenger protection strategies in automobiles include airbags, lap belts and shoulder harnesses, and friendly lower dashboard designs which limit thigh loads imparted during a collision. Typical passenger protection strategies in transport category aircraft, intended to protect passengers during accidents occurring during takeoff or landing, include seatbelts and friendly design of the seatback or bulkhead ahead of the occupant which limit the decelerations of the occupant's head.

The passenger protection devices incorporated into a vehicle must allow occupants to survive the deceleration of the volume within which they are contained. The decelerations of the occupant volume of an automobile in a collision can reach a peak of approximately 30 g's, while the decelerations of transport-category aircraft during a landing accident can reach 18 g's. In order to assure a high likelihood of survival for such high decelerations, the use of occupant restraints are required in automobiles and transport aircraft. The peak deceleration of passenger rail coach equipment is 8 g's for a head on collision. Figure 1 shows the time histories of the occupant volume decelerations for a Ford Taurus colliding into a rigid barrier at 35 mph,[4] a transport category aircraft during a landing accident,[5] and a rail passenger coach during a train-to-train collision at 70 mph.[6] During a collision, the interior of a passenger train is inherently a less hostile environment than those of an automobile or aircraft, owing to the relatively low deceleration of the occupant volume.

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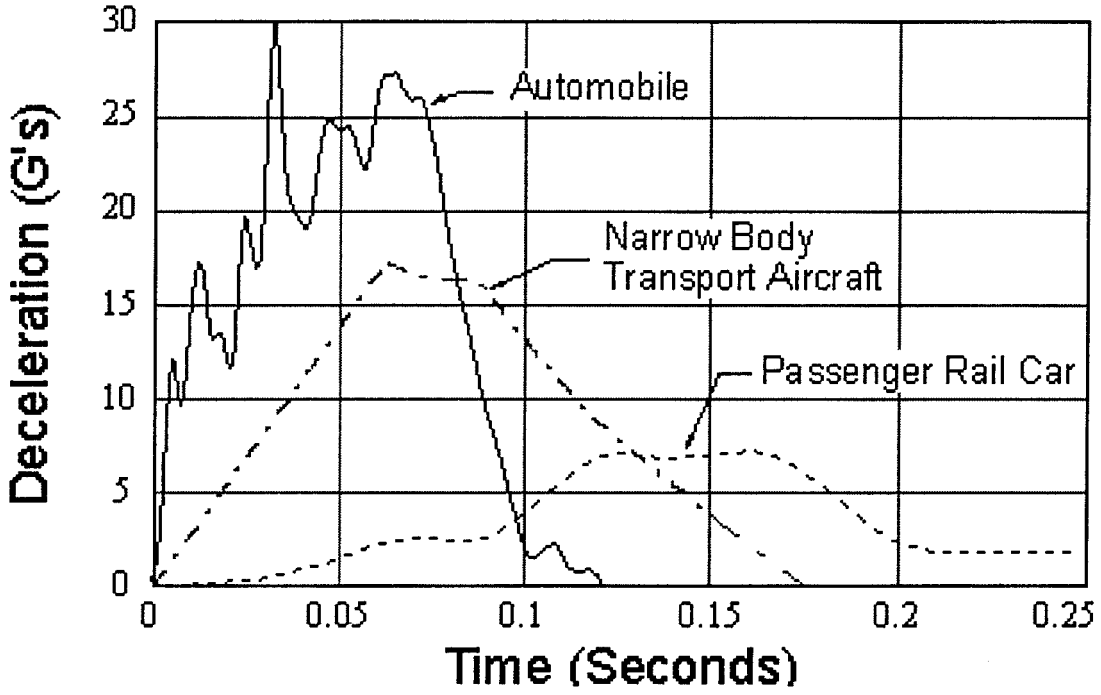
Figure 1.

Typical Automobile, Transport Aircraft, and Passenger Rail Car Decelerations During a Collision



[4] New Car Assessment Program Test #2312. DOT/NHTSA, 1996. A copy of this test has been placed in the public docket for this rulemaking.

[5] The Effect of Aircraft Size on Cabin Floor Dynamic Pulses.'' G. Wittlin, L. Neri. (DOT/FAA/CT–88/15, March 1990). The report is available to the public through the National Technical Information Service, Springfield, VA 22161. A copy of the report has also been placed in the public docket for this rulemaking.

[6] ''Crashworthiness of Passenger Trains.'' (DOT–VNTSC–FRA–96–5, September 1996). The report has not yet been published, but a copy of the report has been placed in the public docket for this rulemaking.

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Simulation studies of occupant impacts with interiors have been conducted in support of this rulemaking effort, and have been placed in the public docket for this rulemaking.[7] Simulation results include detailed time-histories of occupant motions and the forces imparted to occupants during a collision. These motions and forces have been evaluated for the potential for fatality using the criteria employed by the National Highway Traffic Safety Administration (NHTSA) and the FAA in their regulatory requirements for passenger protection in automobiles and transport-category aircraft, respectively. The principal criteria employed by NHTSA and the FAA are the Head Injury Criteria (HIC), which relate the deceleration of the occupant's head to the potential for fatality, and the Chest Deceleration, which relates the deceleration of the occupant's chest (heart) with the potential for fatality. The maximum limit prescribed by NHSTA and the FAA for the HIC is 1000, and 60 g's for Chest Deceleration.

Passenger rail equipment interior configurations studied include rows of forward-facing seats without passenger restraints, with seat belts, and with seatbelts and shoulder harnesses. The seat design employed in these studies is a typical intercity passenger coach seat, for which the floor attachment is sufficient not to fail during the simulated collision. (The occupant protection strategy in which occupant motion during the collision is restricted by fixed equipment such as seats and bulkheads is termed ''compartmentalization.'') Table 1 summarizes the results for passengers seated in the first coach of a locomotive-led consist, initially traveling at 70 mph, which collides head-on with a stationary locomotive-led consist. These data indicate that without restraints, the interior of a typical intercity passenger coach provides a level of protection to the occupants at least as high as that provided to automobile and transport aircraft passengers with restraints, while lap and shoulder belts provide the highest level of protection.

TABLE 1.—SELECTED RESULTS, INTERIOR SIMULATION STUDIES

	No restraint (compartmentalization)		Lap belt		Lap and shoulder belts		NHTSA and FAA Max. permitted values	
	HIC	Chest g's	HIC	Chest g's	HIC	Chest g's	HIC	Chest g's
50th percentile male, Seat ahead Upright	241	20	141	23	21	9	1000	60
50th percentile male, Seat ahead Reclined	401	36	1428–2089	26	21	9	1000	60

The data in Table 1 indicate that lap belts alone result in a greater likelihood of fatal head injury for certain occupants if the seat ahead of the occupant is reclined. This is owing to the lap-belted occupant striking the top of the seatback ahead. Struck in this manner, the seat is stiff and the head deceleration is large, resulting in a high likelihood of head injury. The head of an unrestrained occupant will strike the rear of the seatback ahead of the occupant, along with the knees of the occupant. Struck in this manner, the seat is relatively soft, the impact forces are distributed over the occupant's body, and the decelerations experienced by the occupant are within survivable levels. The head on an occupant restrained by a lap belt and a shoulder harness will not strike an interior surface, and the deceleration of an occupant so restrained is relatively low. The motions of an unrestrained occupant, an occupant restrained by a lap belt, and an occupant restrained by a lap belt and a shoulder harness are sketched in Figure 2.

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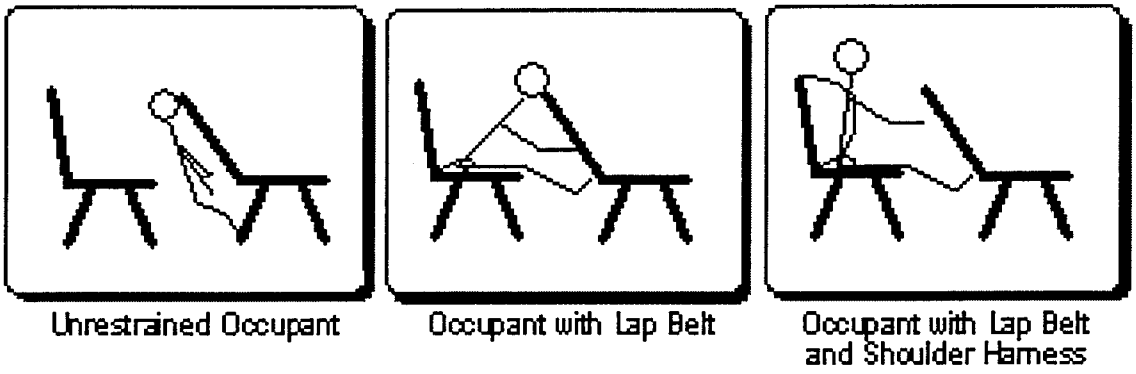
[7] ''Evaluation of Selected Crashwortiness Strategies for Passenger Trains.'' D. Tyrell, K. Severson-Green, & B. Marquis. National Academy Press, Transportation Research Record No. 1989, July 1995; ''Analysis of Occupant Protection Strategies in Train Collisions.'' D. Tyrell, K. Severson, & B. Marquis. American Society of Mechanical Engineers, AMD–Vol. 210/BED–Vol. 30, pp. 539–557, 1995; ''Crashworthiness Testing of Amtrak's Traditional Coach Seat.'' D. Tyrell K. Severson. (DOT/FRA/ORD–96/08—DOT–VNTSC–FRA–96–11, October 1996); and ''Crashworthiness of Passenger Trains.'' See note 6.

Figure 2.

Sketch of Occupant Motions: Unrestrained, with Lap Belt, and with Lap Belt and Shoulder Harness



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The potential effectiveness of occupant restraints in protecting passengers has been inferred from available information on what types of injury occur during passenger train accidents and the equipment involved in causing these injuries. Available criteria which relate these forces and motions to the range of injuries resulting from rail passenger accidents are limited in number and reliability. For example, there is only one accepted criterion for evaluating back injury (an axial load criterion employed by the FAA) while there are many potential modes of back injury, including twisting and excessive flexion. The two principal considerations in inferring the potential effectiveness are the likelihood that the occupant is in a seat and is able to use the restraint, and the potential that the type of injury is prone to prevention or reduction in severity with an occupant restraint.

Table 2 lists the types of injuries, their frequency of occurrence from 1972 to 1973 (see note 3), and the potential effectiveness of occupant restraints. The likely causes of back injury are the seats becoming unlocked and swiveling during an accident and standing passengers subject to falling. Leg, knee, and thigh injuries are potentially caused by leg entrapment beneath the seat ahead of the occupant. Neck injuries are likely the result of ''whiplash'' effects of low seat backs during accidents. The potential effectiveness of occupant restraints can be inferred from the type of injury. For example, seat belts may reduce the occurrence and severity of back injury owing to the longitudinal decelerations from collisions, but may not reduce the occurrence and severity of back injury owing to the lateral accelerations associated with derailment or for a standing passenger falling.

TABLE 2.—INJURY TYPES, NUMBER OF OCCURRENCES, AND POTENTIAL EFFECTIVENESS OF OCCUPANT RESTRAINT

Injury type	Number of Occurrences, 1972–73	Potential/effectiveness		
		No Restraints (Compartmentalization)	Lap Belts	Lap belts and shoulder harnesses
Back	195	Medium	Medium	High
Leg/Knee/Thigh	140	Low	Medium	Medium
Neck	126	Medium	Low	Medium
Head	94	Medium	Low	High
Arm/Hand	89	Low	Low	Low
Chest	64	Medium	Medium	Medium
Shoulder	61	Medium	Medium	Medium
Hip/Pelvis	40	Medium	High	High
Face/Nose	38	Medium	Low	High
Foot/Ankle	27	Low	Medium	Medium
Abdomen	19	Medium	Medium	Medium
Side	15	Medium	Medium	High

Table 3 lists the equipment involved in injury over this same period (see note 3). The likelihood that an occupant was in a seat immediately prior to the injury can be inferred from the type of equipment. For example, the potential effectiveness of occupant restraints protecting occupants from injury with food service and lavatory equipment— the most likely equipment to be involved with injury—is low because such equipment is not located near passenger coach seats. Appropriate measures to assure that such equipment is ''friendly'' during a collision may potentially reduce the severity of injuries associated with food service and lavatory equipment. In fact, since the time of the study, Amtrak has taken significant steps to secure food service equipment and provides for better retention of luggage in overhead storage racks. Further, lavatory design has also been improved in the newer generations of Amtrak equipment.

TABLE 3.—EQUIPMENT INVOLVED IN INJURY, FREQUENCY OF OCCURRENCE, AND POTENTIAL EFFECTIVENESS OF OCCUPANT RESTRAINT

Equipment involved in injury	Frequency of occurrence (percent)	Potential effectiveness		
		No restraints (compartmentalization)	Lap belts	Lap belts and shoulder harnesses
Food Service and Lavatory Equipment	27.5	Medium	Low	Low
Bulkheads, Doors, Window Frames	20	Medium	Low	Low
Seats	16	High	High	High
Floor	10.2	Medium	Medium	Medium
Window Glass	10.2	Medium	Medium	Medium
Tables Counters	7.2	Low	Low	Low
Hand Rail	2.9	Low	Low	Low
Entrance Platform	2.9	Low	Low	Low
Luggage	1.5	Low	Low	Low
Cabinets	1.5	Low	Low	Low

Conclusions from the research conducted to date on passenger protection in train collisions are that lap belts alone may potentially increase fatalities in train collisions; compartmentalization can provide a level of protection for rail passengers at least as effective as that provided by current regulations for automobile and transport-category aircraft passengers; and that lap belts and shoulder restraints provide the highest level of occupant protection of those protection strategies studied.

Current FRA research plans include efforts for developing the means of implementing seat belts and shoulder restraints in intercity and commuter passenger rail equipment and efforts for optimizing compartmentalization for a wide range of occupant sizes, from infants to large adults, and a wide range of interior configurations, including those of food service cars and lavatories in addition to coach car seating configurations. Issues to be addressed in research on implementing seat belts and shoulder restraints include:

- The development of a seat structure design with sufficient integrity to sustain the loads imparted by the restraints during collisions;
- The potential for increased injury of unrestrained occupants striking such strengthened seatbacks and the hard points necessary for lap and shoulder belt securement;
- The potential for increased injury to occupants who misuse the seat and shoulder belts (*e.g.*, placement of the shoulder belt behind the occupant),

The development of mechanisms for adjusting the height location of the shoulder restraint to prevent strangulation of occupants of small stature, including children;

- The overall effectiveness in reducing injury owing to occupant impacts with the interior; and
- The manufacturing costs for a seat which can support the loads imparted by the restraints during collisions.

Although FRA's research and development budget is somewhat limited, FRA is committed to completing the following items within approximately the next 12 months:

- Preliminary cost/benefit analysis on lap belts and shoulder harnesses;
- Preliminary hazard analysis; and
- Preliminary qualitative engineering feasibility work on new seat and belt designs, including cost estimates.

The results of this research will be followed by a final cost/benefit review and will be available when FRA begins the development of the second NPRM on passenger equipment standards.

Based on current research results, the proposed interior passenger protection requirements for Tier I and II passenger equipment rely on compartmentalization as a passenger protection strategy. Research results indicate that during a collision the interior environment of a passenger coach is substantially less hostile than the interiors of automobiles and aircraft. Owing to this lower hostility of the passenger collision environment, the interior of a typical intercity passenger coach can provide a level of protection to passengers without restraints at least as effective in preventing fatality as the protection provided to automobile and transport aircraft passengers with restraints. Such a strategy has the benefits of being passive, requiring no action to be taken on the part of the occupants, of being effective for a range of occupant sizes, and potentially being effective in a wide range of interior configurations. If the results of ongoing research indicate that lap belts and shoulder restraints can provide a greater level of protection for passengers than compartmentalization, while being cost-effective, then FRA will consider requiring passenger restraints in the second NPRM.

Crash Energy Management

FRA is proposing that Tier II equipment be designed with a crash energy management system. Crash energy management is an equipment design technique to provide a controlled deformation and collapse of designated sections of the unoccupied volumes of a passenger train to absorb the energy from a collision. This allows collision energy to dissipate before any structural damage occurs to the occupied volumes of a passenger train and reduces the decelerations experienced by passengers and crewmembers in a collision, thereby mitigating the force of any collisions with objects in a train's interior, such as seats.

In a report prepared by the Volpe Center, the crash energy management approach was found to offer significant safety benefits.[8] For example, the Volpe Center report found the crash energy management approach significantly more effective in preserving occupant volume in a head-on collision at a relative speed above 70 mph between two trains propelled by power cars (locomotives) than when the trains did not employ such an approach. Moreover, for the full range of collision speeds, the crash energy management design provided a significantly gentler initial deceleration of the passenger train occupants than when the trains did not employ such an approach. Further, the crash energy management designed power car train is more compatible with existing equipment. It serves as a softer collision surface to a conventionally designed train owing to the collision energy absorbed as the

[8] Crashworthiness of Passenger Trains.'' (DOT–VNTSC–FRA–96–5, September 1996). See Note 6.

unoccupied volumes of the power car train intentionally crush.

Emergency Systems

In addition to the proposed requirements concerning emergency egress and access discussed above, FRA is considering and proposing other requirements to mitigate harm to passenger train occupants in emergency situations.

Emergency Lighting

In a passenger train emergency, inadequate lighting may make it difficult or impossible to read emergency information, to locate doors and emergency exits, and to move about within the train's interior. Rapid egress from the passenger train may be inhibited, and rescue efforts hampered. Further, a private citizen commented in response to the ANPRM that passengers can be very frightened when a train's head-end power shuts down at night or in a darkened station, and there is no onboard emergency lighting for the passengers' security. Accordingly, the proposed rule requires in § 238.123 that all new or rebuilt passenger equipment be equipped with an emergency lighting system. FRA is also considering requiring that auxiliary portable lighting be available for assistance in a passenger train emergency. FRA may prescribe requirements for such lighting in either the final rule of this rulemaking or in the final rule of FRA's complementary rulemaking on passenger train emergency preparedness.

Emergency Communication: To the Train Control Center

FRA is considering requirements for emergency communication equipment on passenger trains. In Working Group discussions, the UTU emphasized that passenger trains should be equipped with both a primary and a redundant means to communicate with a railroad control center. The UTU and BRC also stressed that both means of communication should be required to operate properly before a passenger train is dispatched.

The ability to communicate in an emergency is important for all trains—freight and passenger. For example, because passenger trains operate commingled with freight trains, the ability of a freight train crew to notify a railroad control center of an emergency involving its train may prevent a collision with an oncoming passenger train. As noted above, FRA is currently engaged in revising the Radio Standards and Procedures in 49 CFR part 220 through the Railroad Communications Working Group established under the RSAC. Although FRA anticipates that this separate effort will establish minimum safety requirements with respect to communications equipment for all train service, it should be noted that intercity passenger and commuter railroads already make extensive provision for ensuring communication capabilities during emergencies.

Emergency Communication: Within the Train

FRA is proposing in § 238.437 that Tier II passenger trains be equipped with a means of emergency communication throughout the train. This will enable crewmembers to provide passengers with information and instructions in an emergency.

FRA has decided to limit this proposal to Tier II passenger trains, however, because such trains are intended to operate as a fixed unit, unlike Tier I passenger trains. Whereas an emergency system to communicate throughout the train may be more easily provided for a train which remains as a fixed unit, the interchangeability of passenger cars and locomotives raises practical considerations about the compatibility of communications equipment in a Tier I passenger train. FRA will seek to address these considerations and further examine requirements concerning emergency communication within a Tier I train in the second phase of the development of passenger equipment safety standards.

Emergency Window Exits

As noted, under 49 CFR part 223 equipment designed to carry passengers must be equipped with a minimum of four emergency window exits which permit rapid and easy removal during a crisis. FRA is proposing in §§ 238.235 and 238.439 to strengthen this requirement by making certain, for example, that passenger cars be equipped with four window exits on each main level of each car. FRA is also proposing that each compartment in a sleeping car be equipped with at least one emergency window exit. Above all, the proposed rule requires that each emergency window exit be easily operable without requiring the use of any tool or other implement to facilitate passenger egress in an emergency.

FRA notes that Canadian passenger equipment typically contain more than four emergency window exits, and that MARC is requiring that at least half of all windows in each passenger car be available for use during an emergency. Commenters are requested to address the issue of whether the final rule should require additional emergency window exits in a passenger car.

Commenters are also requested to address what size requirements for emergency window exits FRA should impose in the final rule. FRA is currently proposing that Tier I equipment have a minimum, unobstructed emergency window exit opening of 24 inches horizontally by 18 inches vertically, and that Tier II equipment have a minimum, unobstructed emergency window exit opening of 30 inches horizontally by 30 inches vertically. The Tier II Equipment Subgroup, including Amtrak, recommended the latter requirement for application to Tier II equipment. However, the full Working Group advised against imposing such a requirement on Tier I equipment. Although FRA would prefer that all emergency window exits afford the larger opening, the Tier I equipment proposal provides the minimum opening needed for a fully-equipped emergency response worker to gain access to the interior of a train, according to the NFPA.

Roof Hatches or Clearly Marked Structural Weak Points

In an emergency, roof hatch exits on railroad passenger equipment may facilitate the rapid egress of passengers. However, APTA and Amtrak have raised concerns about requiring such exits on passenger equipment. Allowing access to the roof of a passenger train can be particularly dangerous, especially when the train operates in electrified territory. As an alternative, passenger equipment could be designed with a clearly marked structural weak point in the roof to provide quick access for emergency personnel. Access to and egress from passenger equipment would be facilitated, without the risk of allowing passengers immediate access to the roof when no emergency is present.

As recommended by the Tier II Equipment Subgroup, the proposed rule requires in § 238.439 that Tier II equipment either be equipped with roof hatches or be designed with clearly marked structural weak points in the roof to permit quick access for properly equipped emergency personnel. The proposed rule does not contain such requirements for Tier I equipment, however. There was no consensus within the full Working Group to recommend that such requirements be included. FRA will consider such requirements for Tier I equipment in the second phase of the rulemaking, and the Working Group agreed to do so as well. FRA does believe that the safety of Tier

I passenger trains will still be significantly advanced by the other requirements for emergency egress and access contained in this proposed rule.

Additional Passenger Train Safety Issues

As detailed below in the section-by-section analysis, the proposed rule will also address additional passenger train safety issues including:

- Equipment (non-brake) inspection, testing, and maintenance;
- Suspension system safety;
- Operating cab controls;
- Safety appliances;
- Electrical system safety;
- Software and hardware safety, and
- Introduction of new technology.

Further, in consultation with the Working Group, FRA has identified issues to address in the second phase of this rulemaking which may lead FRA to propose additional standards for Tier I equipment in a future NPRM. Although certain issues have already been noted above, such as improvements in cab car end structure design, other issues include crash energy management requirements and increased side impact strength requirements for car bodies. FRA intends that the Working Group advise FRA as to which requirements make sense for application to Tier I equipment and which requirements already proposed in this NPRM should be strengthened. It is anticipated that any operational experience gained from the use of Tier II equipment will assist the Working Group in this effort.

June 1997 NTSB Safety Recommendations

On June 17, 1997, the NTSB announced a series of safety recommendations as a result of its investigation of the collision between MARC train 286 and Amtrak train 29 in Silver Spring, Maryland, on February 16, 1996. While its investigation was still ongoing, the NTSB issued an urgent safety recommendation (R–96–7) to FRA on March 12, 1996. As explained earlier in the preamble, FRA convened a joint meeting of the Passenger Equipment Safety Standards Working Group and the Passenger Train Emergency Preparedness Working Group on March 26, 1996, to discuss this recommendation and incorporate the Safety Board's initial findings into each working group's rulemaking, as appropriate. This urgent recommendation has been fully considered and is reflected in this NPRM as well as the NPRM on Passenger Train Emergency Preparedness that was published on February 24, 1997 (*see* 62 FR 8330).

Though the Safety Board has reiterated portions of its earlier, urgent recommendation, FRA has not yet had the opportunity to discuss with the Passenger Equipment Safety Standards Working Group the full array of June 1997 recommendations pertaining to passenger equipment safety. However, for the consideration of interested parties, FRA has set forth below for public comment the recent NTSB recommendations relevant to this rulemaking. In particular, the NTSB has recommended that FRA:

- Require all passenger cars to have easily accessible interior emergency quick-release mechanisms adjacent to exterior passageway doors and take appropriate emergency action to ensure corrective action until these measures are incorporated into minimum passenger car safety standards.
- Require all passenger cars to have either removable windows, kick panels, or other suitable means for emergency exiting through the interior and exterior passageway doors where the door could impede passengers exiting in an emergency and take appropriate emergency measures to ensure corrective action until these measures are incorporated into minimum passenger car safety standards.
- Issue interim standards for the use of luminescent or retro-reflective material or both to mark all interior and exterior emergency exits in all passenger cars as soon as possible and incorporate the interim standards into minimum passenger car safety standards.
- Require all passenger cars to contain reliable emergency lighting fixtures that are each fitted with a self-contained independent power source and incorporate the requirements into minimum passenger car safety standards.
- Provide promptly a prescribed inspection and test cycle to ensure the proper operation of all emergency exit windows as well as provide that the 180-day inspection and maintenance test cycle is prescribed in the final rule.
- Require that all exterior emergency door release mechanisms on passenger cars be functional before a passenger car is placed in revenue service, that the emergency door release mechanism be placed in a readily accessible position and marked for easy identification in emergencies and derailments, and that these requirements be incorporated into minimum passenger car safety standards.
- Require that a comprehensive inspection of all commuter passenger cars be performed to independently verify that the interior materials of these cars meet the expected performance requirements for flammability and smoke emissions characteristics.

FRA has specifically responded in § 238.105 (Fire protection program) of this NPRM to the Board's recent recommendation concerning the flammability and smoke emission characteristics of interior materials in existing passenger cars.

APTA Comments

As explained earlier in the preamble, under the authority of 49 U.S.C. 20133(d) FRA developed the proposed rule in consultation with a Working Group that included Amtrak, individual commuter railroads, and APTA, which represents the interests of commuter railroads in regulatory matters. On March 19, 1997, following the last full meeting of the Working Group, FRA sent a draft of the NPRM to Working Group members and advisors for their review and comment as to whether the rule inaccurately reflected the Working Group's recommendations in a significant way. By letter dated April 28, 1997, APTA requested a meeting with FRA to address its significant concerns about a number of substantive items in the NPRM, as well as the process used to develop the NPRM. A meeting took place on May 23, 1997, at which time APTA provided FRA with extensive written comments on the draft NPRM. These comments have been placed in the public docket for this rulemaking, along with a summary of the meeting. FRA has also included a number of APTA's comments in this NPRM for the consideration of interested parties, and FRA invites all interested parties to address APTA's comments while commenting on the proposed rule.

Section-by-Section Analysis

Amendments to 49 CFR Part 216

Part 216 currently authorizes certain FRA and participating State inspectors to issue Special Notices for Repair, under specified conditions, for freight cars with defects under the part 215, locomotives with defects under parts 229 or 230 or 49 U.S.C. chapter 207, and track with defects under part 213. The proposed revisions to part 216 would create a fourth category of Special Notices for Repair: for passenger equipment with defects under part 238. In summary, if the inspector determines that the noncomplying passenger equipment is ''unsafe for further service'' and issues the proposed Special Notice, it would require the railroad to take the passenger equipment out of service, to make repairs to bring the equipment into compliance with part 238, and to report the repairs to

FRA. The revisions would also make conforming changes to part 216 reflecting this new enforcement tool.

Finally, these proposed revisions include various technical amendments to update part 216 to reflect the following: (1) internal organizational changes within FRA; (2) the division of former part 230, Locomotive Inspection Regulations, into parts 229 and 230 and the redesignation of those portions of former part 230 related to non-steam locomotives as part 229, Railroad Locomotive Safety Standards; and (3) the repeal, reenactment without substantive change, and recodification of the Federal railroad safety laws in 1994. *See* 45 FR 21092, Mar. 31, 1980; Pub. L. 103–272, July 5, 1994.

Amendments to 49 CFR Parts 223, 229, 231, and 232

FRA proposes conforming changes to the applicability sections of FRA's Safety Glazing Standards, Railroad Locomotive Safety Standards, Railroad Safety Appliance Standards, and railroad power brakes and drawbars regulations that were necessitated by proposed provisions of new part 238. In the final rule, FRA may adjust the application of provisions in parts 215, 223, 229, 231, or 232, or possibly delete provisions in those parts, to avoid duplication of provisions in part 238. FRA has not proposed deletion of passenger train brake test and maintenance requirements from part 232 because proposed part 238 would not cover certain operations subject to part 232, e.g., tourist, historic, scenic, and excursion railroad operations on the general system. If any provision in parts 215, 223, 229, 231, or 232 is deleted in the final rule, FRA will revise the schedule of civil penalties for the affected part by removing the entry for the provision deleted. Because such penalty schedules are statements of policy, notice and comment are not required prior to their issuance. *See* 5 U.S.C. 553(b)(3)(A).

49 CFR Part 238

(APTA is concerned that the proposed record keeping and reporting requirements in subparts A–D are extensive and significantly exceed current railroad practice, without any corresponding safety benefit. Commenters are requested to address APTA's concern.)

Subpart A—General

§ 238.1 Purpose and scope. Paragraph (a) states the purpose of the rule to be the prevention of accidents involving railroad passenger equipment and the mitigation of the consequences of accidents involving railroad passenger equipment, to the extent such accidents cannot be prevented. Paragraph (b) states that these regulations provide minimum standards for the subjects addressed. Railroads and other persons subject to this part may adopt more stringent requirements, so long as they are not inconsistent with this part.

§ 238.3 Application. As a general matter, in paragraphs (a)(1) and (a)(2), FRA proposes that this rule apply to all railroads that operate intercity passenger train service on the general railroad system of transportation or provide commuter or other short-haul passenger train service in a metropolitan or suburban area; that is, the rule will apply to commuter or other short-haul service described in paragraph (a)(2) regardless of whether that service is connected to the general railroad system. A public authority that indirectly provides passenger train service by contracting out the actual operation to another railroad or independent contractor would be regulated by FRA as a railroad under the provisions of the proposed rule. Paragraph (a)(3), read in conjunction with paragraph (c)(1), means that rapid transit operations in an urban area that are connected to the general railroad system of transportation would also be covered by this part. Paragraph (b) makes explicit the liability imposed by statute, 49 U.S.C. 20303, on a railroad that owns track over which another railroad hauls or uses equipment with a power brake or safety appliance defect. Under paragraph (b), a railroad that permits operations over its trackage by passenger equipment subject to this part that does not comply with a power brake provision of this part or a safety appliance provision of this part is subject to the power brake and safety appliance provisions of this part with respect to such operations that it permits.

This section contains no explicit reference to private cars. Rather than addressing the scope of applicability of part 238 to private cars in this section, FRA has indicated in the particular substantive sections of the rule whether private cars are covered, according to the terms of those sections. FRA proposes to apply certain requirements of the rule to private cars that operate on railroads subject to this part. FRA has taken into account the burden imposed by requiring private car owners and operators to conform to the requirements of this part. Further, FRA recognizes that private cars are often hauled by railroads such as Amtrak and commuter railroads which often impose their own safety requirements on the operation of the private cars. Accordingly, FRA intends to limit the application of the proposed rule only to those requirements necessary to ensure the safe operation of the passenger train that is hauling the private car. For instance, private cars will be subject to brake inspection, testing, and maintenance requirements.

The proposed rule is structured to apply to intercity and commuter service, but not to tourist, scenic, historic, and excursion operations. The term ''tourist, scenic, historic, or excursion operations'' is defined in § 238.5 to mean ''railroad operations that carry passengers, often using antiquated equipment, with the conveyance of the passengers to a particular destination not being the principal purpose.'' The term refers to the particular physical operation, not to the nature of the railroad company as a whole that conducts the operation. As a result, part 238 would exempt not only a recreational train ride by a tourist railroad company that employed five people but also a recreational train ride by the Union Pacific Railroad Company, a Class I freight railroad. FRA has not yet had the opportunity to fully consult with tourist and historic railroad operators and their associations to determine the appropriate applicability of the provisions contained in the proposed rule to such railroad operations. The Federal Railroad Safety Authorization Act of 1994 directs FRA to examine the unique circumstances of tourist railroads when establishing safety regulations. The Act, which amended 49 U.S.C. 20103, states that:

> In prescribing regulations that pertain to railroad safety that affect tourist, historic, scenic, or excursion railroad carriers, the Secretary of Transportation shall take into consideration any financial, operational, or other factors that may be unique to such railroad carriers. The Secretary shall submit a report to Congress not later than September 30, 1995, on actions taken under this subsection.

Pub. L. No. 103–440, § 217, 108 Stat. 4619, 4624, November 2, 1994. In its 1996 report to Congress entitled ''Regulatory Actions Affecting Tourist Railroads,'' FRA responded to the direction in the statutory provision and also provided additional information related to tourist railroad safety for consideration of the Congress.

Section 215 of the 1994 Act specifically permits FRA to exempt equipment used by tourist, historic, scenic, and excursion railroads to transport passengers from the initial regulations that must be prescribed by November 2, 1997. 49 U.S.C.

20133(b)(1). FRA is addressing the passenger equipment safety concerns for these unique types of operations through the Tourist and Historic Railroads Working Group formed under RSAC. Any requirements proposed by FRA for these operations will be part of a separate rulemaking proceeding.

§ 238.5 Definitions. This section contains a set of definitions to introduce the regulations. FRA intends these definitions to clarify the meaning of important terms as they are used in the text of the proposed rule. Several of the definitions involve new or fundamental concepts which require further discussion.

''Brake indicator'' means a device, actuated by brake cylinder pressure, which indicates whether brakes are applied or released on a car. The use of brake indicators in the performance of brake tests is a controversial subject. Rail labor organizations correctly maintain that brake indicators are not fully reliable indicators of brake application and release on each car in the train. Further, railroads correctly maintain that reliance on brake indicators is necessary because inspectors cannot always safely observe brake application and release. FRA believes that brake indicators serve an important role in the performance of brake tests. FRA has specified three different types of brake tests—Class I, Class IA, and Class II (described below)—that must be performed on passenger equipment. Railroads should perform Class I brake tests so that the inspector is able to actually observe brake application and release. However, FRA believes that during the performance of a Class IA brake test, railroads may rely on brake indicators if they determine that the inspector cannot safely make a direct observation of the brake application or release.

''Primary brake'' and ''secondary brake'' are complementary definitions. ''Primary brake'' refers to ''those components of the train brake system necessary to stop the train within the signal spacing distance without thermal damage to friction braking surfaces,'' while ''secondary brake'' refers to ''those components of the train brake system which develop supplemental brake retarding force that is not needed to stop the train within signal spacing distances or to prevent thermal damage to wheels.'' FRA provides these definitions to help draw the line between safety and economics of brake systems. Railroads have long held that the dynamic portion of a blended brake is not a safety system. Under the provisions proposed in this rule, railroads must demonstrate through testing and analysis that the dynamic brake fits the definition of a secondary brake. Defective primary braking systems are a serious safety problem that railroads must address immediately. Defective secondary braking systems, as defined in § 238.5, are not a serious safety concern, because, by definition, their failure does not result in unacceptable thermal inputs into friction brake components. Accordingly, FRA proposes to allow railroads more flexibility in dealing with defective secondary braking systems.

Three brake tests are fundamental to this proposed rule. A ''Class I brake test'' means a complete passenger train brake system test as further specified in § 238.313. The Class I test is the most complete test. It must be done once a day by qualified mechanical inspectors as opposed to train crews. The Class I test is intended to replace the current initial terminal brake test. *See* 49 CFR 232.12 (c)–(j). The proposed Class I test is much more tailored to the specific designs of passenger equipment than the initial terminal brake test that is required now.

A ''Class IA brake test'' means a test and inspection (as further specified in § 238.315) of the air brake system on each car in a passenger train to ensure the air brake system is 100 percent effective. The Class IA test is a somewhat less complete test than the Class I test. However, the Class IA test is equivalent to the current initial terminal brake test. An important difference between the Class I and Class IA tests is that the Class IA test may be performed by train crews as long as they have been qualified by the railroad to do so. The Class IA test allows commuter railroads the flexibility to have trains depart their first run of the day from an outlying point without having to station qualified mechanical inspectors at all outlying points. If railroads take advantage of the flexibility offered by the Class IA test, they must follow up with a Class I test sometime during the day.

A ''Class II train brake test'' means a test (as further specified in § 238.317) of brake pipe integrity and continuity from controlling locomotive to rear car. The proposed Class II brake test is a simple set-and-release test intended to replace the passenger train intermediate terminal air brake test. *See* 49 CFR 232.13(b). The Class II test is also tailored to the special design of the passenger equipment.

The concept of ''ordered'' or ''date ordered'' is vital to the correct application of this proposed rule. The terms mean the date on which notice to proceed is given by a procuring railroad to a contractor or supplier for new equipment. Many of the provisions of the proposed rule, particularly structural requirements, will apply only to newly constructed equipment. When FRA proposes to apply requirements only to passenger equipment ordered on or after January 1, 1999, or placed in service for the first time on or after January 1, 2001, FRA intends to grandfather any piece of equipment that is both ordered before January 1, 1999, and placed in service for the first time before January 1, 2001. FRA believes this approach will allow railroads to avoid any costs associated with changes to existing orders and yet limit the delay in realizing the safety benefits of the requirements proposed in this rule.

FRA's proposed definition of ''passenger car'' goes beyond its traditional meaning. ''Passenger car'' means a unit of rolling equipment to provide transportation for members of the general public and includes a self-propelled car designed to carry passengers, baggage, mail, or express. This term includes a cab car, an MU locomotive, and a passenger coach. A cab car and an MU locomotive are also a ''locomotive'' under this rule. ''Passenger coach'' means a unit of rolling equipment intended to provide transportation for members of the general public that is without propelling motors and without a control stand; therefore, passenger coaches are a subset of passenger cars.

''Control stand'' is defined in *The Railroad Dictionary of Car and Locomotive Terms* (Simmons-Boardman Publishing Corp. 1980), as ''[t]he upright column upon which the throttle control, reverser handle, transition lever, and dynamic braking control are mounted within convenient reach of the engineer on a locomotive. The air gauges and some switches are also included on the control stand.''

''Passenger equipment'' is the most inclusive definition. It means all powered and unpowered passenger cars, locomotives used to haul a passenger car, and any other unit of rail rolling equipment hauled in a train with one or more passenger cars and includes a (1) Passenger coach, (2) cab car, (3) MU locomotive, (4) private car, (5) locomotive not intended to provide transportation for members of the general public that is used to power a passenger train, and (6) any non-self-propelled vehicle hauled in a train with one or more passenger cars, including a freight car hauled in a train with one or more passenger cars. The term therefore covers a baggage car, mail car, or express car.

The terms ''passenger station'' and ''terminal'' are crucial to the interpretation of the proposed rule for movement of defective equipment. ''Passenger station'' means a location designated in the railroad's timetable where passengers are regularly scheduled to get on or off any train. By contrast, ''terminal'' means a train's starting point or ending point of a single scheduled trip, where passengers may embark or disembark a train; normally, a ''terminal'' is a point where the train would reverse direction or change destinations.

Under certain carefully controlled conditions, FRA proposes to permit a passenger train with defective equipment to move to the next forward passenger station or terminal. This flexibility is allowed to prevent railroads from discharging passengers in potentially unsafe locations and to minimize schedule impacts where this can safely be done.

The concepts of ''qualified person'' and ''qualified mechanical inspector'' are vital to interpreting the proposed inspection, testing, and maintenance provisions of the rule. A ''qualified person'' is a person determined by the railroad to have the knowledge and skills necessary to perform one or more functions required under this part. With the proper training, a train crewmember could be a qualified person.

A ''qualified mechanical inspector'' is a ''qualified person'' who as a part of the training, qualification, and designation program required under § 238.111 has received instruction and training that includes ''hands-on'' experience (under appropriate supervision or apprenticeship) in one or more of the following functions: trouble-shooting, inspection, testing, and maintenance or repair of the specific train brake and other components and systems for which the inspector is assigned responsibility. Further, the mechanical inspector must be a person whose primary responsibility includes work generally consistent with those functions and is designated to (1) Conduct Class I brake tests under this part; (2) inspect MU locomotives or other passenger cars for compliance with this part; or (3) determine whether equipment not in compliance with this part may be moved safely and, if so, under what conditions. A train crewmember would not be a qualified mechanical inspector. (APTA believes that the proposed definition of ''qualified mechanical inspector'' adds nothing to safety, dictates work rules, and creates unnecessary restricted jobs with limited duties.)

FRA includes a clear definition of ''qualified person'' to allow railroads the flexibility of having train crews perform Class IA and Class II brake tests. A qualified person must be trained and designated as able to perform the types of brake inspections and tests that the railroad assigns to him or her. However, a qualified person need not have the extensive knowledge of brake systems or components or be able to trouble-shoot and repair them. The qualified person is the ''checker.'' He or she must have the knowledge and experience necessary to be able to identify brake system problems.

FRA provides a clear definition of qualified mechanical inspector so that a differentiation can be made between the thorough brake test and inspection performed by a professional mechanical employee, and the less comprehensive brake checks performed by train crews. Under FRA's proposal, only qualified mechanical inspectors are permitted to perform the required calendar day inspections and Class I brake tests under this part. This definition largely rules out the possibility of train crewmembers becoming a qualified mechanical inspector. Part of the definition requires the primary job of a qualified mechanical inspector to be inspection, testing, or maintenance of passenger equipment. FRA intends the definition to allow the members of the trades associated with testing and maintenance of equipment such as carmen, machinists, and electricians to become qualified mechanical inspectors. However, membership in labor organizations or completion of apprenticeship programs associated with these crafts is not required to be a qualified mechanical inspector. The two primary qualifications are possession of the knowledge required to do the job and a primary work assignment inspecting, testing, or maintaining the equipment.

Discussions conducted in the Working Group meetings revealed that railroad operators believe these definitions are too restrictive and will require training beyond the minimum needed for many employees to do their jobs. On the other hand, the representatives of labor organizations maintain that this approach will allow unqualified train crewmembers to conduct tests and inspections that should be performed only by mechanical employees.

FRA believes the proposed rule strikes the correct balance between these conflicting points of view. FRA agrees with labor representatives that mechanical employees generally conduct a more thorough inspection than train crewmembers. As a result, the rule calls for a daily Class I brake test and mechanical inspection performed by qualified mechanical inspectors. At the same time, FRA agrees with railroad operators that properly trained train crews are capable of performing brake tests and have been doing so effectively for years. As a result, the proposed rule grants flexibility to railroads to use properly trained train crewmembers to perform certain brake tests.

''System safety'' is another concept that forms a foundation for the proposed rule. System safety means the application of design, operating, technical, and management techniques and principles throughout the life cycle of a system to reduce hazards and unsafe conditions to the lowest level possible through the most effective use of the available resources. FRA proposes that each railroad implement a system safety program to identify and manage safety risks. The system safety program would generate data to be used to make safety decisions. The risk identification and analysis portion of the system safety program would help demonstrate an alternate means of achieving equivalent safety when a proposed operation does not fully comply with the Passenger Equipment Safety Standards.

Definitions of the various types of trains covered by the proposed standards are extremely important to understand how FRA proposes that the rule be applied. The most general definition is that of a ''passenger train.'' The proposed definition makes two points very clear. First, the proposed rule does not apply to tourist and excursion railroads; and, second, the provisions of the rule do apply to non-passenger carrying units included in a passenger train.

An important distinction highlighted in these definitions is the difference between a ''long-distance intercity passenger train'' and a ''short-distance intercity passenger train.'' ''Long-distance intercity passenger train'' means a passenger train that provides service between large cities more than 125 miles apart and is not operated exclusively in the National Railroad Passenger Corporation's (Amtrak) Northeast Corridor. ''Short-distance intercity passenger train'' means a passenger train that provides service exclusively on the Northeast Corridor or between cities that are not more than 125 miles apart. This distinction attempts to recognize the special set of operating conditions on the Northeast Corridor in light of the need to treat long-distance trains differently than short-distance trains. Additionally, APTA has advised FRA that there are

commuter rail systems that operate trains over 100 miles in distance on a single run, and thus recommended the use of the 125-mile distance in these definitions.

The definition of the term ''in service'' is modeled after the definition of that term in the Railroad Freight Car Safety Standards. *See* 49 CFR 215.5(e). Passenger equipment that is in service includes passenger equipment ''in passenger service,'' meaning ''carrying, or available to carry, fare-paying passengers,'' as well as all other passenger equipment unless it falls into one of four categories; specifically, unless the passenger equipment—

(a) Is being handled in accordance with §§ 238.15, 238.17, 238.305(c)(5), or 238.503(f), as applicable;

(b) Is in a repair shop or on a repair track;

(c) Is on a storage track and is not carrying passengers; or

(d) Has been delivered in interchange but has not been accepted by the receiving railroad.

The term ''in service'' is important because if the train or passenger equipment is not in service, it is not subject to a part 238 civil penalty.

The last definition that warrants discussion is ''vestibule.'' FRA proposes ''vestibule'' to mean an area of a passenger car that normally does not contain seating and that leads from the seating area to the side exit doors. The definition of ''vestibule'' is important to determine the requirements for the location of side door emergency-release mechanisms.

§ 238.7 Waivers. This section sets forth the procedures for seeking waivers of compliance with the requirements of this rule. Requests for such waivers may be filed by any interested party. In reviewing such requests, FRA conducts investigations to determine if a deviation from the general criteria can be made without compromising or diminishing rail safety.

FRA recognizes that circumstances may arise when the operation of passenger equipment that does not meet the standards proposed in this rule is appropriate and in the public interest. FRA would entertain petitions for waiver to allow operation of equipment that does not fully comply with the proposed standards, provided the petitioner can demonstrate that the equipment will operate at a level of safety equivalent to that afforded by the provision of this part that is sought to be waived, *i.e.*, demonstrate ''equivalent safety.'' Equivalent safety may be afforded by features that compensate for equipment that does not meet these standards. Equivalent safety is met when railroad employees, passengers, and the general public are no more at risk from passenger equipment that does not meet the requirements of this part, but is protected by compensating features, than when the equipment meets the requirements of this part.

Some of the structural requirements that FRA is proposing would prohibit the operation of most light rail vehicles if the operation is connected to the general railroad system on or after January 1, 1998; however, FRA does not intend to completely foreclose the possibility of the operation of such equipment. FRA is aware of arrangements by which light rail service is conducted during the day, with freight operations conducted at night. FRA will entertain petitions for waiver of the structural requirements from operators of such ''time-separated'' service.

FRA proposes that the risk assessment portion of the system safety program be used to demonstrate equivalent safety. The burden would be on the petitioning railroad to perform a comparative risk assessment and to prove equivalent safety. FRA has experience with two instances involving different passenger equipment operations where a comparative risk assessment has been used successfully. Amtrak commissioned a comparative risk assessment between current Northeast Corridor operations and proposed operations involving the American Flyer trainset at speeds up to 150 mph. The risk assessment demonstrated that proposed countermeasures such as enhancements to the train control system and the increased structural strength and the crash energy management design of the American Flyer should compensate for the increased operating speed. The comparative risk assessment quantitatively showed that passengers were no more at risk travelling on the American Flyer at 150 mph on the Northeast Corridor than if they were travelling on an existing Amtrak passenger train at a lesser speed on the same corridor.

The second instance is the proposed Florida Overland Express (FOX) operation of a French TGV high speed rail system in Florida. FOX performed a comparative risk assessment of three operations: the American Flyer on the Northeast Corridor, the TGV on high speed lines in France, and the proposed FOX operation in Florida. *See* FRA Docket: RM Pet. 97–1. The analysis showed the TGV operation in France to pose less risk to passengers than the American Flyer trainset on the Northeast Corridor and the proposed FOX operation to be even safer than the TGV in France. The FOX risk assessment suggested that collision avoidance provided by a dedicated right-of-way with no grade crossings more than compensated for the increased speed and decreased structural strength of the proposed equipment.

FRA cites these two instances as examples of what is expected to demonstrate equivalent safety for proposed operations where the equipment does not meet the Passenger Equipment Safety Standards. FRA would expect an analysis showing the effectiveness of clearly compensating features, such as closing grade crossings, providing absolute separation of lighter rail equipment from heavy rail equipment, or using highly capable signal and train control systems that significantly reduce the probability of accidents caused by human error. FRA would provide advice and guidance to organizations wishing to demonstrate equivalent safety, but the burden of performing a comparative risk assessment and establishing that the operation provides equivalent safety is on the entity proposing to operate equipment that does not comply with this part.

§ 238.9 Responsibility for compliance. General compliance requirements are proposed in this section. Paragraph (a). Paragraphs (a)(1) and (a)(2) prohibit a railroad subject to part 238 from committing a series of specified acts with respect to a train or a piece of passenger equipment while the train or passenger equipment is in service if it has a condition that does not comply with part 238 or if it has not been inspected and tested as required by part 238. In particular, consistent with 49 U.S.C. chapter 203, under which the provision is proposed, paragraph (a)(1) imposes a strict liability standard with respect to violations of the safety appliance and power brake provisions of part 238. In addition to the acts prohibited by paragraph (a)(2) (that is, the use, haul, offering in interchange, or accepting in interchange of defective or not properly inspected equipment), paragraph (a)(1) prohibits a railroad from merely permitting the use or haul on its line of such equipment if it does not conform with the safety appliance and power brake provisions. *See* § 238.3(b). By contrast, paragraph (a)(2) imposes a lower standard of liability for using, hauling, delivering in interchange, or accepting in interchange a train or passenger equipment that is defective or not properly inspected, in violation of another provision of this part; a railroad subject to this part is liable only if it knew, had notice, or

should have known of the existence of either the defective condition of the equipment or the failure to inspect and test. Finally, paragraph (a)(3) establishes a strict liability standard for noncompliance with any other provision of this part, for example, the requirement to adopt a written system safety plan under § 238.103.

Paragraph (b). In accordance with the ''use'' or ''haul'' language previously contained in the Safety Appliance Acts (49 U.S.C. chapter 203) and with FRA's general rulemaking authority under the Federal railroad safety laws, FRA proposes in paragraph (b) that passenger equipment will be considered ''in use'' prior to departure but after it receives or should have received the necessary tests and inspections required for movement. FRA will no longer wait for a piece of equipment with a power brake defect to be hauled before issuing a violation, a practice frequently criticized by the railroads. FRA believes that this approach will increase FRA's ability to prevent the movement of defective equipment that creates a potential safety hazard to both the public and railroad employees. FRA does not feel that this approach increases the railroads' burden since equipment should not be operated if it is found in defective condition in the pre-departure tests and inspections, unless permitted by the regulations.

Paragraph (c). This paragraph clarifies FRA's position that the requirements contained in the proposed rules are applicable not only to any ''railroad'' subject to this part but also to any ''person,'' as illustrated in § 238.11, that performs any function required by the proposed rules. Although various sections of the proposed rule address the duties of a railroad, FRA intends that any person who performs any action on behalf of a railroad or any person who performs any action covered by the proposed rule is required to perform that action in the same manner as required of a railroad or be subject to FRA enforcement action. For example, private car owner and contract shippers that perform duties covered by these proposed regulations would be required to perform those duties in the same manner as required of a railroad.

§ 238.11 Civil penalties. Section 238.11 identifies the civil penalties that FRA may impose upon any person, including a railroad or an independent contractor providing goods or services to a railroad, that violates any requirement of this part. These penalties are authorized by 49 U.S.C. 21301, 21302, and 21304. The penalty provision parallels penalty provisions included in numerous other safety regulations issued by FRA. Essentially, any person who violates any requirement of this part or causes the violation of any such requirement will be subject to a civil penalty of at least $500 and not more than $10,000 per violation. Civil penalties may be assessed against individuals only for willful violations; where a grossly negligent violation or a pattern of repeated violations creates an imminent hazard of death or injury to persons, or causes death or injury, a penalty not to exceed $20,000 per violation may be assessed. In addition, each day a violation continues will constitute a separate offense. Finally, a person may be subject to criminal penalties under 49 U.S.C. 21311 for knowingly and willfully falsifying reports required by these regulations. FRA believes that the inclusion of penalty provisions for failure to comply with the regulations is important in ensuring that compliance is achieved.

The final rule will include a schedule of civil penalties as appendix A to this part. Because such penalty schedules are statements of policy, notice and comment are not required prior to their issuance. *See* 5 U.S.C. 553(b)(3)(A). Nevertheless, commenters are invited to submit suggestions to FRA describing the types of actions or omissions under each regulatory section that would subject a person to the assessment of a civil penalty. Commenters are also invited to recommend what penalties may be appropriate, based upon the relative seriousness of each type of violation.

§ 238.13 Preemptive effect. Proposed § 238.13 informs the public as to FRA's views regarding what will be the preemptive effect of the final rule. While the presence or absence of such a section does not in itself affect the preemptive effect of a final rule, it informs the public concerning the statutory provision which governs the preemptive effect of the rule. Section 20106 of title 49 of the United States Code provides that all regulations prescribed by the Secretary relating to railroad safety preempt any State law, regulation, or order covering the same subject matter, except a provision necessary to eliminate or reduce an essentially local safety hazard that is not incompatible with a Federal law, regulation, or order and that does not unreasonably burden interstate commerce. With the exception of a provision directed at an essentially local safety hazard, 49 U.S.C. 20106 will preempt any State regulatory agency rule covering the same subject matter as the regulations proposed today when issued as final rules.

§ 238.15 Movement of passenger equipment with defective power brakes. This section contains the proposed requirements for movement of passenger equipment with a power brake defect without civil penalty liability under this part. (Railroads remain liable, however, ''in a proceeding to recover damages for death or injury of a railroad employee arising from the movement of'' the defective equipment. *See* 49 U.S.C. 20303(c).) A ''power brake defect,'' as defined in paragraph (a), ''is a condition of a power brake component, or other primary brake component, that does not conform with this'' rule. The term does not include a failure to properly inspect such a component.

The Passenger Equipment Safety Standards Working Group did not reach a consensus on the requirements proposed in this section; however, the Working Group did agree that passenger operations needed some flexibility to get passengers to their destination or, at a minimum, to a location where passengers can safely disembark. The proposed requirements regarding the movement of passenger equipment with defective power brakes are based on the extensive discussions and information presented in the Working Group meetings and in response to the previous NPRM on power brakes.

As previously noted in the general discussion, FRA proposes to utilize the authority granted in 49 U.S.C. 20306 to exempt passenger train operations covered by this part from the statutory requirements contained in 49 U.S.C. 20303(a) permitting the movement of equipment with defective or insecure brakes only if various requirements are met, including the requirement that the movement for repair be only to the nearest location where the necessary repairs can be made. FRA believes that the granting of this exemption is justified based on the technological advances made in the brake systems and equipment used in passenger operations, and is necessary for these operations to make efficient use of the technological advances and protect the safety of the riding public.

FRA also proposes to exempt passenger train operations from a long-standing agency interpretation, based on a 1910 Interstate Commerce Commission order codified at 49 CFR 232.1, that prohibits the movement of a train for repairs under 49 U.S.C. 20303 if less than 85 percent of the train's brakes are operative. As noted in the previous discussion, many passenger operations utilize a small number of cars in their trains and the necessity to cut out the brakes on just one car can easily result in noncompliance. FRA

believes that speed restrictions can readily be used to compensate for the loss of brakes on a minority of cars.

Paragraph (b)(1). This paragraph addresses the movement for repair of equipment with a power brake defect found during a Class I or IA brake test or, for Tier II equipment, the equivalent of a Class I or IA brake test. This paragraph allows railroads the flexibility to move passenger equipment with a power brake defect found during such a test if the following three conditions are satisfied: (1) if the train is moved for purposes of effecting repair of the defect, without passengers; (2) the applicable operating restrictions set forth in paragraph (d) are complied with; and (3) the information concerning the defect is recorded on a tag affixed to the equipment or in an automated defect tracking system as specified in paragraph (c)(2).

Paragraph (b)(2). This paragraph permits railroads to move, for purposes of scrapping or sale, passenger equipment with a power brake defect found during a Class I or IA brake test (or the Tier II equivalent) if each of the following conditions is satisfied: if the movement is without passengers, if the speed of the movement is 15 mph or less, and if the railroad's air brake or power brake instructions are followed when making the movement. This provision allows railroads to move surplus equipment without having to request permission for one-time moves from FRA, as is currently required. FRA has not had any serious safety concerns with the methods currently used by railroads to move this equipment and does not believe its limited resources should be tied up in approving these types of moves.

Paragraph (c), generally. This paragraph addresses the use of passenger equipment with a power brake defect that develops en route from a location where a Class I or IA brake test (or the Tier II equivalent) was performed on the equipment. The two basic requirements are that at the location where the railroad first finds the defect, specified information (such as the nature of the defect and the destination where the defect will be repaired) must be placed on tags attached to the equipment or in a computer tracking system and that the railroad must observe the applicable operating restrictions in paragraph (d). A third requirement, found in paragraph (c)(3) is a special, applying only if the defect causes any brakes to be cut out.

Paragraph (c)(2) requires that equipment being hauled for repairs be adequately identified. Currently, there is no requirement that equipment with defective power brakes be tagged or otherwise identified, although most railroads voluntarily engage in such activity. Furthermore, the current regulations regarding freight cars and locomotives contain tagging requirements for the movement of equipment not in compliance with those parts. *See* 49 CFR 215.9 and 229.9. Consequently, FRA proposes to require the identification of equipment with defective power brakes through either the traditional tags which are placed in established locations on the equipment or by an automated tracking system developed by the railroad. FRA proposes certain information which must be contained whichever method is used by a railroad. FRA believes that the proposed tagging or tracking requirements add reliability, accountability, and enforceability for the timely and proper repair of equipment with defective power brakes.

In addition, under paragraph (c)(3), if the defect causes the brakes on the equipment to be cut out, then the railroad must first find out what percentage of the power brakes in the train are cut out or inoperative in some other way, using the formula in paragraph (d)(1). Next, the railroad must notify the dispatcher of the percentage of operative brakes and the movement restrictions imposed by paragraph (d), inform the railroad's mechanical desk or department about the brake defect, and walk the train to confirm the percentage of operative brakes at the next point where it is safe to do so.

Paragraph (d)(1). This paragraph explains the term ''inoperative power brakes'' and proposes a new method for calculating the percentage of operative power brakes (operative primary brakes) in a train. Regarding the term itself, a cut-out power brake is an inoperative power brake, but the failure or cutting out of a secondary brake system (as defined in § 238.5) does not result in inoperative power brakes. For example, failure of dynamic brakes does not render a power brake inoperative unless the dynamic brakes are in fact primary brakes. Although the statute discusses the percentage of operative brakes in terms of a percentage of vehicles, the statute was written nearly a century ago and at that time the only way to cut out the brakes on a car or locomotive was to cut out the entire unit. *See* 49 U.S.C. 20302(a)(5)(B). Today, virtually every piece of equipment used in passenger service can have the brakes cut out on a per-truck or per-axle basis. Consequently, FRA merely proposes a method of calculating the percentage of operative brakes based on the design of passenger equipment used today, and thus, a means to more accurately reflect the true braking ability of the train as a whole. FRA believes that the proposed method of calculation is consistent with the intent of Congress when it drafted the statutory requirement and simply recognizes the technological advancements made in braking systems over the last century. Consequently, FRA proposes to permit the percentage of operative brakes to be determined by dividing the number of axles in the train with operative brakes by the total number of axles in the train. Furthermore, for equipment utilizing tread brake units (TBU), FRA proposes that the percentage of operative brakes be determined by dividing the number of operative TBUs by the total number of TBUs.

Paragraphs (d)(2)–(d)(4), generally. These paragraphs propose various speed and other operating restrictions based on the percentage of operative brakes in order to permit passenger railroads the flexibility to efficiently move passengers without compromising safety. FRA believes that the proposed movement restrictions actually enhance the safety of the riding public. The proposed requirements retain the basic principle that a train carrying passengers shall not depart a location where a major brake inspections or tests are performed on that train unless the train has 100 percent operational brakes.

FRA recognizes that there are major differences in the operations of commuter or short-distance intercity passenger trains, and long-distance intercity passenger trains. Commuter and short-distance intercity passenger trains tend to operate fairly short distances between passenger stations and generally operate in relatively short turn-around service between two terminals several times in any given day. On the other hand, long-distance intercity passenger trains tend to operate for long distances, with trips between the beginning terminal and ending terminal taking a day or more and traversing multiple States with relatively long distances between passenger stations. Consequently, FRA proposes slightly different requirements with regard to the movement of defective brake equipment in long-distance intercity passenger trains.

FRA believes that passenger railroads can safely and efficiently operate trains with en route brake failures under the strict set of conditions proposed. FRA has long held that the industry can safely operate trains at normal track speeds with as low as 85 percent effective brakes as long as the inoperative brakes were due to failures which occurred en route or due to

defective cars being picked up en route and being moved for repairs. The only change being proposed to current practice is the additional flexibility for certain passenger operations to move the equipment past a location capable of performing the repairs.

Paragraph (d)(2). This paragraph proposes operating requirements for the movement of any passenger train that develops en route brake failures resulting in 74 to 50 percent operative brakes. In these circumstances, FRA proposes to allow the trains to proceed only to the next passenger station at a reduced speed, not to exceed 20 mph, to discharge passengers before proceeding, without passengers, to the nearest location where the necessary repairs can be made. This provision recognizes the dangers of unloading passenger at locations other than passenger stations by allowing railroads to move the equipment to a location with the facilities to handle the discharge of passengers. Furthermore, engineering evidence and test data demonstrate that the reduced speed more than compensates for the reduced braking force. At the reduced speed, even with only 50 percent effective brakes, a train is able to stop in a much shorter distance than the same train traveling at the maximum operating speed with 100 percent operative brakes.

Paragraph (d)(3)(i). FRA also proposes to permit commuter, short-distance intercity, and short-distance Tier II passenger trains experiencing en route brake failures resulting in 84 to 75 percent operative brakes to continue in service to the next terminal prior to being moved without passengers to the nearest location were repairs can be made. However, in these circumstances, FRA proposes that the speed of the train must be reduced to 50 percent of the train's maximum operating speed or 40 mph, whichever is less. Engineering evidence and test data demonstrate that the reduced speed more than compensates for the reduced braking force. At the reduced speed, even with only 75 percent effective brakes, a train is able to stop in a much shorter distance than the same train traveling at the maximum operating speed with 100 percent operative brakes.

Paragraph (d)(3)(ii). FRA proposes to permit commuter and short-distance intercity passenger trains that develop defective brake equipment en route resulting in 99 to 85 percent operative brakes, the flexibility to move the defective equipment to the next terminal where passengers can be unloaded, prior to the defective equipment being moved to the nearest location were repairs can be made. During Working Group meetings, APTA presented engineering evidence and test data that demonstrated that stopping distances remained well within signal spacing distances with a large margin of safety even for trains with as low as 85 percent effective brakes.

Paragraph (d)(4). As noted above, most long-distance intercity passenger trains, both in Tier I and Tier II, have considerable distances between their starting terminal and their ending terminal, thus FRA does not intend to provide these operations the latitude to move those large distance with defective equipment entrained. This paragraph permits the movement of defective brake equipment in these trains only to the nearest forward location designated as a repair location for this equipment by the operating railroad in the list required by § 238.19(d). FRA also proposes to permit long-distance intercity passenger trains to continue in service past a designated repair location to the next forward passenger station only if the designated repair location does not have the facilities to safely unload passengers. Although FRA proposes to permit the continued operation of long-distance intercity passenger trains that develop en route brake failures resulting in 99 to 85 percent operative brakes at normal speeds, FRA proposes a speed restriction of no greater than 40 mph when the en route brake failures result in 84 to 75 percent operative brakes. Therefore, although long-distance intercity passenger trains do not have the flexibility to continue in service to the next terminal, these trains do gain flexibility in being permitted to move a greater percentage of defective equipment than currently allowed and are able to move that equipment to the next forward repair location rather than the ''nearest'' repair location as currently required. 49 U.S.C. 20303(a). As noted previously, FRA believes that the safety of the traveling public mandates the flexibility of permitting passenger trains to continue to the next forward repair location or passenger station because requiring trains to reverse directions and perform back hauls to the nearest repair location increases the risk of collision on the railroad.

APTA, in its comments on a draft of the NPRM, agreed that many of the defects need to be repaired but do not require stopping the car or immediately taking it out of service. Commenters are requested to address APTA's concern.

§ 238.17 Movement of passenger equipment with other than power brake defects. This section contains the proposed requirements for the movement of passenger equipment with a condition not in compliance with part 238, excluding a power brake defect and including a safety appliance defect, without civil penalty liability under this part. (Railroads remain liable, however, under 49 U.S.C. 20303(c), as described in the discussion of the previous section.)

The Working Group was unable to reach full consensus on the requirements contained in this section. There are currently no statutory or regulatory restrictions on the movement of passenger cars with defective conditions that are not power brake or safety appliance defects. The proposed provisions contained in this section are similar to the provisions for moving defective locomotives and freight cars currently contained in 49 CFR 229.9 and 215.9, respectively. As these provisions have generally worked well with regard to the movement of defective locomotives and freight cars and in order to maintain consistency, FRA has modeled the proposed movement requirements on those existing requirements. FRA proposes to allow passenger railroads the flexibility to continue to use equipment with non-safety-critical defects until the next scheduled calendar day exterior mechanical inspection. However, FRA intends the calendar day mechanical inspection to be the tool used by railroads to repair all reported defects and to prevent continued use of defective equipment to carry passengers. (Compare § 238.17(b) with § 238.17(c).)

FRA intends for 49 CFR 229.9 to continue to govern the movement of locomotives used in passenger service which develop defective conditions, not covered by part 238, that are not in compliance with part 229. In the final rule, FRA will make any necessary conforming amendments to part 229 in order to remove provisions that will now be covered in this part or to make inapplicable to locomotives subject to part 238 provisions of part 229 that will now be covered in part 238. Part 229 will continue to cover (non-steam) locomotives that are used by the tourist railroads until such railroads are covered by part 238.

FRA also does not intend to alter the current statutory requirements contained in 49 U.S.C. 20303 regarding the movement of passenger equipment with defective or insecure safety appliances. *See* proposed §§ 238.229, 238.429, 238.431. Consequently, in paragraph (d), FRA proposes to require that passenger equipment that develops a defective or insecure safety appliance continue to be subject to all the

statutory restrictions on its movement. Under the current statutory language—

> A vehicle that is equipped in compliance with this chapter whose equipment becomes defective or insecure nevertheless may be moved when necessary to make repairs * * * from the place at which the defect or insecurity was first discovered to the nearest available place at which the repairs can be made-
>
> (1) on the railroad line on which the defect or insecurity was discovered; or
>
> (2) at the option of a connecting railroad carrier, on the railroad line of the connecting carrier, if not farther than the place of repair described in clause (1) of this subsection.

49 U.S.C. 20303(a). It should be noted that the proposed requirement applicable to Tier I equipment merely references the Railroad Safety Appliance Standards (49 CFR part 231); however, FRA has proposed separate safety appliance requirements for Tier II passenger equipment. *See* proposed §§ 238.429 and 238.431.

FRA proposes that passenger equipment that is found with conditions not in compliance with this part, other than power brake defects, be moved only after a qualified mechanical inspector has determined that the equipment is safe to move and determined any restrictions necessary for the equipment's safe movement. FRA also proposes to allow railroads to move equipment based on an assessment made by a qualified mechanical inspector in communication with on-site personnel. FRA proposes this allowance based on the reality that mechanical personnel are not readily available at every location on a railroad's line of road. However, FRA further proposes that if a qualified mechanical inspector does not actually inspect the equipment to determine that it is safe to move, then, at the first forward location where a qualified mechanical inspector is on duty, an inspector will perform a physical inspection of the equipment to confirm the initial assessment made while in communication with on-site personnel previously. Paragraph (c)(3) requires tracking of the defect in either of two ways. One option is to tag the equipment in a manner similar to what is currently required under § 215.9 for freight cars. The second option is to record the specified information in an automated tracking system. The latter alternative is offered to provide railroads some flexibility and in recognition of advances made in electronic recordkeeping.

Under paragraph (c), FRA proposes that after a mechanical inspector verifies that a noncomplying piece of equipment is safe to remain in passenger service, that piece of equipment may remain in passenger service until its next calendar day mechanical inspection. However, under paragraph (b), equipment containing noncomplying conditions at the time of the calendar day mechanical inspection may be moved from that location only if the noncomplying conditions are repaired or if all of the following conditions are satisfied: (1) if the equipment is moved out of passenger service and in a non-revenue train for the purpose of effectuating the repairs; (2) if the requirements of paragraphs (c)(2) and (c)(3) (regarding tagging and notification) are satisfied; and (3), in the case of a safety appliance defect, if the special conditions of paragraph (d) are met. As discussed previously, FRA has intentionally provided railroads wide flexibility in where and when it will perform the calendar day mechanical inspection in order to permit railroads to get the equipment to locations most conducive to conducting the inspections. Thus, FRA intends for calendar day mechanical inspections of passenger equipment to be conducted at locations where qualified mechanical inspectors are available and where virtually any necessary repair can be made. Consequently, FRA does not believe that the proposed restrictions on the movement of noncomplying equipment will be overly burdensome to the industry.

Paragraph (d) states the special statutory restrictions on the movement of passenger equipment with a safety appliance defect.

APTA, in its comments on a draft of the NPRM, agreed that many of the defects need to be repaired but do not require shopping the car or immediately taking it out of service. APTA further noted that this section does not take into account the fact-based maintenance cycles for equipment, subsystems, and components as the introduction of technology outpaces the regulatory process. Commenters are requested to address APTA's concerns.

§ 238.19 Reporting and tracking defective equipment. This section contains the reporting and tracking requirements that passenger railroads must maintain regarding defective passenger equipment. The Working Group did not reach consensus on the requirements proposed in this section. FRA proposes to require that each railroad develop and maintain a system for reporting and tracking equipment defects. FRA proposes that for each equipment defect discovered by the railroad on equipment used by the railroad the system record: the number by which the equipment is identified, type of defect, when the defect occurred, the determination made by a qualified mechanical inspector on how to handle the defect, and finally how and when the defect was corrected. FRA has not proposed any specific method or means by which a railroad should gather and maintain the required information. FRA believes that each railroad is in the best position to determine the method of obtaining the required information which is most efficient and effective based on its specific operation. Thus, railroads could maintain this information electronically in conjunction with their automated tracking system, if so desired.

FRA believes that reporting and tracking of defective equipment are essential features of any effective system safety program. Railroad managers are able to utilize such systems to ensure that the railroad complies with safety regulations, does not use unsafe equipment, makes needed repairs, and has failure data to make reliability-based decisions on maintenance intervals. Furthermore, most passenger railroads currently have some sort of reporting and tracking system in place. FRA recognizes that some railroads may have to incur additional initial costs to develop or improve defect reporting and tracking systems; however, FRA believes these costs can be recouped through the increased operating efficiency that an effective recording and tracking system provides.

Paragraph (b) requires that railroads maintain the required information for a period equal to one periodic maintenance interval for each specific type of equipment as described in the railroad's system safety plan. FRA believes that this minimum retention period will ensure that the records remain available when they are most needed, but will not place a burdensome record storage requirement on railroads. However, FRA strongly encourages railroads to keep these records for longer periods of time because they form the basis for future reliability-driven decisions concerning test and maintenance intervals.

Paragraph (d) requires railroads operating long-distance passenger trains to list the locations where repairs can be made to the equipment. FRA believes that the operators are in the best position to determine which locations have the necessary expertise to handle the repairs of the somewhat advanced braking systems utilized in passenger trains. FRA also proposes a broad performance-based requirement that railroads operating this equipment designate a sufficient number of repair locations to ensure the safe and timely

repair of the equipment. FRA intends to fine a railroad for violating this proposed requirement or take other enforcement action if, based on its expertise and experience, FRA believes the railroad is failing to designate an adequate number repair locations.

§ 238.21 Special approval procedure. This section states the procedures to be followed when seeking to obtain FRA approval of a pre-revenue service acceptance testing plan under §§ 238.113 or 238.603 or an alternative standard under §§ 238.115 (''Fire safety''), 238.223 (''Fuel tanks''), 238.309 (''Periodic brake equipment maintenance''), 238.311 (''Single car test''), 238.405 (''Longitudinal static compressive strength''), or 238.427 (''Suspension system''). Procedures for obtaining FRA approval of inspection, testing, and maintenance programs for Tier II equipment under § 238.503 are found at § 238.505.

Subpart B—System Safety and General Requirements

§ 238.101 Scope. This subpart contains the system safety program requirements to be applied to all passenger equipment subject to this part. Although FRA initially considered addressing system safety requirements for Tier I and Tier II equipment separately, FRA is proposing broad, minimum requirements which can be applied to all types of passenger railroad systems. Therefore, separate requirements are not needed.

The Working Group did not reach consensus on the system safety requirements as they apply to Tier I equipment, but strong support exists among Working Group members to apply formal system safety planning to Tier I equipment. The Tier II Subgroup did reach full consensus on the system safety program requirements as they apply to Tier II equipment.

Tier I and Tier II passenger equipment is used in a heavy rail environment that includes a mixture of freight and rail passenger traffic and highway-rail grade crossings used by heavy highway vehicles. Such an environment makes reliance on collision avoidance risky. As a result, crashworthiness must be designed into the equipment.

However, situations may arise where requiring strict adherence to either the Tier I standards or the Tier II standards may prevent rail passenger transportation that is in the public interest. As a result, FRA intends that the system safety planning process allow railroads to develop approaches to providing rail passenger transportation that do not meet all the Passenger Equipment Safety Standards but compensate by providing safety equivalency to that provided by meeting the full set of equipment safety standards. For example, a rail passenger operator would be allowed to seek relief from some of the structural standards based on a dedicated right-of-way or an advanced signaling system. However, the burden of demonstrating safety equivalency based on a comprehensive risk assessment falls squarely on the organization proposing the rail passenger operation that does not meet all the equipment standards.

The system safety plan must be a living document that evolves with the passenger rail system, and the system safety program detailed in the plan should be enforced until the system is decommissioned. Ideally, the system safety program would be in place at the inception of the system. This allows the maximum benefit of the program to be achieved. Tier II equipment and major new purchases of Tier I equipment will allow system safety planning to be used in the design and development phase of the new equipment. However, for the most part, Tier I system safety programs must be tailored to existing operations and equipment.

The system safety approach can be instituted at any point in the life cycle of a passenger rail system. APTA currently publishes a voluntary system safety program guide. Several APTA members, which operate existing Tier I equipment, instituted this system safety program on their existing rail systems. APTA periodically audits these programs and provides the operating authority with feedback on how well the system safety program has been implemented. As previously noted, APTA has suggested that commuter railroads be allowed to regulate themselves in this area, and that FRA not issue any regulations governing such plans. See preamble discussion; in the preamble FRA asked a variety of questions that commenters should address regarding the need for system safety plans, and if such plans should be required what their contents should contain and whether FRA should enforce the various elements of the plans.

In addition, Amtrak recently started a corporate system safety program initiative to make a formal system safety program an integral part of the way Amtrak conducts business. The value of the formal system safety process is rapidly being recognized by the passenger railroad industry and is becoming an accepted way of doing business.

§ 238.103 General system safety requirements. Paragraph (a) requires each railroad operating equipment subject to this part to adopt and annually update a system safety plan and implement a system safety program using MIL–STD–882(C) as a guide. MIL–STD–882(C) is a military standard issued by the Department of Defense that describes system safety planning and system safety programs used by the Unites States military for procuring and operating weapon systems. *See* also the discussion under § 238.5 of this section-by-section analysis. FRA does not attempt to dictate to railroads how to apply this guidance. Railroads should tailor their application of the guidance to their unique safety needs and operating scenarios.

Paragraphs (b)–(d) describe the various elements required to be included in the plan. In particular, paragraph (e) requires the operating railroad to document how the design meets safety requirements and to track how safety issues were raised and resolved. This is a necessary step to demonstrate that risks were identified and eliminated or mitigated.

Paragraph (f) requires the system safety plan to describe how operational limitations are to be imposed if the design cannot meet certain safety requirements. Operational limits are the least desirable and thus the last means considered to reduce a safety risk.

Paragraph (g) establishes the dates by which the operating railroad must adopt a system safety plan for each of the three categories of passenger equipment.

Paragraph (h) obliges the railroad to allow FRA to inspect and copy its system safety plan and the documentation required by paragraph (e).

§ 238.105 Fire protection program. Paragraph (a) requires that the operating railroad's system safety program address the fire safety of new equipment during the design stage so as to reduce the risk of harm due to fire on such equipment to an acceptable level as defined in MIL–STD–882(C). Paragraph (b) requires that railroads make a written analysis of the fire protection problem. These paragraphs require the operating railroad to ensure that good fire protection practice is used during the design and operation of the equipment. Using this good practice will allow the FRA fire safety regulations to be kept to a minimum. Four elements of this analysis correspond to required action under § 238.115, ''Fire safety': the installation of overheat detectors, a fire or smoke detection system, and a fixed, automatic, fire-suppression system where the railroad's written analysis determines they are required and compliance with the railroad's written

procedures for the inspection, testing, and maintenance of fire safety systems and equipment that such procedures designate as mandatory. *See* § 238.115(c)–(f).

Paragraph (c) requires the operating railroad to exercise reasonable care to assure that the system developer follows the design criteria and performs the tests required by the railroad's fire safety program during the design of new equipment. To fulfill this obligation in part, the operating railroad must include fire safety requirements in each of its contracts for the purchase of new equipment.

Paragraph (d) requires that existing passenger equipment and operations be subjected to a fire safety analysis similar to that proposed for new equipment in paragraphs (a)–(c). A preliminary fire safety analysis would be required within the first year. This effort would constitute an overview of the fleet and service environments, together with known elements of risk (e.g., tunnels). For any category of equipment and service identified as possibly presenting unacceptable risk, a full analysis and any necessary remedial action would be required within the following year. A full fire safety analysis, including review of the extent to which interior materials in all existing cars comply with the test performance criteria for flammability and smoke emission characteristics contained in Appendix B to this part or alternative standards approved by FRA under this part, would be required within 4 years. This overall review would closely parallel and reinforce the passenger train emergency preparedness planning effort that will be mandated under a separate docket (*see* 62 FR 8330; February 24, 1997).

This paragraph responds to NTSB concerns announced on June 17, 1997, in adopting its report on the collision of the MARC commuter train with Amtrak's Capitol Limited at Silver Spring, Maryland, and approving related recommendations. Among 13 recommendations to be addressed to FRA was the following:

> Require that a comprehensive inspection of all commuter passenger cars be performed to independently verify that the interior materials in these cars meet the expected performance requirements for flammability and smoke emissions characteristics.

The Abstract of Final Report did not include any express finding that materials in the MARC cab car did not meet FTA/FRA criteria for flammability and smoke emission characteristics. However, FRA understands that the full report may point to the introduction of some non-standard materials during refurbishing and repair of the car. The Board did find as follows:

> 19. Because other commuter passenger cars may also have interior materials that may not meet specified performance criteria for flammability and smoke emission characteristics, the safety of passengers in those cars could be at risk.
>
> 20. The federal guidelines on the flammability and smoke emission characteristics and the testing of interior materials do not provide for the integrated use of passenger car interior materials and, as a result, are not useful in predicting the safety of the interior environment of a passenger car in a fire.

FRA believes that existing fire safety guidelines have continuing value for their specific purpose. Those guidelines are proposed for codification in § 238.115 as the best currently available criteria for analysis of individual materials, and NTSB representatives on the working group have not suggested alternative proposals. However, as explained in the preamble, FRA is conducting research through the National Institute of Standards and Technology to address the interaction of materials and other aspects of fire safety from a broader, systems approach. This philosophy is embodied in proposed § 238.105(a)–(c) with respect to new equipment. Based on this ongoing research, FRA may propose new fire safety performance criteria in the second phase of this rulemaking.

FRA agrees with the Board that steps must be taken to minimize fire safety vulnerabilities in the existing rail passenger equipment fleet. Present fire safety guidelines are advisory and were not introduced by FRA until 1984. Even in recent years, passenger railroads have been free to utilize non-compliant materials (particularly during interior refurbishment funded locally without FTA support). It is appropriate for each commuter authority and Amtrak to evaluate the mix of materials, possible sources of ignition, and potential fire environments—including tunnels, cuts and elevated structures where evacuation to the outside of the vehicle may be difficult or ineffectual in reducing the risk of injury—relevant to the risk of injury due to fire or smoke exposure.

FRA is concerned in particular with the risk arising from the operation of cab cars forward and MU locomotives. Due to their position in the lead of a passenger train, these vehicles are more greatly exposed to the risk of fire from collisions with other rail vehicles as well as highway vehicles at grade crossings. In a collision, fire may erupt from the fuel tanks of both the rail and highway vehicles, and also from tanks used by highway vehicles that transport loads of flammable material. The level of risk on each railroad corresponds to the number of highway-rail grade crossings, density of rail traffic, and opportunities for collisions.

FRA requests comments on the costs and benefits associated with the approach contained in paragraph (d) should railroads be successful in establishing the categorical framework assumed for the analysis. Is the period of time allowed adequate to complete a review of the existing fleet and differing operating environments? To what extent does available fire safety literature adequately support this undertaking? What difficulties will be faced in identifying the source and current characteristics of interior materials, particularly in older cars and cars that have been transferred from the initial purchaser? In cars that have been refurbished by the railroad's own shop or a contract shop?

§ 238.107 Software safety program. This section provides requirements for the software portion of the system safety program and ties the system safety program to § 238.121, which describes the requirements for software that controls safety features of Tier I or Tier II equipment.

§ 238.109 Inspection, testing, and maintenance program. This section contains the general requirements for the railroad's program for inspecting, testing, and maintaining Tier I equipment. (The inspection, testing, and maintenance program for Tier II equipment is covered under § 238.503.) FRA's goal is a set of standards to ensure that the equipment remains safe as it wears and ages, to protect the workers who perform the inspection, testing, and maintenance tasks, and to provide flexibility enough to allow individual railroads to adapt the maintenance standards to their own unique operating environment. FRA based the proposed requirements on the extensive discussions and information presented in the Working Group meetings.

Paragraph (a) requires a railroad that operates Tier I passenger equipment subject to this part to provide to FRA, if requested, particulars about its inspection, testing, and maintenance program for that equipment, including the following:

- Safety inspection procedures, intervals and criteria;Washington, DC
- Testing procedures and intervals;
- Scheduled preventive maintenance intervals;
- Maintenance procedures; and
- Training of workers who perform the tasks.

Since FRA does not dictate the contents of the program, individual railroads retain much flexibility to tailor the program to their individual needs and experience. At the same time, FRA believes this requirement is an important component of the overall system safety program and the approach will cause railroads to re-examine their inspection, testing, and maintenance procedures to determine that they are adequate to ensure that the safety-related components of their equipment are not deteriorating over time. This approach represents good business practice and in most cases merely formalizes what passenger railroads are already doing. However, FRA believes this section will provide valuable guidance to regional governments or coalitions attempting to establish new commuter rail service.

Paragraph (b) defines broadly the types of conditions that can endanger the safety of the crew, passengers, or equipment that the inspection, testing, and maintenance program should be designed to prevent or to detect and correct. Beyond promulgating and enforcing an extensive set of Federal safety regulations on this subject, FRA is not proposing to specify how a railroad should prevent or detect these conditions. Instead, the proposed standards leave these details to be developed by each individual railroad.

Paragraph (c) establishes a link between scheduled maintenance intervals and the system safety program. Scheduled maintenance intervals should be set so that worn parts are replaced before they fail. Initial intervals should be based on manufacturer's recommendations. As operating experience is gained, FRA believes that accumulated reliability data should be used as the basis for changing preventive maintenance intervals on safety-critical components. This standard will encourage railroads to keep reliability records on safety-critical components that will provide confidence that any safety or economic trade-offs have a firm basis.

Paragraph (d) requires operating railroads to adopt standard operating procedures, in writing, on how to safely perform all safety-critical inspection, testing, and maintenance tasks. This provision is intended to provide protection to the workers who perform these tasks. Inspecting, testing and maintaining rail passenger equipment involves many inherently dangerous tasks. FRA does not intend to prescribe to how to perform these tasks. The proposed standard requires each individual railroad to think through how to safely perform these tasks and to develop procedures that are safe under its individual set of working conditions. Standard operating procedures can be a key component of a training program to ensure new employees know how to do their jobs safely.

§ 238.111 Training, qualification, and designation program. This section contains the proposed training, qualification, and designation requirements for workers (that is, both railroad employees and contractors as defined in the section) who perform inspection, testing, and maintenance tasks. FRA believes that worker training, qualification, and designation are central to a safe operation.

Labor organizations representing mechanical employees believe that only employees who receive a long-term apprenticeship and on-the-job training—typical of their membership—are qualified to perform inspection, testing, and maintenance tasks. Labor organizations representing operating employees (train crews) believe the work of inspecting and testing is largely outside the scope of work that should be performed by their members, and that railroads do not provide adequate training to their members for them to effectively inspect and test equipment.

Operating railroads believe a different level of skills is needed for simple inspections and tests (''checkers'') than is required for trouble-shooting and correction of problems (''maintainers''). As a practical reality, operating railroads make the point that they cannot afford to train their entire inspection, testing, and maintenance work force to be highly-skilled maintainers. Operating railroads claim that operating employees can be easily trained to perform the less complex inspection and testing tasks and in fact have been performing these tasks effectively for years.

Mechanical employee labor organizations counter this point with a strong belief that operating employees—lacking the experience and trained eye of a mechanical employee—perform a cursory inspection that misses defects or problems that would be caught by a mechanical employee.

As a result of these widely different points of view, the Working Group failed to reach overall consensus on the requirements contained in this section. FRA based the proposed requirements on the extensive discussions and information presented in the Working Group meetings as the merits and drawbacks of various approaches to setting the safety standards covered in this section were debated.

Paragraph (a) requires railroads to establish and comply with a training, qualification, and designation program for employees and contractors who perform safety-related inspection, testing, or maintenance tasks under this part. ''Contractor,'' in this context, means ''a person under contract with the railroad or an employee of a person under contract with the railroad.'' Paragraph (b) lists the steps that must be followed in developing a training, qualification, and designation program.

FRA believes that the list of general requirements enumerated in this section informs railroads what their training, qualification, and designation program must do reasonably to ensure that employees know how to keep the equipment running safely. Most passenger railroads have training programs in place that meet or come close to meeting these proposed requirements. The list of actions that FRA proposes would compel railroads to evaluate their operation and focus their training resources where the need is greatest.

FRA recognizes that some passenger railroads will be forced to place a greater emphasis on training and qualifications than they have in the past, and this requirement will result in additional costs for those railroads. However, the proposed rule allows the railroads the flexibility that they need to provide only that training which an employee needs for a specific job. The proposed rule does not require the ''checkers'' to receive the intensive training needed for the ''maintainers.'' The training can be tailored to the need. Across the industry as a whole, this proposal will not require extensive changes in the way passenger railroads currently operate. But it will prevent railroads from using minimally trained and unqualified people to perform crucial safety tasks.

Benefits can be gained from this increased investment in training. Better inspections will be performed, resulting in the running of less defective equipment, which translates to a better safety record. Equipment conditions requiring maintenance attention are more likely to be found while the equipment is at a maintenance or yard site where repairs can be more easily done. Trouble-shooting will take less time. More maintenance will be done right the first time, resulting in cost savings due to less rework.

APTA, in commenting on a draft of the NPRM, believes that this section's requirements are overly detailed in scope, content, and record keeping. APTA maintains that broad interpretation of the regulation could lead to arbitrary enforcement resulting in misdirection of training resources. In

addition, APTA contends that the proposal adds costs without a corresponding safety benefit—the cost to develop and implement the training programs and the cost to hire additional work force to perform the duties of those employees attending the required training classes. Commenters are invited to address APTA's concerns.

§ 238.113 Pre-revenue service acceptance testing plan. This section provides requirements for pre-revenue service testing of passenger equipment and ties the system safety program to subpart G, which describes the requirements for the introduction of new technology that could affect safety systems of Tier II passenger equipment. These tests are extremely important in that they are the culmination of all the safety analysis and component tests of the system safety program. The pre-revenue service tests are intended to demonstrate the effectiveness of the system safety program and prove that the equipment can be operated safely in its intended environment.

For equipment that has not previously been used in revenue service in the United States, paragraph (a) requires the operating railroad to develop a pre-revenue service acceptance testing plan and obtain FRA approval of the plan under the procedures stated in § 238.21 before beginning testing. Previous testing of the equipment at the Transportation Test Center, on another railroad, or elsewhere will be considered by FRA in approving the test plan. Paragraph (b) requires the railroad to fully execute the tests required by the plan, to correct any safety deficiencies identified by FRA, and to obtain FRA's approval to place the equipment in revenue service prior to introducing the equipment in revenue service. Paragraph (c) requires the railroad to comply with any operational limitations imposed by FRA. Paragraph (d) requires the railroad to make the plan available to FRA for inspection and copying. Paragraph (e) enumerates the elements that must be included in the plan. FRA believes this set of steps and the documentation required by this section are necessary to ensure that all safety risks have been reduced to a level that permits the equipment to be used in revenue service.

In lieu of the requirements of paragraphs (a) through (e), paragraph (f) provides for an abbreviated testing procedure for equipment that has previously been used in revenue service in the United States. The railroad need not submit a test plan to FRA; however, a description of the testing shall be kept by the railroad and made available to FRA for inspection and copying.

General Requirements

§ 238.115 Fire Safety

Paragraph (a) contains the fire safety requirements for materials used in constructing the interiors of passenger cars and cabs of locomotive ordered on or after January 1, 1999, or placed in service for the first time on or after January 1, 2001. Further, as of the effective date of the final rule, fire safety requirements also apply to materials used in refurbishing the interiors of passenger cars and locomotive cabs. Currently, the rail industry follows FRA's fire safety guidelines as revised on January 17, 1989. *See* 54 FR 1837. Several Working Group members believe that current fire safety practice has worked well in addressing the flammability of passenger car and locomotive cab interiors. However, since FRA's guidelines were first established, considerable fire safety and fire resistance testing technology has developed and some Working Group members believe that new information is available to improve fire safety.

As discussed earlier in the preamble, FRA is proposing that the existing fire safety guidelines be made mandatory for the construction of new equipment as well as the refurbishing of existing equipment, and they are contained in Appendix B. However, railroads can request, under § 238.21, FRA approval to utilize alternative standards issued or recognized by an expert consensus organization. As part of the second phase of the rulemaking, the Working Group will consider how to apply new fire safety information to improve the fire safety standards, including information being gathered by the NIST and the NFPA.

Paragraph (b) requires railroads to obtain certification that combustible materials to be used in constructing and refurbishing passenger car and locomotive cab interiors have been tested and comply with the fire safety standards as specified in paragraph (a) and Appendix B to this part.

Paragraphs (c) through (e) contain requirements for installing various detection and suppression equipment when shown to be necessary by analyses conducted as part of the fire protection program in § 238.105.

Paragraph (f) requires the railroad to comply with those elements of its written procedures, under § 238.105(12), for the inspection, testing, and maintenance of all fire safety systems and equipment that is has designated as mandatory as part of its fire protection program.

Paragraph (g) requires the railroad, after completing each fire safety analysis required by § 238.105(d), to take action to reduce the risk of personal injuries due to fire and smoke exposure as provided in § 238.105(d).

§ 238.117 Protection Against Personal Injury

As recommended by the Working Group, this section contains a general requirement to protect passengers and crewmembers from moving parts, electrical shock and hot pipes. This section extends to passenger equipment not classified as locomotives the protection against personal injury which applies to locomotives under 49 CFR 229.41. The proposed requirements represent common-sense safety practice; reflect current industry practice; and should result in no additional cost burden to the industry. These requirements apply to all passenger equipment on or after January 1, 1998.

§ 238.119 Rim-Stamped Straight-Plate Wheels

This section addresses the NTSB's safety recommendation concerning the use of rim-stamped straight-plate wheels on tread-braked rail passenger equipment, as discussed earlier in the preamble. Because a wheel having a rim-stamped straight-plate character is a sufficient safety concern in itself, FRA is extending the NTSB's safety recommendation to apply to all such wheels used on passenger equipment regardless whether the equipment is tread-braked or not.

§ 238.121 Train System Software and Hardware

This section contains the proposed requirements for the hardware and software that controls train safety functions that is ordered on or after January 1, 1999, and such systems implemented or materially modified for new or existing equipment on or after January 1, 2001. This section reflects the growing role of automated systems to control passenger train safety functions. FRA had presented for consideration a rather complex set of software safety requirements in the ANPRM, but the Working Group recommended simplifying these requirements and combining them with the requirements for the hardware components of control systems.

Paragraph (a) proposes a requirement for a formal safety methodology that includes a Failure Modes, Effects, Criticality Analysis (FMECA) and full verification tests for all components of safety system controls. A formal safety analysis that includes full verification is now standard practice for safety systems that contain software components.

In paragraph (b), FRA proposes to require a comprehensive hardware and software integration testing program to ensure that the hardware and the software installed in the hardware function together as intended. Again, this is a practice that has become common for critical control systems that include both software and hardware.

Paragraph (c) contains a provision for safety-related control systems driven by computer software to have design features that result in a safe condition in the event of a computer hardware or software failure. This is a design feature that is used in aircraft and in weapon control systems.

These requirements are not complex and will not limit the flexibility of equipment designers. Yet, they reflect good design practices that have led to reliable, safe computer hardware and software control systems in other industries. Computer hardware and software systems designed to these requirements may require a larger initial investment to develop, but experience in other industries has shown that this investment is quickly recovered by significantly reducing hardware and software integration problems and minimizing trouble-shooting and debugging of equipment.

§ 238.123 Emergency Lighting

Experience gained during rescues conducted after recent passenger train accidents indicates that emergency lighting systems either did not work or failed after a short time, greatly hindering rescue operations. This section requires that passengers cars and locomotives ordered or rebuilt on or after January 1, 1999, or placed in service for the first time on or after January 1, 2001, be equipped with emergency lighting providing a minimum average illumination level of 5 foot-candles at floor level for all potential evacuation routes and a back-up power feature capable of operation for a minimum of two hours after loss of normal power. Although members of the Working Group advised that the lighting intensity requirement be 0.05 foot-candle, FRA does not believe that 0.05 foot-candle provides enough illumination for passengers to locate emergency exits, read instructions for their operation, and operate the exits, as demonstrated by Volpe Center staff at a Working Group meeting in December, 1996. FRA requests comments whether the lighting intensity requirement need be 5 foot-candles at floor level for all potential evacuation routes if the rail vehicle has a combination of lower intensity floor proximity lighting, similar to that used on aircraft to mark the exit path, and higher intensity lighting at the vehicle's exits.

FRA is considering requiring that emergency lighting meeting the requirements of this section be implemented in existing passenger equipment sooner than when the equipment is rebuilt. Existing passenger equipment may not be rebuilt for 20 years or more. FRA therefore invites comments whether the proposed requirements should be implemented in existing passenger equipment within a specified time such as 5 years.

The two-hour time duration for availability of back-up power is based on experience gained during rescue operations for passenger train accidents in remote locations. In such accidents, fully-equipped emergency response forces can take an hour or more to arrive at the site, and additional time is required to deploy and reach people trapped or injured in the train. In addition, the back-up power system must be able to operate in all orientations within 45 degrees of vertical and after experiencing a shock due to a longitudinal acceleration of 8g and vertical and lateral accelerations of 4g. The shock requirement will ensure that the back-up power system has a reasonable chance of operating after the initial shock caused by a collision or derailment. FRA originally considered that the back-up power system be capable of operation within a vehicle in any orientation. However, members of the Working Group advised that some battery technologies utilize a liquid electrolyte which can leak when the battery is tilted. FRA is further considering whether the back-up power system should be made capable of operation within a vehicle in any orientation, including allowing railroads to continue using any existing batteries through their permanent life before implementing such a requirement on replacement batteries. Commenters are requested to address this issue.

FRA is further investigating emergency lighting requirements as part of a systems approach to effective passenger train evacuation through a research study to be performed by the Volpe Center. FRA welcomes input from knowledgeable persons as to what emergency lighting requirements would be appropriate for passenger trains to assist in passenger evacuation.

Subpart C—Specific Requirements for Tier I Passenger Equipment

§ 238.201 Scope

This subpart contains specific requirements for railroad passenger equipment operating at speeds not exceeding 125 mph. Unless otherwise specified in the discussion of this subpart and with the following qualifications, the proposed requirements represent the consensus recommendations of the Working Group. FRA has proposed the specific implementation dates for these requirements. Additionally, in structuring the rule FRA has specified the type of equipment subject to each requirement more finely than in the Working Group's recommendations, while at the same time reflecting those recommendations as closely as possible. Further, FRA has made other changes to the recommendations to make the proposed requirements more clear, enforceable, and compatible with other rail safety laws.

Structural standards for new equipment. Unless otherwise specified, the requirements of this subpart apply only to passenger equipment ordered on or after January 1, 1999, or placed in service for the first time on or after January 1, 2001.

The proposed rule also provides that passenger equipment placed in service for the first time on or after January 1, 1998, unless otherwise provided in the cited sections, must meet the minimum structural requirements specified in: §§ 238.203 (static end strength); 238.205(a) (anti-climbing mechanism); 238.207 (link between coupling mechanism and car body); and 238.211(a) (collision posts). Together, these four proposed requirements are virtually identical to existing Federal requirements, found in 49 CFR 229.141(a)(1)–(4), that apply to MU locomotives built new after April 1, 1956, and operated in trains having a total empty weight of 600,000 pounds or more. These proposed requirements reflect the current construction practice for North American passenger equipment, and FRA believes they are minimum safety requirements for new equipment.

In addition to the structural requirements identified above, the proposed rule also requires that passenger equipment ordered on or after January 1, 1999, or placed in service for the first time on or after January 1, 2001, unless otherwise provided in the cited sections, comply with other structural requirements specified in: §§ 238.205(b) (anti-climbing mechanism for locomotives); 238.209 (forward-facing end structure of locomotives); 238.211(b) (collision posts for locomotives); 238.213 (corner posts); 238.215 (rollover strength); 238.217 (side impact strength); 238.219 (truck-to-car-body attachment); and 238.223 (fuel tanks).

Structural standards for existing equipment. The proposed rule would require that passenger equipment (other than private cars, or vehicles of a special design operating at the rear of a passenger train and used solely to transport freight) in use on or after January 1, 1998, have a minimum static end strength of 800,000 pounds (§ 238.203). Static end strength is critical in protecting passenger equipment from crushing in a head-on or rear-end collision, especially in the North American railroad operating environment that includes frequent highway-rail grade crossings and the mixed operation of freight and passenger trains.

FRA is confident that existing North American passenger cars have been built to basic compressive strength requirements. Beginning in 1939, the AAR recommended that new passenger cars operated in trains of over 600,000 pounds empty weight have a minimum static end strength of 800,000 pounds, and since 1956, Federal Regulations (49 CFR 229.141) require that new MU locomotives operated in such trains must meet this standard.

FRA is considering requiring that one or more of the other structural requirements for new passenger equipment, discussed above, be made applicable to existing equipment as soon as one of the following events occurs: the equipment is sold to another railroad; the equipment is rebuilt; the equipment reaches 40 years of age; or 10 years after the effective date of the rule. FRA invites comments on: (1) what equipment would be affected by each of these structural requirements; (2) the feasibility and costs of retrofitting such equipment, with costs broken out for each of the different structural requirements, in the event such triggering events were adopted in the final rule; (3) whether these triggering events are reasonable, or whether some other fixed deadline should be established for making one or more of these structural requirements applicable to existing passenger equipment; and (4) the safety benefits that could accrue by making these requirements applicable to existing equipment.

FRA notes that older passenger equipment may not meet the collision post requirements in § 238.211(a) because of a change in collision post design following a collision between two Illinois Central Gulf Railroad commuter trains in Chicago, Illinois, on October 30, 1972. Moreover, APTA is opposed to making structural requirements applicable to existing equipment. In particular, APTA has advised FRA that a significant number of such equipment either may not meet the structural requirements in §§ 238.203, 238.205(a), 238.207, and 238.211(a), or the equipment must undergo potentially costly testing to determine whether the requirements are met. FRA will discuss with the Working Group alternatives that would avoid unnecessary expense to document design features of older equipment.

No new safety appliance requirements. FRA is not proposing new safety appliance requirements for passenger equipment subject to this subpart. The safety appliance requirements referenced in § 238.229 continue to apply to such passenger equipment and are noted in this rule for clarity, on the advice of the Working Group.

§ 238.203 Static End Strength

This section contains the requirements for the overall compressive strength of rail passenger equipment. The proposed requirements make mandatory the long-standing, North American design practice of specifying a minimum static end strength of 800,000 pounds, and a minimum static end strength of 800,000 pounds in the line of draft at the ends of occupied volumes, without permanent deformation of the car body structure. This requirement has proven effective in the North American railroad operating environment that includes frequent highway-rail grade crossings, mixed operation of freight and passenger trains, and less than fully-capable signal and train control systems. The requirement is effective on or after January 1, 1998. Although FRA would prefer that every vehicle in a passenger train have a minimum static end strength as specified in this section, FRA recognizes that imposing this requirement universally may effectively prohibit the use of some private cars and all auto-carriers and RoadRailer equipment.

To prevent sudden, brittle-type failure of the main structure of passenger equipment, the proposed rule requires that the body structure be designed, to the maximum extent possible, to fail by buckling or crushing, or both, of structural members rather than by fracture of structural members or failure of structural connections. To allow a crash energy management design approach to be employed, this requirement applies only to the occupied volume of the equipment. Unoccupied volumes may have a lesser static end yield strength.

§ 238.205 Anti-Climbing Mechanism

This section contains the vertical strength requirements for anti-climbing mechanisms on rail passenger equipment. The purpose of the anti-climbing mechanism is to prevent override or telescoping of one passenger train unit into another in the event of high compressive forces caused by a derailment or collision.

FRA is proposing that all passenger equipment placed in service for the first time on or after January 1, 1998, shall have an anti-climbing mechanism at each end capable of resisting an upward or downward vertical force of 100,000 pounds without permanent deformation. When coupled together in any combination to join two vehicles, AAR Type H and Type F tight-lock couplers satisfy this requirement. This requirement incorporates a long-standing industry practice into the proposed rule.

The proposed rule further requires that the forward end of a locomotive ordered on or after January 1, 1999, or placed in service for the first time on or after January 1, 2001, be equipped with an anti-climbing mechanism capable of resisting an upward or downward vertical force of 200,000 pounds without failure. This requirement applies to locomotives or power cars of permanently coupled trains. AAR Standard S–580, which addresses the crashworthiness of locomotives, has included this requirement for all locomotives built since August 1990. FRA believes this industry practice represents sound equipment design.

§ 238.207 Link Between Coupling Mechanism and Car Body

This section contains the vertical strength requirements for the structure that links the coupling mechanism to the car body on passenger equipment. The purpose of this requirement is to avoid a premature failure of the draft system so that the anti-climbing mechanism will have an opportunity to engage.

FRA is proposing that all passenger equipment placed in service for the first time on or after January 1, 1998, be provided with a coupler carrier or other coupler-to-car-body linking structure that is designed to resist a vertical downward thrust from the coupler shank of 100,000 pounds, without permanent deformation for any normal horizontal position of the coupler.

§ 238.209 Forward-Facing End Structure of Locomotives

This section contains the requirement for the covering or skin of the forward-

facing end structure of each passenger locomotive ordered on or after January 1, 1999, or placed in service for the first time on or after January 1, 2001. The purpose of this requirement is to protect the occupied area of a locomotive cab, which is especially vulnerable in a highway-rail grade crossing collision if a fuel tank that is part of or being transported by a highway vehicle ruptures.

FRA is proposing that the skin covering the forward-facing end of each passenger locomotive, *e.g.*, a cab car and an MU locomotive, be equivalent to a ½-inch steel plate with a 25,000 pounds-per-square-inch yield strength and be designed to inhibit the entry of fluids into the occupied area of the equipment. Higher yield strength material may be used to decrease the required thickness of the material provided an equivalent strength is maintained. AAR Standard S–580 has included this requirement for all locomotives built since August 1990. From observations of the improved performance of locomotives during collisions, FRA believes that this industry standard should become part of the proposed safety standards.

§ 238.211 Collision Posts

This section contains the structural strength requirements for collision posts. Collision posts provide protection against the crushing of occupied areas of passenger equipment in the event of a collision or derailment. This section does not apply to a vehicle of special design that operates at the rear of a passenger train and is used solely to transport freight, such as an auto-carrier or RoadRailer.

Paragraph (a) requires that all passenger equipment placed in service for the first time on or after January 1, 1998, shall have either two full-height collision posts at each end where coupling and uncoupling are expected, each collision post having an ultimate longitudinal strength of not less than 300,000 pounds; or an equivalent end structure.

The proposed 300,000-pound strength requirement makes mandatory the long-standing North American passenger equipment design practice for collision posts. This requirement has proven effective in the North American railroad operating environment. This requirement is similar to that contained in 49 CFR 229.141(a)(4), which applies to MU locomotives operated in trains having a total empty weight of 600,000 pounds or more, but also requires the collision posts to be full-height. Full-height collision posts provide additional protection because they extend higher than posts attached only at the underframe. Little, if any, additional cost is imposed on builders by requiring full height posts. The spacing at approximately the one-third points laterally will allow both collision posts to be engaged in many collision scenarios. An equivalent single rear end structure may be used in place of the two collision posts provided it can withstand the sum of the forces that each collision post is required to withstand.

Paragraph (b) requires that each locomotive ordered on or after January 1, 1999, or placed in service for the first time on or after January 1, 2001, have two forward collision posts, located at approximately the one-third points laterally, each capable of withstanding a 500,000-pound longitudinal force without exceeding the ultimate strength of the joint. In addition, each post must be capable of withstanding a 200,000-pound longitudinal force exerted 30 inches above the joint of the post to the underframe, without exceeding its ultimate strength. AAR Standard S–580 has included this requirement for all locomotives built since August 1990. From observation of the improved performance of these locomotives during collisions, FRA believes this industry practice should become part of the proposed safety standards.

As an option, an equivalent end structure may be used in place of the two forward collision posts. The single end structure shall withstand the sum of the forces that each collision post is required to withstand. This option is proposed to allow for the design of unitized or aircraft-type structures.

FRA is proposing that collision posts be required at the ends of passenger equipment where coupling and uncoupling are expected or where separation is likely in the event of a violent derailment. Paragraph (c) provides that if a train is made up of vehicles with articulated units, collision posts are required only at the ends of the permanently joined assembly of units, not at the ends of each unit of the assembly. Articulated units are not likely to experience impacts on other than the outside ends of the assembly.

§ 238.213 Corner Posts

This section contains the requirements for corner posts on passenger cars, *e.g.*, passenger coaches, cab cars and MU locomotives.

A corner post is the vertical structural member normally located at the intersection of the end of a rail vehicle with a side of that vehicle. However, FRA intends for the proposed rule to allow flexibility so that the corner post may be located at positions other than the extreme outside corner of a vehicle. For example, on cars equipped with end vestibules, the corner posts may be located in the side structure inboard of the side door opening.

The structural parameters proposed for corner post strength represent the current design practice for passenger cars built for North American service. They are being proposed as an interim measure to prevent the introduction of equipment not meeting such requirements. FRA recognizes that current design practice has proven inadequate to protect the occupied volume in several recent side-swipe collisions involving passenger trains with cab cars leading. Crash modeling suggests that it is not feasible to protect against collisions of the magnitude that occurred at Secaucus, New Jersey, and Silver Spring, Maryland, in February of 1996. Nevertheless, stronger corner posts are necessary to address collisions involving lower closing speeds, and determining what may be feasible in terms of cost and weight will be a priority in the second phase of the rulemaking.

§ 238.215 Rollover Strength

This section contains the structural requirements intended to prevent significant deformation of the normally occupied spaces of a passenger car in the event it rolls onto its side or roof. The proposal essentially requires the vehicle structure to be able to support twice the dead weight of the vehicle while the vehicle is resting on its side or roof. Deformation of sheathing and framing is allowed to the extent necessary for the vehicle to be supported directly by more substantial structural members of the frame, including the top chords and side frames. Analysis has shown that current passenger car design practice meets this requirement. This requirement has proven effective in preventing massive structural deformation of cars that have rolled during collisions or derailments. For this reason, FRA believes this requirement should be incorporated into the proposed safety standards.

FRA invites comment on whether this requirement should also apply to locomotives. Representatives from RPI advised that locomotives do not roll over frequently enough to justify such requirements for locomotives. Nevertheless, even if a locomotive does not roll over, this requirement should help protect its roof from crushing if it is forced to support the weight of another vehicle thrown onto its roof in an accident.

§ 238.217 Side Impact Strength

This section contains the car body strength requirements intended to resist penetration of the side structure of a passenger car by a highway or rail vehicle.

FRA believes that a side impact strength requirement is necessary because approximately 14% of the grade crossing accidents involving a passenger train result from a highway vehicle striking the side of the passenger train. In addition, during a derailment or train-to-train collision, trains frequently buckle, exposing the sides of cars to potential impacts during the collision. The proposed requirement was an AAR recommended design practice for passenger cars, as last revised in 1984, and represents current North American design practice.

In designing a side impact strength requirement for a passenger car, the objective is to cause the side of the passenger car to be strong enough so that the car derails rather than collapses when struck in the side by another rail vehicle or a heavy highway vehicle. FRA believes that current design practice may not be adequate to meet this goal. FRA also believes that cars with low floors, such as bi-level equipment, are particularly vulnerable to penetration when struck in the side. A more meaningful side impact strength requirement is necessary and will be a priority in the second phase of the rulemaking, as research determines what may be feasible in terms of cost and weight. The proposed requirement is therefore an interim measure to prevent the introduction or use of equipment not meeting this basic strength requirement.

§ 238.219 Truck-to-Car-Body Attachment

This section contains the truck-to-car-body attachment strength requirement for passenger equipment. The attachment is required to resist without failure a 2g vertical force on the mass of the truck and a force of 250,000 pounds in any horizontal direction. The requirement for the attachment to resist a horizontal force is intended to allow the truck to act as an anti-climbing device during a collision. With the truck attached to the car body, the truck of an overriding rail vehicle is likely to be caught by the underframe of the overridden rail vehicle, thus arresting the override. The parameter selected represents the current design practice that has proven effective in preventing horizontal shear of trucks from car bodies.

The requirement for the attachment to resist a vertical force is intended to keep the truck attached if the car body is raised or rolls over. If the truck remains attached to the car body, the truck is less likely to be struck by other units of the train. The attachment must resist, without failure, a force equal to twice the weight of the truck and all the components attached to the truck. Many types of keepers are used to keep trucks attached to car bodies. FRA believes that the majority of them are capable of meeting this requirement.

§ 238.221 Glazing

FRA is proposing additional requirements concerning the safety glazing of passenger equipment subject to the requirements of 49 CFR part 223. Existing safety glazing requirements for windows have largely proven effective in passenger service at speeds up to 125 mph. However, part 223 does not address the performance of the frame which attaches the glazing to the car body. This section requires the glazing frame to be capable of holding the glazing in place against all forces which the glazing is required to resist under part 223. In addition, the glazing frame must hold the glazing in place against the forces created by air pressure differences caused when two trains pass at their maximum authorized speeds in opposite directions at the minimum track separation for two adjacent tracks. This requirement is intended to prevent the glazing from being forced from the window opening and potentially injuring passengers and crewmembers. FRA that believes most existing passenger equipment subject to part 223 meets these requirements. However, they should not be left to chance and need to be required in the equipment design.

§ 238.223 Fuel Tanks

This section contains the structural requirements for external and integral fuel tanks on locomotives ordered on or after January 1, 1999, or placed in service for the first time after January 1, 2001. A discussion of fuel tank safety issues is provided above.

External fuel tanks must comply with AAR Recommended Practice-506, Performance Requirements for Diesel Electric Locomotive Fuel tanks. FRA believes that RP–506 represents an improvement in fuel tank crashworthiness and should be incorporated into the proposed standards. Labor representatives on the Working Group object to a direct incorporation of industry standards that effectively allow an industry organization to change a Federal safety standard by changing the industry standard. FRA agrees and is proposing that the rule incorporate the industry standard as adopted on July 1, 1995.

§ 238.225 Electrical System

This section contains the proposed requirements for the design of electrical systems on passenger equipment. The Working Group advised that no single, well-recognized electrical code or set of standards applied directly to the design of railroad passenger equipment. As a result, the Working Group recommended broad performance requirements which reflect common electrical safety practice and are widely recognized as good electrical design practice. FRA had offered for comment more detailed electrical system design requirements in the ANPRM, but as advocated by the Working group the proposed rule is more performance-oriented and provides wide latitude in equipment design. FRA believes that this approach helps to ensure good electrical design practice without imposing unnecessary costs on the industry.

The electrical system requirements include provisions for:

- Electrical conductor sizes and properties to provide a margin of safety for the intended application;
- Battery system design to prevent the risk of overcharging or accumulation of dangerous gases that can cause an explosion;
- Design of resistor grids that dissipate energy produced by dynamic braking with sufficient electrical isolation and ventilation to minimize the risk of fires; and
- Electromagnetic compatibility within the intended operating environment to prevent electromagnetic interference with safety-critical equipment systems and to prevent interference of the rolling stock with other systems along the rail right-of-way.

§ 238.227 Suspension System

This section contains the proposed requirements for suspension system performance of all Tier I passenger equipment on or after January 1, 1998, and represents the minimum requirements for a safe operation. In the ANPRM, FRA presented for comment a large set of fairly detailed suspension system performance requirements very similar to those now being proposed for Tier II passenger equipment. The Working Group advised that such an extensive set of requirements was not needed for Tier I passenger equipment.

Overall, FRA is proposing that all passenger equipment shall exhibit

freedom from hunting oscillations at all speeds. Further, FRA is proposing particular suspension system safety requirements for passenger equipment operating at speeds above 110 mph but not exceeding 125 mph, near the transition speed range from Tier I to Tier II requirements. Although FRA believes that for speeds not exceeding 110 mph existing equipment has not demonstrated serious suspension system stability problems, most of this same equipment is only operated at speeds that do not exceed 110 mph. Accordingly, when new or existing passenger equipment is intended for operation above 110 mph, this equipment must demonstrate stable operation during pre-revenue service qualification tests at all speeds up to 5 mph in excess of its maximum intended operating speed under worst-case conditions—including component wear—as determined by the operating railroad. The Working Group advised FRA that a single definition of worst-case conditions could not be applied generally to all railroads; and, as a result, the definition of worst-case conditions shall be determined by each railroad based upon its particular operating environment.

§ 239.229 Safety Appliances

This section references current safety appliance requirements contained in 49 U.S.C. chapter 203 and 49 CFR part 231. These existing requirements continue to apply independently to all Tier I passenger equipment, and FRA is referencing them here for clarity on the recommendation of the Working Group.

§ 238.231 Brake System

This section contains general brake system performance requirements that apply on or after January 1, 1998, to Tier I passenger equipment except as otherwise provided. Although the Working Group did not reach consensus on these proposed requirements due to the inability of the group to resolve the brake inspection, testing, and maintenance issues, the proposed provisions had widespread support among many of the members of the Working Group. Several of the proposed requirements contained in this section were included in written positions provided by both rail labor and management members of the Working Group. Virtually all of the proposed provisions were discussed in the 1994 NPRM on power brakes. *See* 59 FR 47676.

Paragraph (a) contains a requirement that the primary braking system be capable of stopping the train with a service application of the brakes from its maximum authorized operating speed within the signal spacing existing on the track. FRA believes that this proposed requirement is the most fundamental performance standard for any train brake system. This section merely codifies a requirement which is current industry practice and is the basis for safe train operation in the United States.

Paragraph (b) requires that passenger equipment ordered on or after January 1, 1999, or placed in service for the first time on or after January 1, 2001, be designed not to require an inspector to place himself or herself on, under, or between components of the equipment to observe brake actuation or release. The proposal allows railroads the flexibility of using a reliable indicator in place of requiring direct observation of the brake application or piston travel because the current designs of many passenger car brake systems make direct observation extremely difficult without the inspector placing himself or herself underneath the equipment. Brake system piston travel or piston cylinder pressure indicators have been used with satisfactory results for many years. Although indicators do not provide 100 percent certainty that the brakes are effective, FRA believes that they have proven themselves effective enough to be preferable to requiring an inspector to assume a dangerous position.

Paragraph (c) proposes to require that an emergency brake application feature be available at any time and that it produce an irretrievable stop. This section merely codifies current industry practice and ensures that passenger equipment will continue to be designed with an emergency brake application feature. In the 1994 NPRM on power brakes, FRA proposed a requirement that all trains be equipped with an emergency application feature capable of increasing the train's deceleration rate a minimum of 15 percent. *See* 59 FR 47729. Comments received in response to that proposal indicated that passenger brake equipment should provide a deceleration rate with a full service application that is close to the emergency brake rate and that the proposed requirement would require the lowering of full service brake rates, thereby compromising safety and lowering train speeds. Based on these comments, FRA proposes the current requirement which is in accordance with suggestions made by several passenger operations.

Paragraph (d) proposes to require that the train brake system respond as intended to brake control signals and that the brake control system be designed so that a loss of control signal causes a redundant control to take over or cause the brakes to apply. These proposed provisions are fundamental requirements necessary for effective brake system performance, and a codification of current industry practice. FRA intends the requirement to apply to all types of brake control signals, including pneumatic, electric, and radio signals.

Paragraph (e) proposes to prohibit the introduction of alcohol or other chemicals into the brake line. During periods of extreme cold weather, railroad employees at times resort to adding alcohol or other freezing point depressants to the brake line in an attempt to prevent accumulated moisture in the line from freezing. Virtually every railroad has a policy against this practice because alcohol and other chemicals attack the o-rings and gaskets that seal the brake system, causing them to age or fail prematurely. This practice can lead to dangerous air leaks and it increases maintenance costs. FRA proposed a similar requirement in the 1994 NPRM on power brakes and received numerous comments supporting this provision. *See* 59 FR 47728.

Paragraph (f) proposes to require that the brake system be designed and operated to prevent dangerous cracks in wheels. Passenger equipment wheels are normally heat treated so that the wheel rim is in compression. This condition forces small cracks that form in the rim to be closed. Heavy tread braking can heat wheels to the point that a stress reversal occurs and the wheel rim is in tension to a certain depth. Rim tension is a dangerous condition because it promotes surface crack growth. In the 1994 NPRM on power brakes, FRA proposed a wheel surface temperature limit to prevent this condition. *See* 59 FR 47729. Several brake manufacturers and railroads objected to this approach, claiming that the temperature limit was too conservative and did not allow for the development of new materials that can withstand higher temperatures. Based on these comments and concerns, FRA is proposing a more flexible performance requirement rather than a wheel tread surface temperature limit. This is an extremely important safety requirement because a cracked wheel that fails at high speed can have catastrophic consequences. In addition, the proposed requirement will lead to longer wheel life, and thus should provide maintenance savings to the railroads.

Paragraph (g) proposes to require that brake discs be designed and operated so that the disc surface temperature does not exceed manufacturer recommendations. In the 1994 NPRM,

FRA proposed a disc surface temperature limit. *See* 59 FR 47729. As noted above, several brake manufacturers and railroads objected to this approach, claiming that the temperature limit was too conservative and did not allow for the development of new materials that can withstand higher temperatures. Based on these comments and concerns, FRA proposes a more flexible requirement rather than a single disc surface temperature limit. FRA believes this requirement will lead to longer disc life, and thus will produce maintenance savings to railroads.

Paragraph (h) proposes to require that, except for a locomotive that is ordered before January 1, 1999, and placed in service for the first time before January 1, 2001, and except for a private car, all passenger equipment shall be equipped with a hand or parking brake that can be set and released manually and can hold the equipment on the maximum grade anticipated by the operating railroad. A hand or parking brake is an important safety feature that prevents the rolling or runaway of parked equipment. The proposed requirement represents current industry practice. In the 1994 NPRM on power brakes, FRA proposed requiring that a hand brake be equipped on cars and locomotives. *See* 59 FR 47729. FRA received several comments to that proposal suggesting that the term ''parking brake'' be added to the requirement since that is what is used in many passenger operations. Based on those suggestions, FRA has added the term in this proposal.

Paragraph (i) proposes to require that passenger cars be equipped with a means for the emergency brake to be applied that is clearly identified and accessible to passengers. This is a longstanding industry practice and an important safety feature because crucial time may be lost requiring passengers sensing danger to find a member of the train crew to stop the train.

Paragraph (j) contains proposed provisions to ensure that the dynamic brake does not become a safety-critical device. Railroads have consistently held that dynamic brakes are not safety devices because the friction brake alone is capable of safely stopping a train if the dynamic brake is not available. The proposed provisions include requiring that the blending of the friction and dynamic brakes be automatic, that the friction brakes alone be able to stop the train in the allowable stopping distance, and that a failure of the dynamic brake does not cause thermal damage to wheels or discs due to the greater friction braking load. FRA believes that without these requirements the dynamic brake would most likely become a safety-critical item and railroads would not be permitted to dispatch trains unless the dynamic brake were fully operational.

Paragraph (k) proposes to require that either computer modeling or dynamometer tests be performed to confirm that new brake designs not result in thermal damage to wheels or discs. Further, if the operating parameters of the new braking system change significantly, a new simulation must be performed. This proposal provides a means to ensure that the requirements proposed in paragraphs (f) and (g) are being complied with by new brake designs.

Paragraph (l) proposes to require that all locomotives ordered on or after January 1, 1999, or placed in service for the first time on or after January 1, 2001, be equipped with effective air coolers or air dryers on those locomotives that are equipped with air compressors. The coolers or dryers must be capable of providing air to the main reservoir with a dew point suppression at least 10 degrees F. below ambient temperature. FRA and most members in the industry agree that moisture is a major cause of brake line contamination. Consequently, reducing moisture leads to longer component life and better brake system performance. Currently, virtually all passenger railroads purchase only locomotives equipped with air dryers or coolers. Therefore, FRA proposes to require the continuation of what it believes is good industry practice.

§ 238.233 Interior Fittings and Surfaces

This section contains proposed requirements concerning interior fittings and surfaces that apply, as specified in this section, to passenger cars and locomotives ordered on or after January 1, 1999, or placed in service for the first time on or after January 1, 2001. This section should be read in connection with an earlier discussion of train interior safety features in the preamble.

FRA and NTSB investigations of passenger train accidents have revealed that luggage, seats, and other interior objects breaking or coming loose is a frequent cause of injury to passengers and crewmembers. During a collision, the greatest decelerations and thus the greatest forces to cause potential failure of interior fitting attachment points are experienced in the longitudinal direction, *i.e.*, in the direction parallel to the normal direction of train travel. Current practice is to design seats and other interior fittings to withstand the forces due to accelerations of 6g in the longitudinal direction, 3g in the vertical direction, and 3g in the lateral direction. Due to the injuries caused by broken seats and other loose fixtures, FRA believes that the current design practice is inadequate.

Accordingly, paragraph (a) proposes that each seat in a passenger car remain firmly attached to the car body when subjected to individually applied accelerations of 4g in the vertical direction and 4g in the lateral direction acting on the deadweight of the seat or seats, if a tandem unit. In addition, the attachment must resist a longitudinal inertial force of 8g acting on the mass of the seat plus the impact force of the mass of a 95th-percentile male occupant(s) being decelerated from a relative speed of 25 mph and striking the seat from behind. By resisting the force of an occupant striking the seat from behind, a potential domino effect of seats breaking away from their attachments is avoided.

Paragraph (b) proposes that overhead storage racks provide longitudinal and lateral restraint for stowed articles to minimize the potential for these objects to come loose and injure train occupants. Further, to prevent overhead storage racks from breaking away from their attachment points to the car body, these racks shall have an ultimate strength capable of resisting individually applied accelerations of 8g longitudinally, 4g vertically, and 4g laterally acting on the mass of the luggage stowed. This mass shall be specified by each railroad. Paragraph (c) requires that all other interior fittings in a passenger car be attached to the car body with sufficient strength to withstand individually applied accelerations of 8g longitudinally, 4g vertically, and 4g laterally acting on the mass of the fitting. FRA believes the proposed attachment strength requirements for seats, overhead storage racks, and other interior fittings will help reduce the number of injuries to occupants in passenger cars.

Passenger car occupants may also be injured by protruding objects, especially if the occupants fall or are thrown against such objects during a train collision or derailment. As a result, FRA is proposing in paragraph (d) that, to the extent possible, all interior fittings in a passenger car, except seats, shall be recessed or flush-mounted. Such fittings do not protrude above interior surfaces and thereby help to minimize occupant injuries.

Paragraph (e) is a general, common sense prohibition against sharp edges and corners in a locomotive cab and a passenger car. Just as FRA is concerned about protruding objects, these surfaces could also injure passenger train

occupants. If sharp edges and corners cannot be avoided, they should be padded to mitigate the consequences of occupant impacts.

Paragraph (f) contains the requirements for floor-mounted cab seats provided solely for the crewmembers in locomotive cabs. FRA proposes to require the seat attachment to have an ultimate strength capable of resisting the loads due to individually applied accelerations of 8g longitudinally, 4g vertically, and 4g laterally acting on the combined mass of the seat and its occupant. This requirement is more stringent than the requirement for seats in passenger cars in paragraph (a) because the mass of the seat occupant is included in determining the load that must be resisted. Cab seats designed to this requirement will allow the use of seat belts and shoulder harnesses to restrain crewmembers in a collision. Further, when turned backwards during a collision, seats designed to this requirement can effectively restrain crewmembers.

§ 238.235 Emergency Window Exits

This section should be read with the earlier discussion of emergency window exits in the preamble. With the exception of paragraph (b), the requirements in this section are applicable to passenger cars on or after January 1, 1998, thereby including existing passenger cars. However, the emergency window exit size requirements in paragraph (b) are only applicable to passenger cars placed in service for the first time on or after January 1, 1998. APTA has advised FRA that not all emergency window exits on existing passenger cars meet the size requirements of paragraph (b), and FRA invites comment on this point.

This section requires that a single-level passenger car, other than a passenger car of special design, have a minimum of four emergency window exits, either in a staggered configuration or with one located at each end of each side of the car. A bi-level car shall have a minimum of four emergency window exits on each main level, configured as above, so that the car has a minimum total of eight emergency window exits. Safety may be advanced by staggering the configuration of emergency window exits so that the window exits are located diagonally across from each other on opposite sides of a car, instead of placing them directly across from each other. Commenters are invited to address this issue. In addition, concern has been raised that the seat arrangement of passenger cars may block access to and the removal of emergency window exits. Commenters are also requested to address this issue.

FRA is proposing that each passenger car of special design, such as a sleeper car, have at least one emergency window exit in each compartment. Occupants of a sleeper car may have difficulty reaching the car doors quickly in an emergency from their compartments, for example, if an emergency window exit is not provided in their individual sleeping compartments. An emergency window exit is necessary in each compartment to enable occupants to quickly exit the car when time is of the essence, especially if the car is submerged.

Each emergency window exit must be easily operable by a 5th-percentile female without requiring the use of a tool or other implement. FRA has added to the Working Group's recommendation by specifying that a 5th-percentile female must be able to easily operate the emergency exit, thereby making clear the degree to which the exit need be easily operable by members of the general public. FRA believes this is consistent with the desire of the Working Group to promote the safety of the travelling public.

Paragraph (f) is reserved for emergency window exit marking and operating instruction requirements. These requirements are currently being addressed in the proposed rule on passenger train emergency preparedness. *See* 62 FR 8330, Feb. 24, 1997.

§ 238.237 Doors

This section contains the requirements for exterior side doors on passenger cars. These doors are the primary means of egress from a passenger train. This section should be read in connection with the preamble discussion of NTSB safety recommendation (R–96–7) arising from the 1996 Silver Spring, Maryland accident.

Paragraph (a) requires that within two years of the effective date of the final rule, each powered, exterior side door in a vestibule that is partitioned from the passenger compartment of a passenger car shall be equipped with a manual override that is: capable of opening the door without power from inside the car; located adjacent to the door which it controls; and designed and maintained so that a person may access the override device from inside the car without requiring the use of a tool or other implement. Passenger cars subject to this requirement that are not already equipped with such manual override devices must be retrofitted accordingly. As noted above, FRA's proposal is not a consensus recommendation of the Working Group.

FRA invites comment on whether the location of the manual override device should be specified in terms of distance from the door it controls or some other measure. FRA is proposing that the manual override device be ''adjacent'' to the door, as stated in the NTSB safety recommendation. Railroad representatives on the Working Group have suggested a time performance requirement that includes the time necessary for locating and opening the door.

Currently, there is no Federal requirement that passenger cars be equipped with side doors. Accordingly, in paragraph (b) FRA is proposing that passenger cars ordered on or after January 1, 1999, or placed in service for the first time on or after January 1, 2001, shall have a minimum of four side doors, or the functional equivalent, each permitting at least one 95th-percentile male to pass through at a single time. Although the Working Group did not discuss this proposal, FRA believes that such a requirement is necessary, at least as an interim measure, so that each passenger car have sufficient doorway openings to allow passengers to quickly exit in a life-threatening situation. Exiting a passenger car through a window exit is slower.

FRA recognizes that existing designs of passenger cars do not always provide for four side doors, and the proposed requirement does not specifically require that passenger cars have four side doors. For instance, the requirement would be met if a passenger car had two double-wide doors that permit two 95th-percentile males to pass through each door at the same time—the functional equivalent of four side doors having openings of the specified size. FRA is interested in comments concerning the extent to which existing designs of passenger cars cannot comply with the proposed requirement, and FRA may modify the proposal based on the information supplied. As a longer term approach, FRA is investigating an emergency evacuation performance requirement similar to that used in commercial aviation where a sufficient number of emergency exits must be provided to evacuate the maximum passenger load in a specified time for various types of emergency situations.

Paragraph (b) also provides that each powered, exterior side door be equipped with a manual override feature the same as that required in paragraph (a) for existing equipment, except that the manual override must also be capable of opening the door from outside the car.

This requirement is intended to provide quick access to a passenger car by emergency response personnel, and represents the consensus recommendation of the Working Group.

FRA is also considering, but has not proposed in this rule, that for passenger cars ordered on or after January 1, 1999, or placed in service for the first time on or after January 1, 2001, the status of each powered, exterior side door shall be displayed to the crew in the operating cab of the train. Such a proposal had support from Working Group members and would enable a crewmember in the operating cab to determine whether train doors are closed before departure, for example. However, FRA is concerned that railroads operating Tier I passenger equipment would be unable to meet this requirement. Because Tier I passenger trains are not intended to operate as a fixed unit and instead passenger cars are freely switched into and out of such trains, practical concerns exist about the compatibility of door sensor equipment in a Tier I passenger train. Commenters are invited to address this issue.

To make sure that manual override devices are easily accessible by passengers, FRA is proposing requirements in paragraph (c) addressing covers and screens used to protect such devices from casual or inadvertent use. FRA desires to balance the concern that passengers may unnecessarily exit cars when no emergency is present with the need for passengers to easily access a door-release mechanism in an emergency. Although this proposal reflects general discussions within the Working Group, it is not specifically a Working Group recommendation.

Paragraph (d) is reserved for door marking and operating instruction requirements. These requirements are currently being addressed in the proposed rule on passenger train emergency preparedness. See 62 FR 8330, Feb. 24, 1997.

§ 238.239 Automated Monitoring

This section requires on or after January 1, 1998, an operational alerter or a deadman control in the controlling locomotive of each passenger train operating in other than cab signal, automatic train control, or automatic train stop territory. This section further requires that such locomotives ordered on or after January 1, 1999, or placed in service for the first time on or after January 1, 2001, must be equipped with a working alerter. As a result, the use of a deadman control alone on these new locomotives would be prohibited. The Working Group recommended that new locomotives be equipped with a working alerter, and FRA is proposing that existing locomotives also be equipped with either a working alerter or a deadman control as provided in paragraph (a).

An alerter will initiate a penalty brake application if it does not receive the proper response from the engineer. Likewise, a deadman control will initiate a penalty brake application if the engineer fails to maintain proper contact with the device. The Working Group discussed establishing specific setting requirements for alerters or deadman controls based on maximum train speed and the capabilities of the signal system. This discussion led to the conclusion that settings should be left to the discretion of individual railroads as long as they document the basis for the settings that they select. If the device fails en route, the proposed rule requires a second person qualified on the signal system and brake application procedures to be stationed in the cab or the engineer must be in constant radio communication with a second crewmember until the train reaches the next terminal. This is intended to allow the train to complete its trip with the device's function of keeping the operator alert taken over by another member of the crew.

Alerters are safety devices intended to verify that the engineer remains capable and vigilant to accomplish the tasks that he or she must perform. Equipping passenger locomotives with an alerter is current industry practice. These devices have proven themselves in service, and the requirement will not impose an additional cost on the industry.

Subpart D—Inspection, Testing, and Maintenance Requirements of Tier I Passenger Equipment

§ 238.301 Scope

This subpart contains the proposed requirements regarding the inspection, testing, and maintenance of all types of passenger equipment operating at speeds of 125 mph or less. FRA originally considered developing one set of requirements for MU locomotives and one set for push-pull equipment. However, the Working Group determined that this approach would be redundant because nearly identical requirements could be applied to both types of equipment. Consequently, this subpart includes the proposed requirements for the inspection, testing, and maintenance of Tier I passenger equipment brake systems as well as the other mechanical and electrical safety components of Tier I passenger equipment.

§ 238.303 Exterior Calendar Day Mechanical Inspection of Passenger Cars and Unpowered Vehicles Used in Passenger Trains

This section contains the proposed requirements for an exterior calendar day mechanical inspection on passenger cars and unpowered vehicles used in passenger trains that is patterned after a combination of the current calendar day inspection required for locomotives under the Railroad Locomotive Safety Standards and the pre-departure inspection for freight cars under the Railroad Freight Car Safety Standards. *See* 49 CFR 229.21 and 215.13, respectively. FRA proposes that the calendar day mechanical inspection apply to all passenger cars and all unpowered vehicles used in passenger trains (which includes, e.g., not only coaches, MU locomotives, and cab cars but also any other unit of rail rolling equipment used in a passenger train). A mechanical safety inspection of freight cars has been a longstanding Federal safety requirement, and FRA believes that the lack of a similar requirement for passenger equipment creates a serious void in the current Federal railroad safety standards.

Paragraphs (a) and (b). Rail labor representatives advocate a daily inspection of all safety-related mechanical components with pass/fail criteria or limits written into the Federal safety standards much like the requirements contained in 49 CFR part 215, whereas, APTA and other passenger railroad representatives strongly maintain that specific inspection criteria or limits are not necessary. During the ongoing meeting of the Working Group, FRA repeatedly requested that railroad representatives provide a recommended list of mechanical components and criteria for their inspection. These representatives consistently responded with very broad requirements basically limited to inspections for obvious and visible defects. Although passenger railroad representatives do not object to the safety principle of a mechanical inspection, they do not want their operations to be bound by a rigid list of components and criteria for the inspection.

FRA agrees with labor representatives that a specific list of components to be inspected with enforceable inspection or pass/fail criteria needs to be included as part of the proposed Passenger Equipment Safety Standards. For several years, Amtrak has been conducting voluntary mechanical safety inspections of passenger train components. Amtrak, working in conjunction with FRA, has

developed a list of components to be inspected and ''go'' ''no go'' inspection criteria for the various components. Amtrak has trained mechanical employees to conduct these inspections and has issued pocket guides containing the inspection criteria to all mechanical employees. FRA commends Amtrak for its progressive and voluntary efforts. Furthermore, based upon investigations conducted by FRA field inspectors, it appears that virtually every passenger railroad currently performs some type of daily mechanical inspection on its passenger equipment. Consequently, FRA proposes to codify various requirements and minimum standards for conducting a calendar day mechanical inspection.

Paragraph (a) requires that each passenger car and each unpowered vehicle used in a passenger train receive an exterior mechanical safety inspection at least once each calendar day that the equipment is placed in service except under the circumstances described in paragraph (d). Paragraph (b) requires that this inspection be performed by a qualified mechanical inspector. FRA believes the combination of a daily Class I brake test and a mechanical safety inspection performed by fully qualified mechanical employees is a key to safer passenger railroad operations. Such a practice will most likely detect and correct equipment problems before they become the source of an accident or incident resulting in personal injuries or damage to property. FRA recognizes that this requirement may create a problem for some commuter railroads that operate trains on weekends or other days when qualified mechanical inspectors are not scheduled to work. Some railroads may be forced to schedule qualified mechanical inspectors to work on these days at additional expense. However, based on independent investigations performed by FRA, it is believed that the impact of this proposal will be much less than several railroad representatives have indicated. Nevertheless, FRA is willing to consider whether to allow railroads that have demonstrated an ability to operate passenger trains safely over weekends without a mechanical safety inspection being performed by qualified mechanical inspectors to continue that practice. The problem, from FRA's position, is that it is difficult to allow this flexibility without creating a loophole that could be abused in certain circumstances. Consequently, FRA solicits detailed comments from interested parties on whether the granting of such flexibility is even necessary and on possible methods for providing such flexibility.

Paragraph (c) identifies the components that FRA proposes to be inspected as part of the exterior daily mechanical safety inspection and provides measurable inspection criteria for the components. The railroad is required to ascertain that each passenger car, and each unpowered vehicle used in a passenger train conforms with the conditions enumerated in paragraph (c). Deviation from any listed condition makes the passenger car or unpowered vehicle defective if it is in service. The Working Group members generally agreed that the components contained in this section represent valid safety-related components that should be frequently inspected by railroads. However, members of the Working Group had widely different opinions regarding the criteria to be used to inspect these components. Therefore, as FRA was not provided any clear guidance from the Working Group, FRA selected inspection criteria based on the locomotive calendar day inspection and the freight car safety pre-departure inspection required by 49 CFR parts 229 and 215, respectively. FRA believes that, at a minimum, passenger cars should receive an inspection which is at least equivalent to that received by locomotives and freight cars. FRA solicits comments from interested parties concerning other sets of mechanical safety inspection criteria. For example, a concern has been raised by some parties regarding the securement of doors on baggage cars. Consequently, FRA seeks comments from interested parties on the necessity to inspect these doors as part of any required daily mechanical inspection.

APTA believes that this section contains exterior inspection requirements that cannot be safely or practically performed in the field. In particular, APTA maintains that the inspections concerning the draft gear, truck attachment, suspension system, and coupler knuckle can only be properly performed by placing each car individually over a repair pit.

FRA intends for the daily mechanical inspection to serve as the time when the railroad repairs defects that occurred en route. Thus, this section proposes to require that safety components not in compliance with this part be repaired before the equipment is permitted to remain in or return to passenger service. (*See* § 238.9 for a discussion of the prohibitions against using passenger equipment containing defects; and §§ 238.15 and 238.17 for a discussion of movement of defective equipment for purposes of repair or sale). The purpose of the defect reporting and tracking system proposed in § 238.19 is to have the mechanical forces make all necessary safety repairs to the equipment before it is cleared for another day of operation. In other words, FRA intends for the flexibility to operate defective equipment in passenger service to end at the calendar day mechanical inspection.

The narrow exception in paragraph (d) allows long-distance intercity passenger trains that miss a scheduled exterior calendar day mechanical inspection due to a delay en route to continue in passenger service to the location where the inspection was scheduled to be performed. At that point, a calendar day mechanical inspection must be performed prior to returning the equipment to service of any kind. This flexibility applies only to the mechanical safety inspections of coaches. FRA does not intend to relieve the railroad of the responsibility to perform a locomotive calendar day inspection as required by 49 CFR part 229.

Paragraph (e) specifies an additional contingent component of the calendar day exterior mechanical inspection. If a car requiring a single car test is moved in a train carrying passengers or available to carry such passengers to a place where the test can be performed, then the single car test must be performed before or during the exterior calendar day mechanical inspection.

§§ 238.305 and 238.307 Interior Calendar Day Mechanical Inspection and Periodic Mechanical Inspection of Passenger Cars

Section 238.305 requires the performance of an interior inspection of passenger cars (which includes, e.g., passenger coaches, MU locomotives, and cab cars) each calendar day that the equipment is used in service except under the circumstances described in paragraph (d). Unlike the exterior calendar day mechanical inspection, FRA proposes in § 238.305(b) to permit the interior inspections of passenger cars to be performed by ''qualified persons,'' individuals qualified by the railroad to do so. Thus, these individuals need not meet the definition of a ''qualified mechanical inspector.''

FRA's original position was to require the interior inspections to be performed by qualified mechanical inspectors. However, after several discussions with members of the Working Group and several other representatives of passenger railroads, FRA determined that the training and experience typical of qualified mechanical inspectors is not necessary and often does not apply to

inspecting interior safety components of passenger equipment. In addition, the flexibility created by permitting someone less qualified than a mechanical inspector can reduce the cost of performing the mechanical safety inspection since the most economical way to accomplish the mechanical inspection is to combine the exterior inspection with the Class I brake test and then have a crewmember or train coach cleaner combine the interior coach inspection with coach cleaning.

Section 238.305(c) lists various components that FRA proposes to be inspected as part of the interior daily mechanical safety inspection. As a minimum, FRA proposes that the following components be inspected: trap doors; end and side doors; manual door releases; safety covers, doors and plates; vestibule step lighting; and safety-related signs and instructions. Consistent with the proposed exterior inspection requirements, FRA proposes that all en route defects and all noncomplying conditions must be repaired at the time of the daily interior inspection in order for the equipment to be placed or remain in passenger service with the exception of a defect under § 238.305(c)(5). (*See* § 238.9 for a discussion of the prohibitions against using passenger equipment containing defects, and § 238.17 for a discussion of the movement of defective equipment for purposes of repair.) Furthermore, § 238.305(d) allows long-distance intercity passenger trains that miss a scheduled calendar day mechanical inspection due to a delay en route to continue in passenger service to the location where the inspection was scheduled.

Initially, FRA considered requiring a more extensive list of components to be checked at each daily interior inspection. However, based on discussions conducted with the Working Group, FRA determined that the daily inspection and repair of some interior items could be burdensome to the railroads without producing an offsetting safety benefit. As a result, FRA in § 238.307 proposes a periodic mechanical inspection for passenger cars (which include, e.g., passenger coaches, MU locomotives, and cab cars) in order to reduce the frequency with which certain components require inspection and repair. FRA proposes to require that the following components be inspected for proper operation and repaired, if necessary, as part of the periodic maintenance of the equipment: emergency lights; emergency exit windows; seats and seat attachments; overhead luggage racks and attachments; floor and stair surfaces; and hand-operated electrical switches.

Virtually all passenger railroads currently have defined periodic maintenance intervals for all of the equipment they operate. These intervals vary depending on the type of equipment and the service in which it is used, but typically range from 60 to 180 days. Although FRA does not intend to limit the railroad's flexibility to set periodic maintenance intervals, FRA believes that an outside limit must be placed on the performance of the periodic mechanical inspection. Thus, FRA proposes that the periodic mechanical inspection be performed at least every 180 days, as that appears to be the outside limit of currently established maintenance cycles. As with the daily inspection, any known defects or conditions not in compliance with this section which are uncovered by the periodic inspection must be repaired in order for the equipment to remain in or return to passenger service.

APTA has advised FRA that most of the daily interior inspection requirements proposed in this section are currently performed as part of a railroad's own periodic inspection. Moreover, APTA maintains that the daily interior inspection requirements do not add to safety and will create delays impacting on-time performance. APTA believes that many cars with defects found during both the daily interior and exterior inspections can be operated safely with appropriate restrictions without first shopping the cars. Commenters are asked to address the various concerns raised by APTA.

§ 238.309 Periodic Brake Equipment Maintenance

This section contains the proposed requirements for the performance of periodic brake maintenance for various types of passenger equipment, referred to in the industry as clean, oil, test, and stencil (COT&S).

Paragraph (b) extends the periodic maintenance interval for MU locomotive fleets that are 100 percent equipped with air dryers and modern brake systems from 736 days to 1,104 days. The requirement remains 736 days for fleets that are not 100 percent equipped with air dryers or that are equipped with older brake systems. FRA bases this proposed extension on tests conducted by Metro-North and monitored by FRA field inspectors. These tests revealed that after three years, brake valves on MU locomotives equipped with air dryers were very clean and showed little or no signs of deterioration. Based on the results of these tests, FRA is confident that these valves can safely operate for three years between periodic maintenance. FRA believes this extension of the periodic maintenance interval will result in a cost savings to those railroads that operate MU locomotives equipped with air dryers.

Paragraph (c) extends the periodic maintenance interval on conventional locomotives equipped with 26–L or equivalent types of brakes from the current standard of 736 days to 1,104 days. The required periodic maintenance interval remains at 736 days for locomotives equipped with other types of brake systems. The proposed requirement merely makes universal a practice that has been approved by waiver for several years. *See* H–80–7. FRA believes that locomotives equipped with 26–L brakes have demonstrated an ability to operate safely for three years between periodic maintenance.

Paragraph (d) extends the periodic maintenance interval on passenger coaches and other unpowered vehicles equipped with 26–C or equivalent brake systems from 1,104 days to 1,476 days. This extension is based on tests performed by Amtrak. Based on these tests, FRA granted Amtrak a waiver for this extension on July 26, 1995. *See* FRA Docket No. PB 94–3. Amtrak has operated under the terms of this waiver for several years with no problems. Consequently, based on Amtrak's experience, FRA believes all passenger cars with 26–C equipment can safely be operated for four years between periodic maintenance.

Paragraph (e) proposes that the same extensions applicable to locomotives and passenger coaches should be applied to control cab cars that use brake valves that are identical to the 26–C valves used in passenger cars or the 26–L valves used on locomotives. Consequently, based on the information and tests conducted on those valves as well as waivers currently existing, FRA proposes to extend the periodic maintenance interval for cab cars to 1,476 days or 1,104 days for those cab cars that use brake systems identical to the 26–C and 26–L, respectively. This proposed extension is consistent with recent requests for waivers received by FRA.

A railroad may petition FRA, under § 238.21, to approve alternative maintenance procedures providing equivalent safety. Railroads could propose using periodically scheduled single car tests to extend the time between required periodic maintenance on passenger coaches. FRA believes that the single car test provides a good alternative to more frequent periodic

maintenance. In fact, in the previous NPRM on power brakes, FRA proposed the elimination of time-based COT&S and in its stead proposed time intervals for conducting single car tests, ranging from three to six months, depending on the utilization rate of the passenger equipment. *See* 59 FR 47690–47691, 47710–47711, and 47740–47741. However, comments received and discussions with members of the Working Group revealed that many passenger railroads would rather perform periodic maintenance than more frequent single car tests. One reason for this is that some operators would rather take equipment out of service every few years and perform the overhaul of the brake system rather than having equipment out of service for shorter periods every few months. Therefore, FRA proposes to retain periodic maintenance intervals but provide the alternative to railroads to propose single car testing intervals in order to reduce the frequency with which the periodic maintenance is performed. Consequently, railroads are afforded some flexibility to determine the type of maintenance approach that best suits their operations.

§ 238.311 Single Car Test

This section contains the proposed requirements for single car tests of passenger equipment. Although the Working Group failed to reach consensus on the requirements contained in this section, the group did agree that single car tests are a valuable tool to demonstrate that a car's brake system performs correctly after repairs have been made that could affect the brakes. A major issue raised both in comments to the previous NPRM on power brakes and by various members of the Working Group was the method for specifying how the test is to be performed. Labor representatives objected to specifying the method of testing by reference to an industry standard that could be changed unilaterally by the organization that maintains the standard. These representatives insisted that the requirements specifying how to conduct the test must be contained in the rule text so that the only way that changes can be made is through the administrative procedures required by the formal rulemaking process. FRA agrees and proposes in paragraph (a) to require that passenger railroads perform the single car test of the brake system in accordance with AAR Standard S–044 contained in AAR's ''Instruction Pamphlet 5039–4, Supp. 3 (April 1991),'' which is the most recent version of the test description. FRA also proposes that the special approval process detailed in § 238.21 would be employed to evaluate any proposed changes in this highly technical procedure.

The single car test proposed in this section has proven effective in uncovering brake system problems that are the root cause of certain wheel defects or that have been caused by repairs made to the brake system. FRA believes that this test has contributed to the current trend of greater brake system reliability and fewer brake-related accidents/incidents of passenger equipment. Currently, the regulations require that a single car test be performed on passenger cars whenever they are on a shop or repair track. In the previous NPRM on power brakes, FRA discussed the potential loophole that the current regulations permit. *See* 59 FR 47710. Basically, it has the potential of allowing railroads to avoid the performance of the tests by calling repair tracks something other than a repair track. Although this is an issue that has arisen in the freight context, it does appear prudent to base the requirement to perform a single car test on the type of defect involved rather than the location where the defect is repaired.

Paragraph (b) lists the wheel defects that would trigger the requirement to perform a single car test. FRA believes that the proposed wheel defects indicate some type of braking equipment problem. FRA believes that merely changing a wheel to correct a wheel defect that is actually caused by a brake system problem will only lead to a continuation of the problem on the new wheel and will increase repair costs to the railroad. A test that checks for the root cause of the defect is not only a good safety practice, but is a good business practice that will lead to reduced operating costs.

Paragraph (c) requires a railroad to conduct a single car test if one or more of the identified brake system components is removed, repaired, or replaced. This paragraph also proposes that a single car test be performed if a passenger car or vehicle is placed in service after having been out of service for 30 or more days. FRA believes that these requirements will ensure that brake system repairs have been performed correctly and that the car's brake system will operate as intended after repairs are made or after the car has been in storage for extended periods. The proposed requirements are consistent with the current practices of most passenger railroads.

Paragraph (d) requires that all single car tests be performed by qualified mechanical inspectors. A single car test is a comprehensive brake test that requires the skills and knowledge of a professional mechanical employee. Railroads currently use the ''qualified mechanical inspector'' as defined by this part to perform single car tests, and FRA believes that this practice should continue.

Paragraph (e) provides that if a single car test cannot be made at the point where repairs are made, the car may be moved in service to the next forward location where the test can be made. The single car test shall be completed prior to, or as a part of, the car's next calendar day mechanical inspection.

APTA has advised FRA that the proposed section on single car tests contains an outdated standard and requires a large number of tests which do not serve to enhance safety. APTA believes that actual operating experience does not support a requirement for this level of testing, and the proposal will increase maintenance costs and require additional spare vehicles to maintain service. Additionally, APTA maintains that the proposed regulation provides a disincentive to updating single car test procedures as needed.

§ 238.313 Class I Brake Test

This section contains the proposed requirements related to Class I brake tests. FRA proposes that the requirements in this section apply to all passenger coaches, control cab cars, MU locomotives, and all nonself-propelled vehicles that are part of a passenger train. The Working Group was unable to reach consensus on the requirements proposed in this section.

This section proposes to require that a Class I brake test be performed at least once each calendar day that a piece of equipment is placed in service. As discussed previously, the Working Group discussed and debated when and how a Class I brake test should be performed. Labor representatives stressed the need for a thorough brake test performed by qualified mechanical inspectors on every passenger train. These representatives strongly contended that this brake test must be performed prior to the first daily departure of each passenger train. On the other hand, representatives of passenger railroads expressed the desire to have flexibility in conducting a comprehensive brake inspection, arguing that safety would be better served if railroads were permitted to conduct these inspections on a daily basis.

Although FRA agrees with the position advanced by many labor

representatives that some sort of car-to-car inspection must be made of the brake equipment prior to the first run of the day, FRA does not agree that it is necessary to perform a full Class I brake test in order to ensure the proper functioning of the brake equipment. As FRA proposes that a Class I brake test consist of a comprehensive inspection of the braking system, including the proper operation of supplemental braking systems, FRA believes that commuter and short-distance intercity passenger train operations must be permitted some flexibility in conducting these inspections. Consequently, FRA proposes in paragraph (a) to require that commuter and short-distance intercity passenger train operations perform a Class I brake test sometime during the calendar day in which the equipment is used.

However, FRA also recognizes the differences between commuter or short-distance intercity operations and long-distance intercity passenger train operations. Long-distance intercity passenger trains do not operate in shorter turnaround service over the same sections of track on a daily basis for the purpose of transporting passengers from major centers of employment. Instead, these trains tend to operate for extended periods of time, over long distances with greater distances between passenger stations and terminals. Further, these trains may operate well over 1,000 miles in any 24-hour period, somewhat diminishing the opportunity for conducting inspections on these trains. Therefore, FRA believes that a thorough inspection of the braking system on these types of operations must be conducted prior to the trains' departure from an initial starting terminal. Consequently, FRA proposes in paragraph (b) that a Class I brake inspection be performed on long-distance intercity passenger trains prior to departure from an initial terminal. FRA does not believe there would be any significant burden placed on these operations as the current regulations require that an initial terminal inspection be performed at these locations. Furthermore, virtually all of the initial terminal inspections currently conducted on these types of trains are performed by individuals who would be considered qualified mechanical employees under this proposal.

FRA also recognizes that these long-distance intercity passenger trains could conceivably travel over 3,000 miles if Class I inspections were required only once every 24 hours that the equipment is in service, as proposed for commuter and short-distance intercity passenger trains. Thus, FRA believes that some outside mileage limit must be placed on these trains between brake inspections. Currently, a passenger train can lawfully travel no further than 1,000 miles from its initial terminal, at which point it must receive an intermediate inspection of brakes, which includes application of the brakes to ensure brake pipe continuity and the inspection of the brake rigging to ensure it is properly secured. *See* 49 CFR 232.12(b). However, in recognition of the improved technology used in passenger train brake systems, combined with the comprehensive nature of the proposed Class I brake tests and mechanical safety inspections both being performed by qualified mechanical inspectors, FRA proposes to require that the proposed Class I brake test be performed once every calendar day that the equipment is used or every 1,500 miles, whichever occurs first.

Paragraph (c) requires that the Class I brake tests be performed by qualified mechanical inspectors. As FRA intends for these Class I brake inspections to be in-depth inspections of the entire braking system, which most likely will be performed only one time in any given day in which the equipment is used, FRA believes that these inspections must be performed by individuals possessing the knowledge to not only identify and detect a defective condition in all of the brake equipment required to be inspected but also the knowledge to recognize the interrelational workings of the equipment and the ability to trouble-shoot and repair the equipment. Furthermore, most passenger railroads currently have a daily brake test performed by mechanical employees so this requirement is not really a departure from current industry practice.

FRA recognizes that these requirements may create a problem for some commuter railroads that operate trains on weekends or other days when qualified mechanical inspectors are not scheduled to work. Some railroads may be forced to schedule qualified mechanical inspectors to work on these days at additional expense. However, based on independent investigations performed by FRA, it is believed that the impact of this proposal will be much less than several railroad representatives have indicated. However, FRA is willing to consider whether to allow railroads that have demonstrated an ability to operate passenger trains safely over weekends without a mechanical safety inspection being performed by qualified mechanical inspectors to continue that practice. The problem, from FRA's position, is that it is difficult to allow this flexibility without creating a loophole that could be abused in certain circumstances. Consequently, FRA solicits detailed comments from interested parties on whether the granting of such flexibility is even necessary and on possible methods of providing such flexibility.

Paragraph (d) provides railroads with the option to perform the Class I brake test either separately or in conjunction with the calendar day mechanical inspections. FRA proposes this provision simply to clarify that the two inspections need not be done at the same time or location as long as they are both performed sometime during the day.

Paragraph (e) prohibits a railroad from using or hauling a passenger train in passenger service from a location where a Class I brake test has been performed, or was required to have been performed, with less than 100 percent operating brakes. (*See* § 238.15 for a discussion of movement of defective equipment for purposes of repair or sale).

Paragraph (f) contains a proposed list of the safety-related items that must be inspected, tested, or demonstrated as part of a Class I brake test. This list was developed based on the experience and knowledge of FRA's motive power and equipment field inspectors familiar with the operations and inspection practices of passenger operations. The Working Group extensively discussed the items contained in this proposal. Paragraph (f)(1) requires that an inspection be conducted on each side of each car to verify the application and release of each brake. This requirement is consistent with FRA's longstanding interpretation of what the current regulations require when conducting initial terminal and 1,000 brake inspections pursuant to § 232.12. For clarity and consistency, FRA has explicitly incorporated the requirement into this proposal.

The requirements included in paragraph (f) which FRA proposes to be included in a Class I brake test contain two items that would bar the use of a train that current regulations allow to be placed in service. These include the requirement that the secondary brake systems must be fully operational and the requirement that brake indicators must function as intended. These requirements will require railroads to make more frequent repairs than are currently required. However, FRA believes these added costs are necessitated by and offset by the added flexibility to move defective equipment as well as the ability to use brake indicators during the performance of

certain brake tests in lieu of direct observation of the brakes.

Paragraph (g) proposes to require the qualified mechanical inspector that performs a Class I brake test to record the date, time and location of the test as well as the number of the controlling locomotive of the train. This minimal information would be required to be available in the cab of the controlling locomotive to demonstrate to the train crew and future inspectors that the train is operating under a current Class I brake test. Furthermore, the use of such records or ''brake slips'' as they are known in the industry is the current practice of virtually all passenger railroads. FRA believes that this recordkeeping requirement adds necessary reliability, accountability, and enforceability to the inspection requirements proposed in this section.

Paragraph (h) also proposes to allow long distance, intercity passenger trains that miss a scheduled Class I brake test due to a delay en route to proceed to the point where the scheduled brake test was to be performed. This flexibility prevents Amtrak or other operators of long distance trains from having to dispatch qualified mechanical inspectors to the location of a delayed train merely to meet the calendar day Class I brake test requirement. This is a common sense exception that will not compromise safety.

§ 238.315 Class IA Brake Test

This section contains the proposed requirements regarding Class IA brake tests. As mentioned previously, although FRA agrees with the position advanced by many labor representatives that some sort of car-to-car inspection must be made of the brake equipment prior to the first run of the day, FRA does not agree that it is necessary to perform a full Class I brake test in order to ensure the proper functioning of the brake equipment in all situations. However, contrary to the position espoused by several railroad representatives, FRA believes that something more than just a determination that the brakes on the rear car set and release is necessary.

Currently, the quality of initial terminal tests performed by train crews is likely adequate to determine that brakes apply on each car. However, most commuter equipment utilizes ''tread brake units'' in lieu of cylinders and brake rigging of the kind prevalent on freight and some intercity passenger cars. It is undoubtedly the case that train crewmembers do not verify application of the brakes by tapping brake shoes while the brakes are applied, the only effective means of determining that adequate force is being applied. This is one reason why the subject railroads typically conduct redundant initial terminal tests at other times during the day. Further, train crews are not asked to inspect for wheel defects and other unsafe conditions, nor should they be asked to do so, given the conditions under which they are asked to inspect and the training they receive.

Consequently, paragraph (a) requires that, at a minimum, a Class I or Class IA brake test be performed prior to a commuter or short-distance intercity passenger train's first departure on any given day. FRA believes that the proposed Class IA brake test is sufficiently detailed to ensure the proper functioning of the brake system, yet not so intensive that it requires individuals to perform an inspection for which they are not qualified. FRA proposes in paragraph (a) that a qualified mechanical inspector or a properly trained and qualified train crewmember perform a Class IA brake test.

As noted in the discussion of Class I brake tests, FRA recognizes the differences between commuter or short-distance intercity operations and long-distance intercity passenger train operations. FRA believes that a thorough inspection of the braking system on these types of operations must be conducted prior to each train's departure from an initial starting terminal. Consequently, FRA will not permit the use of Class IA brake tests for these trains, and requires that a Class I brake inspection be performed on long-distance intercity passenger trains prior to departure from an initial terminal.

Paragraph (a) also requires that a Class IA brake test be performed prior to placing a train in service if that train has been off a source of compressed air for more than four hours. This requirement formalizes a long-standing agency interpretation of the existing power brake regulations but increases the time limit from two hours to four hours. Labor representatives maintain that any number of brake system problems can develop with equipment off air for only a short time, while management representatives contend that equipment can be left off air for extended periods of time with no problems. FRA believes the proposed requirement is a fair compromise that allows railroads some operating flexibility, but does not allow equipment to be off air without a new brake test for extended periods of time. As stated in the previous NPRM on power brakes, FRA agrees that its longstanding administrative interpretation of allowing cars to be ''off air'' for only two hours was established prior to the development of new equipment that has greatly reduced leakage problems. However, contrary to the contentions of some commenters, FRA does not believe that cars should be allowed to be ''off air'' for extended periods without being retested. The longer cars sit without a supply of compressed air attached, the greater the chances are that the integrity of the system will be compromised, either by weather conditions or vandalism.

Paragraph (b) allows a commuter or short-distance intercity passenger train that provides continuing late night service that began prior to midnight to complete its daily operating cycle after midnight without performing another Class I or Class IA brake test.

Paragraph (c) allows a Class IA brake test to be performed at a shop or yard site without needing the test repeated at the first passenger terminal if the train remains on air and in the custody of the crew. This provision is an incentive for railroads to conduct the tests at locations where they can be performed more safely and easily. FRA believes that a shop or yard location is more conducive for conducting a proper brake test. Raised platforms and other conditions frequently found at terminals can make the performance of a brake test difficult, if not hazardous.

Paragraph (d) permits the Class IA test to be performed by either a qualified person or a qualified mechanical inspector. Paragraph (e) prohibits a railroad from using or hauling a passenger train from a location where a Class IA brake test has been performed, or was required to have been performed, with less than 100 percent operative brakes. (*See* §§ 238.15–238.17 for a discussion of movement of defective equipment for purposes of repair or sale). Paragraph (f) establishes the requirements for conducting a proper Class IA brake test. It is proposed that a Class IA brake test include: a check that each brake sets and releases, a test of the emergency brake application feature, a check of the deadman or other emergency control device, a check that piston travel is in the nominal range for the type of brake equipment, and an observation that angle cocks and cutout cocks are properly set and that brake pipe pressure changes are communicated to the rear of the train.

Paragraph (g) requires that the inspection of the set and release of the brakes be performed by walking the train so the inspector actually observes the set and release of each brake. Labor representatives strongly contended that this is the only way to do a proper brake test. They believe that observation of brake indicators does not give a reliable

indication of effective brakes because the indicators sense brake cylinder pressure rather than the force of the brake shoe against the wheel or the pad against the disc. However, this section proposes to allow an exception when railroads determine that direct observation of the set and release can place the inspector in danger. FRA acknowledges the contention of rail management representatives that conditions at certain locations where Class IA tests may be performed could place the inspector in danger if he or she is required to place himself or herself in a position to actually observe the set and release of each brake. Where railroads determine this to be the case, FRA will permit the use of brake indicators for the set and release step of the Class IA brake test as long as the inspector takes a position where an accurate observation of the indicators can be made.

§ 238.317 Class II Brake Test

This section proposes the requirements regarding how a Class II brake test is to be performed and contains the proposed conditions for when a railroad is required to perform the brake test. The Class II brake test provides passenger railroads the flexibility to continue to use train crew personnel to perform the limited brake tests required when minor changes to the train occur. Both labor and management representatives to the Working Group recognized that train crews are capable of performing the relatively simple checks required by a Class II brake test and that the operations of most commuter and passenger railroads require the flexibility of having operating personnel perform these tests.

Paragraph (c) requires that passenger trains not depart from Class II brake tests which are performed at a terminal or a yard with any brakes known to be cut-out, inoperative, or defective. This requirement was agreed to by members of the Working Group and is consistent with the movement for repair provisions contained in this proposal. *See* § 238.15. Terminals and yards are generally the best locations available to a railroad for either conducting repairs or removing a vehicle from a train. This requirement only applies to brake equipment which is known to be cut-out, inoperative, or otherwise defective by the railroad prior to the train's departure from the yard or terminal where the Class II brake test is performed.

Paragraph (d) requires that a Class II brake test consist of: a check that the brakes on rear unit of the train apply and release in response to brake control signals, a test of the emergency brake application, a test of the deadman pedal or other emergency control device, and a check that brake pipe pressure changes are properly communicated at the rear of the train. FRA believes that if the equipment receives a full Class I brake test and a calendar day mechanical inspection at some time during each operating day, then these simple checks are adequate to confirm brake system performance at intermediate terminals or turning points. This requirement basically codifies current industry practice.

§ 238.319 Running Brake Tests

This section contains the proposed requirements for conducting running brake tests on the brakes of passenger trains. A running brake test is merely a brake application at the first safe opportunity to confirm that the brake system works as expected by the engineer. FRA proposes that a running brake test be performed in accordance with the railroad's established operating rules after the train has received a Class I, Class IA, or Class II brake test as safety permits. FRA believes that railroads are in the best position to determine when and where running tests can be safely performed. As most passenger railroads routinely conduct running brake tests, FRA believes that the proposal requirement captures an important safety check without changing current operating practice to any great extent.

Tier II Passenger Equipment Requirements

Most of the requirements proposed for Tier II equipment are based on lengthy discussions between Amtrak and FRA over safety requirements for operation of passenger train sets at speeds up to 150 mph in the Northeast Corridor (NEC). Amtrak voluntarily included many of the provisions proposed for Tier II equipment in their procurement specification for American Flyer trainsets—the first Tier II equipment which should be placed in regular revenue service in the United States.

The process used by the Working Group to discuss proposed Tier II equipment standards differed from that used for the Tier I standards. Many members of the full Working Group stated that they will never be involved in the operation of such high-speed equipment and participation in Tier II standards was outside their area of interest and expertise. As a result, the full Working Group recommended the formation of a smaller subgroup to consider Tier II standards. Consequently, a subgroup consisting of representatives from Amtrak, equipment builders, labor organizations, the NTSB and FRA was formed to consider Tier II equipment safety standards.

The Tier II Equipment Subgroup came very close to reaching full consensus recommendations on the proposed Tier II safety standards. Only two exceptions to a full consensus on recommendations resulted from the process. The first exception involves a disagreement between Amtrak and labor organizations over the proper use of brake indicator technology.

The second exception results from a joint meeting between the Tier II equipment subgroup and the RSAC High Speed Track Standards Working Group. The purpose of this joint meeting was to ensure that the two sets of proposed standards not conflict at the wheel-rail interface where the two sets of standards overlap.

These two exceptions to full consensus will be more fully discussed under the appropriate section of this section-by-section analysis. In all other cases, the section-by-section analysis assumes the full consensus of the Subgroup without actually repeating it as part of each of the discussions.

Subpart E—Specific Requirements for Tier II Passenger Equipment

§ 238.401 Scope

This subpart contains the design and performance requirements for Tier II passenger equipment operating at speeds exceeding 125 mph but not exceeding 150 mph. Unless otherwise specified, the proposed requirements represent the consensus recommendations of the Tier II Equipment Subgroup with refinements by FRA for clarity, enforceability, and compatibility with other rail safety laws. For the most part, compliance with the requirements of this section will be demonstrated by one-time analysis or initial acceptance tests.

The requirements contained in this subpart have their basis in discussions between Amtrak and FRA involving safety requirements for the operation of passenger trainsets at speeds up to 150 mph on the Northeast Corridor (NEC). Aware that FRA was considering the development of safety standards for high-speed passenger rail equipment, Amtrak asked FRA for assistance in developing a set of safety specifications for the procurement of high-speed trainsets which would address FRA's safety concerns. As a result, Amtrak's American Flyer trainsets, scheduled to begin regular passenger service in 1999, will very likely comply with all of the proposed safety standards in this subpart.

Amtrak's discussions with FRA led it to sponsor a risk assessment of high speed rail passenger systems on the north end of the NEC—from New York to Boston. The discussions also prompted FRA to sponsor computer modeling to predict the performance of various equipment structural designs and configurations in collisions. A copy of the risk assessment performed by Arthur D. Little, Inc., for Amtrak is included in the docket of this rulemaking. The risk assessment was based on existing and predicted future right-of-way configurations and traffic density patterns. The risk assessment concluded that a significant risk of collisions at speeds below 20 mph and a risk of collisions at speeds exceeding 100 mph exist over the 20-year projected operational life of the American Flyer trainsets—due to heavy and increasing conventional commuter rail traffic, freight rail traffic on the NEC, highway-rail grade crossings, moveable bridges, and a history of low speed collisions in or near stations and rail yards.

Based on the risk assessment and the results of the computer modeling, Amtrak and FRA determined that reliance on collision avoidance measures rather than crashworthiness, though the hallmark of safe high-speed rail operations in several parts of the world, could not be implemented in corridors like the north end of the NEC. Existing traffic and right-of-way configurations do not permit implementation of the same collision avoidance measures that have proven successful in Europe and Japan. To compensate for the increased risk of a collision, a more crashworthy trainset design is needed. As a result, the set of structural design requirements proposed for Tier II passenger equipment is more stringent than current design practice for North American passenger equipment or for high-speed rail equipment in other parts of the world.

§ 238.403 Crash Energy Management Requirements

This section requires that each power car and trailer car be designed with a crash energy management system to dissipate kinetic energy during a collision. This section should be read with the discussion of crash energy management in the preamble.

During discussions with Amtrak over the safety provisions for the American Flyer trainsets, FRA proposed very challenging crash energy management requirements based on predictions using computer modeling. Amtrak believed that meeting these requirements would be well beyond the current state of the art for passenger equipment design, and that an extensive and costly research and testing program would be required. As an alternative, Amtrak proposed a crash energy management design based on the demonstrated, commercially viable design developed by France and incorporated in the most recent design of the TGV trainset. FRA believes that Federal safety standards must be capable of implementation in the design of passenger equipment without driving the cost of implementation to the point that high speed rail systems are no longer financially viable.

As a result, paragraph (c) proposes a crash energy management system capable of absorbing a minimum of 13 megajoules (MJ) of energy at each end of the trainset. The ability to absorb this energy must be partitioned as follows: a minimum of 5 MJ by the front end of the power car ahead of the operator's control compartment; a minimum of 3 MJ by the power car structure behind the operator's control compartment; and a minimum of 5 MJ by the unoccupied end of the first trailer car adjacent to the power car. This requirement can be met using existing technology. However, it will effectively prevent a conventional cab car from operating as the lead vehicle in a Tier II passenger train because such equipment cannot absorb 5 MJ of collision energy ahead of the train operator's position. Recent accidents involving trains operating with a cab car forward have demonstrated the vulnerability of this type of equipment in collisions. FRA believes such equipment should not be used in the forward position of a train that travels at speeds greater than 125 mph. Further, FRA is specifically proposing in paragraph (f) that passenger seating be prohibited in the leading unit of a Tier II train, though not a specific recommendation of the Subgroup.

Paragraph (e) proposes the analysis process to demonstrate that equipment meets the crash energy management design performance requirements. The process allows simplifying assumptions to be made so computer modeling techniques can be used to confirm compliance.

§ 238.405 Longitudinal Static Compressive Strength

This section contains the proposed requirements for longitudinal compressive strength of power cars and trailer cars. Paragraph (a) requires the ultimate compressive strength of the underframe of the power car cab to be a minimum of 2,100,000 pounds. To form an effective crash refuge, this strength is needed to take advantage of the strength of the power car's two end frames. Alternate design approaches that provide equivalent protection are allowed, but the equivalent protection must be demonstrated through analysis and testing and approved by the FRA Associate Administrator for Safety under the provisions of § 238.21.

Paragraph (b) contains the requirements for the static compressive strength of the occupied volumes of trailer cars. This proposal adopts the traditional North American design practice of a static strength of 800,000 pounds, without deformation of the underframe. Paragraph (c) makes clear that unoccupied or lightly occupied volumes of power cars or trailer cars may have a static end strength of less than 800,000 pounds to accommodate crash energy management designs.

The crash energy management design requirement ensures that the stronger end structures and the stronger static compressive strength of the cab of a power car will not make Tier II passenger equipment incompatible with existing passenger equipment should a collision between the two different types of equipment occur. The crash energy management design makes a Tier II passenger train appear as a softer collision surface to a conventionally designed train owing to the collision energy absorbed by the Tier II train as its unoccupied volumes intentionally crush.

§ 238.407 Anti-Climbing Mechanism

This section contains the proposed requirements for anti-climbing mechanisms on power and trailer cars. Paragraph (a) requires a power car to have a forward anti-climbing mechanism capable of resisting an upward or downward static vertical force of 200,000 pounds. This proposal is identical to that required of locomotives by AAR S-580. However, designs are permitted that require the crash energy management controlled crushing to occur prior to the anti-climber fully engaging.

Paragraph (b) requires that interior train coupling points between units, including between units of articulated cars or other permanently joined units of cars, have an anti-climbing device capable of resisting an upward or downward vertical force of 100,000 pounds. This is consistent with current design practice. Paragraph (c) requires the forward coupler of a power car to resist a vertical downward force of 100,000 pounds for any horizontal position of the coupler without yielding, and is virtually identical to that provided in 49 CFR 229.141(a) for MU locomotives built new after April 1,

1956, and operated in trains having a total empty weight of 600,000 pounds or more.

§ 238.409 Forward End Structures oF Power Car Cabs

This section contains the proposed requirements for forward end structures of power car cabs. The forward end structure of a power car cab plays a vital role in a collision with another object. This structure must resist override, prevent the entry of fluids into occupied spaces of the cab, and allow the crash energy management system to function. The proposed requirements in paragraphs (a)-(c) are based on a specific end structure design that consists of a full-height center collision post, two side collision posts located at approximately the one-third points laterally, and two full-height corner posts. The proposal includes loading requirements that each of these structural members must withstand. In addition, the proposal permits flexibility for using other equipment designs that provide equivalent structural protection. End structures meeting these requirements will provide considerably greater protection to the train operator than provided by existing passenger equipment designs. For example, much stronger corner posts are proposed here than for Tier I passenger equipment. FRA believes these end structures help provide a degree of crashworthiness to compensate for the increased risk associated with operating at higher speeds.

The front end structure design also includes in paragraph (d) a skin requirement equivalent to that required by AAR S–580 and proposed in § 238.209 for Tier I locomotives.

§ 238.411 Rear End Structures of Power Car Cabs

The rear end structure of a power car cab provides protection to crewmembers from intrusion of locomotive machinery or trailing cars into the occupied volume as a result of a collision or derailment. The proposed requirements are based on a specific end structure design that consists of two full-height corner posts (paragraph (a)) and two full-height collision posts (paragraph (b)). The proposal includes loading requirements that each of these structural members must withstand. Further, the proposal permits flexibility for using other equipment designs that provide equivalent structural protection. The proposed rear end structure will provide considerably greater protection to the train operator than that provided by existing passenger equipment designs. Together, the front and rear end structures proposed in this rule for a power car cab make the cab a highly survivable crash refuge.

§ 238.413 End Structures of Trailer Cars

The proposed requirements in paragraph (a) are based on a specific end structure design that consists of two full-height corner posts and two full-height collision posts. The proposal includes loading requirements that each of these structural members must withstand. The proposal also allows flexibility for other designs that provide protection structurally equivalent to the proposed design.

Paragraph (b) makes clear how the requirements proposed in paragraph (a) apply to a trailer car that consists of multiple articulated units not designed for uncoupling in other than at a maintenance shop. The end structure requirements apply only to the two ends of the entire articulated assembly of units. Paragraph (b) explains that the interior ends of the individual units of the articulated assembly need not be equipped with an end structure that meets the requirements proposed in paragraph (a). Articulated assemblies have a history of remaining in line during derailments and collisions and if not designed to be uncoupled, only the exposed ends of the entire assembly will be exposed to the risks of override. However, interior units that are merely semi-permanently coupled, but not articulated, are subject to the proposed end structure requirements in paragraph (a).

Paragraph (c) contains an additional requirement for trailer cars designed with an end vestibule. Such designs provide an opportunity for additional corner post structures inboard of the vestibule side doors. These corner posts can be supported by the side sill and therefore be structurally more substantial than the corner posts outboard of the side doors. The proposal includes loading requirements that these additional full-height corner posts must withstand. Overall, the double corner post design provides significantly increased protection to passengers in such trailer cars.

§ 238.415 Rollover Strength

This section contains the proposed requirements for the rollover strength of power cars and trailer cars. If the occupied volumes of these vehicles remain intact when they roll onto their side or roof structures, occupant injury from vehicle collapse will be avoided. The proposal essentially requires the vehicle structure to support twice the deadweight of the vehicle as it rests on its side or roof. Minor deformations of the side and roof sheathing and smaller structural members are allowed to the extent necessary for the vehicle to be supported directly by more substantial structural members of the frame. Passenger equipment constructed to North American design practice performs well in rollover situations. FRA believes this proposal captures this design practice.

§ 238.417 Side Loads

This section contains the proposed requirements intended to resist penetration of the side structure of a passenger car by a highway or rail vehicle. The objective is to make the side of the passenger car strong enough so that the car derails rather than collapses when struck in the side by a highway or rail vehicle. If the passenger car moves sideways (derails), less structural damage and potential to injure train occupants will result.

§ 238.419 Truck-to-Car-Body and Truck Component Attachment

Paragraph (a) requires the truck-to-car-body attachment on Tier II passenger equipment to resist without failure a vertical force equivalent to 2g acting on the mass of the truck and a force of 250,000 pounds acting in any horizontal direction. The earlier discussion of the proposed truck-to-car-body attachment strength requirement in § 238.219 for Tier I passenger equipment is also applicable here.

Paragraph (b) requires that each component of the truck must remain attached to the truck when a force equivalent to 2g acting on the mass of the component is exerted in any direction on that component. Whereas paragraph (a) is intended to keep the truck attached to the car body, paragraph (b) is intended to keep truck components attached to the truck.

§ 238.421 Glazing

This section contains the proposed glazing requirements for Tier II passenger equipment. FRA believes that the higher speed of Tier II passenger equipment requires more stringent glazing standards than currently required by 49 CFR part 223.

Paragraph (a) requires each power car and trailer car to be equipped with glazing meeting the following requirements. First, under paragraph (a)(1), end-facing glazing shall resist the impact of a 12-pound solid steel sphere traveling at the maximum speed of the vehicle in which the glazing will be installed. The test must be conducted so that the sphere strikes the glazing at the same angle as an object would strike the

glazing when installed in a train. To successfully pass the test, the glazing must neither spall nor be penetrated by the sphere. This test is similar to the requirements imposed under European glazing standards for high-speed trains, and should be much more repeatable than the cinder block test specified in 49 CFR part 223.

Second, under paragraph (a)(2)(i), side-facing glazing shall resist the impact of a 12-pound solid steel sphere traveling at 15 mph and impacting at an angle of 90 degrees to the surface of the glazing, with no penetration or spall. This is a highly repeatable test that demonstrates whether side-facing glazing can protect occupants from a relatively heavy object thrown against the side of the train. This test is more stringent than the large object impact test required for side facing glazing under 49 CFR part 223.

Third, under paragraph (a)(2)(ii), side-facing exterior glazing shall resist the impact of a granite ballast stone weighing a minimum of 0.5 pounds, traveling at 75 mph, and impacting at a 90-degree angle to the glazing surface, with no penetration or spall. This is a highly repeatable test to demonstrate whether the glazing can protect occupants against impact from a common stone found along the railroad thrown at a speed slightly faster than a human could throw such an object.

Fourth, under paragraph (a)(3)(i), all exterior glazing shall resist the single impact of a 9-mm, 147-grain bullet traveling at an impact velocity of 900 feet per second, with no bullet penetration or spall. This bullet is a much more common handgun round than the 22-caliber bullet specified in 49 CFR part 223. The proposed requirement does represent a balance between the degree of bullet impact protection and window weight, however. Ballistic tests revealed that a requirement to resist a round fired at velocities typical of high-powered rifles requires a glazing thickness that creates a window weight that is impractical for use as an emergency exit.

Fifth, under paragraph (a)(3)(ii), all exterior glazing shall demonstrate anti-spalling performance by the use of a 0.001 aluminum witness plate, placed 12 inches from the glazing surface during all impact tests. The witness plate must not contain any marks from spalled glazing particles after any impact test. When impacted on the exterior surface, glazing currently used in railroad equipment tends to spall from the inside surface. Several eye injuries to crewmembers have resulted. FRA believes that the witness plates used in conducting the spalling tests to qualify current glazing are too thick and have allowed glazing that actually spalled to pass the test. The witness plate specified in this paragraph is much thinner and therefore more sensitive to detecting spall.

Paragraph (b) requires glazing material to be marked to indicate that it has passed the testing requirements proposed in paragraph. This marking requirement is similar to that provided in 49 CFR part 223.

Paragraph (c) requires glazing frames to hold the glazing in place against all the forces which the glazing is required to resist in paragraph (a). This proposal is intended to prevent the glazing from being knocked out of its frame by the force of an object striking the glazing, even though no penetration of the glazing itself occurs. Since FRA is proposing more stringent impact testing requirements for glazing in Tier II passenger equipment than for Tier I passenger equipment, stronger glazing frames will be required to keep the glazing in place and achieve the additional safety benefit provided by the stronger glazing.

Paragraph (d) requires the glazing securement components to resist the forces due to air pressure differences caused by trains passing with the minimum separation for two adjacent tracks while traveling in opposite directions, each traveling at maximum speed. The higher speed of Tier II passenger equipment makes this a more stringent requirement than proposed for Tier I passenger equipment.

Paragraph (e) requires interior glazing to meet the minimum requirements of AS1 type laminated glass as defined in American National Standard ''Safety Code for Glazing Materials for Glazing Motor Vehicles Operating on Land Highways,'' ASA Standard Z26.1–1966. This requirement alleviates the need for interior glazing to meet the stringent impact resistance requirements placed on exterior glazing, while ensuring that the glazing will shatter in a safe manner like automotive glazing.

Paragraph (f) requires that each vehicle be stencilled on an interior wall to indicate that it meets the glazing requirements contained in this section. This requirement is already provided for existing equipment in 49 CFR 223.17.

§ 238.423 Fuel Tanks

This section contains the proposed requirements for fuel tanks for fossil-fueled Tier II passenger equipment. FRA is proposing separate requirements for external fuel tanks, which are traditional, under the car body fuel tanks, and for internal tanks, which are built into the structure of the car body.

Paragraph (a) requires the following of external fuel tanks:

- A minimum height above the rail;
- A minimum penetration resistance for end bulkheads;
- A minimum exterior skin strength;
- A temperature range to which material properties must not degrade;
- A vent system that prevents spills in any tank orientation;
- Skid surfaces on the bottom of the tank; and
- An overall structural strength adequate to support 1½ times the dead weight of the locomotive without deformation of the tank.

This set of proposed requirements is based on investigations of accidents involving fuel tank rupture; analysis and testing of improved fuel tank designs; reports by railroads of reductions in fuel spills on locomotives built with more crashworthy fuel tanks; and an analysis of the common methods of damaging fuel tanks. FRA believes the proposed requirements will result in significantly fewer fuel spills and fewer post-collision fires. Although the proposed requirements reduce the range of a train by adding weight and reducing fuel carrying capacity, FRA does not believe that this reduced range will impact passenger train service because food and other supplies will likely need replenishing first before a train needs refueling.

Paragraph (b) requires that internal fuel tanks be a minimum height above the rail, be equipped with a vent system that prevents spills in any tank orientation, and have a minimum penetration resistance of the bulkheads and skin. Amtrak has included internal fuel tanks in the design of many new locomotives. Experience with these tanks has shown them to be much less vulnerable than external fuel tanks due to protection provided by the structure of the car body. This reduced vulnerability lessens the need for many of the requirements proposed for external fuel tanks.

§ 238.425 Electrical Systems

This section contains the proposed requirements for electrical system design. These requirements reflect common electrical safety practice and are widely recognized as good electrical design practice. They include provisions for:

- Circuit protection against surges, overload and ground faults;
- Electrical conductor sizes and properties to provide a margin of safety for the intended application;
- Battery system design to prevent the risk of overcharging or accumulation of

dangerous gases that can cause an explosion;

- Design of resistor grids that dissipate energy produced by dynamic braking with sufficient electrical isolation and ventilation to minimize the risk of fires; and
- Electromagnetic compatibility within the intended operating environment to prevent electromagnetic interference with safety-critical equipment systems and to prevent interference of the rolling stock with other systems along the right-of-way.

§ 238.427 Suspension System

Suspension system performance parameters are crucial to the safe operation of high-speed rail passenger equipment. The suspension system requirements that FRA is proposing served as safety limits for the successful demonstrations of the X–2000 and the ICE trainsets on the NEC at speeds up to 135 mph. These proposed requirements are also part of the suspension system performance requirements for Amtrak's American Flyer trainsets.

Safety requirements concerning the wheel-rail interface have traditionally been addressed as part of the track safety standards. In parallel with the Tier II Equipment Subgroup's effort to develop high-speed equipment safety standards, the RSAC Track Working Group developed an NPRM on track safety standards which includes proposed high-speed track standards. *See* 62 FR 36138, Jul. 3, 1997. FRA sponsored a joint meeting of the Tier II Equipment Subgroup and members of the Track Working Group focusing on the development of high-speed track standards to ensure that the two sets of standards not conflict at the wheel-rail interface, where they overlap. Overall, the two groups proposed very similar standards, but members of the Track Working Group recommended some modifications to Tier II passenger equipment standards so that these standards would dovetail with the high-speed track standards. FRA has revised the proposed Tier II passenger equipment standards accordingly, as noted in discussions below of the specific requirements of this section.

To ensure safe, stable performance and ride quality, paragraph (a) requires suspension systems to be designed to reasonably prevent wheel climb, wheel lift, rail rollover, rail shift, and a vehicle from overturning. These requirements must be met in all operating environments, and under all track and loading conditions as determined by the operating railroad. In addition, these requirements must be met under all track speeds and track conditions consistent with the Track Safety Standards (49 CFR part 213), up to the maximum operating speed and maximum cant deficiency of the equipment. These broad suspension system performance requirements address the operation of equipment at both high speed over well maintained track and at low speed over lower classes of track. Suspension system performance requirements are needed at both high and low speeds as exemplified by recent incidents where stiff, high-speed suspension systems caused passenger equipment to derail while negotiating curves in yards at low speeds.

Compliance with paragraph (a) must be demonstrated during pre-revenue service acceptance testing of the equipment and by complying with the safety performance standards for suspension systems contained in Appendix C to this part. Because better ways to demonstrate suspension system safety performance may be developed in the future, the rule allows the use of alternative standards to those contained in Appendix C if they provide equivalent safety and are approved by the FRA Associate Administrator for Safety under the provisions of § 238.21.

Paragraph (b) requires the steady-state lateral acceleration of passenger cars to be less than 0.1g, as measured parallel to the car floor inside the passenger compartment, under all operating conditions. Passenger cars shall not operate when the steady-state lateral acceleration is 0.1g or greater. FRA originally considered limiting the cant deficiency, but Track Working Group members recommended that the steady-state lateral acceleration requirement alone is sufficient to ensure safe operation. The Tier II Equipment Subgroup concurred, and FRA is proceeding according to these recommendations.

Paragraph (c) requires each truck to be equipped with a permanently installed lateral accelerometer mounted on the truck frame. If hunting oscillations are detected, the train must be slowed. The proposal contained in the paragraph did not have the full support of the Tier II Equipment Subgroup and the Track Working Group members because of disagreement over where the accelerometer should be located.

Paragraph (d) provides ride vibration (quality) limits for vertical accelerations, lateral accelerations, and the combination of lateral and vertical accelerations. These limits must be met while the equipment is traveling at the maximum operating speed over its intended route. The limiting parameters and the means to measure them represent the consensus recommendations of both working groups and have proven effective during the demonstrations of the X–2000 and ICE trainsets.

Paragraph (e) provides that compliance with the ride quality requirements contained in paragraph (d) be demonstrated during the equipment pre-revenue service qualification tests required under § 238.113 and § 213.345 of the proposed federal track safety standards. One of the most important objectives of pre-revenue service qualification testing is to demonstrate that suspension system performance requirements have been met.

Paragraph (f) requires bearing overheat sensors to be provided either on board the equipment or at reasonable wayside intervals. FRA prefers sensors to be on board the equipment to eliminate the risk of a hotbox that develops between wayside locations. However, FRA does recognize that onboard sensors have a history of falsely detecting overheat conditions that have caused significant operating difficulties for some passenger railroads.

§ 238.429 Safety Appliances

This section contains the proposed requirements for safety appliances for Tier II passenger equipment. FRA has attempted to simplify and clarify how the Safety Appliance Standards contained in 49 CFR part 231 and 49 U.S.C. 20302(a) will be applied to Tier II passenger equipment. The proposed requirements are basically a restatement of existing requirements but tailored specifically for application to this new and somewhat unconventional equipment. They represent the consensus recommendation of the Tier II Equipment Subgroup.

Paragraph (b) deserves special mention; it proposes to require that Tier II passenger trains be provided with a parking or hand brake that can be set and released manually and can hold the equipment on a 3-percent grade. A hand brake is an important safety feature that prevents the rolling or runaway of parked equipment.

§ 238.431 Brake System

This section contains proposed brake system design and performance requirements for Tier II passenger equipment, and, except for one provision, represents the consensus recommendation of the Tier II Equipment Subgroup. The main issue of concern among Subgroup members involved the capability of sensor technology used to monitor the application and release of brakes. Labor

representatives maintained that a technology that actually measures the force of brake shoes and pads against wheels and brake discs is required for a reliable indication of brake application and release. Railroad operators contended that this technology is not commercially available and that monitoring pressure in brake cylinders does provide a reliable indication of brake application and release, particularly when those cylinders are directly adjacent to the point where brake friction surfaces are forced together.

Aside from this issue, the rest of the proposed brake system design and performance requirements received widespread support. In fact, several of the proposed requirements were contained in written positions provided by both rail labor and management members of the Subgroup, and virtually all of the proposed requirements were discussed in the high-speed passenger equipment section of the 1994 NPRM on power brakes. *See* 59 FR 47693–47694, 47699–47700, and 47730. Many of the requirements proposed in this section are similar to the requirements proposed for Tier I passenger equipment in § 238.231, thus the discussion related to that section should be read in conjunction with the following discussion.

The proposal contained in paragraph (a) is virtually identical to the proposal related to the braking systems of Tier I passenger equipment in § 238.231(a).

Paragraph (b) proposes a requirement similar to that proposed in § 238.231(b) and is intended to protect railroad employees. FRA believes that inspectors of equipment must be able to ascertain if brakes are applied or released without placing themselves in a vulnerable position. The proposed rule allows railroads the flexibility of using a reliable indicator in place of requiring direct observation of the brake application or piston travel because the designs of many of the brake systems used on passenger equipment make direct observation of the brakes extremely difficult. Brake system piston travel or piston cylinder pressure indicators have been used with satisfactory results for many years. Although indicators do not provide 100 percent certainty that the brakes are effective, they have proven effective enough to be preferable to requiring an inspector to assume a dangerous position.

Paragraph (c) is virtually identical to the requirement proposed in § 238.231(c), and is a fundamental brake system performance requirement that an emergency brake application feature be available at any time and produce an irretrievable stop. This paragraph proposes an additional requirement that a means to actuate the emergency brake be provided at two locations in each unit of the train. This additional requirement ensures the availability of the emergency brake feature and is in accordance with the current available design of high-speed passenger equipment.

Paragraph (d) requires the brake system to be designed to prevent thermal damage to wheels and brake discs.

Paragraph (e) proposes requirements related to blended braking systems. These requirements are similar to those proposed in § 238.231(j). The only additional requirement is that the operational status of the electric portion of the blended brake be displayed in the operator's cab. Operators use different train handling procedures when the electric portion of blended brake is not available. A very dangerous situation can arise when an operator expects the electric portion of the blended brake to be available and it is not. FRA believes that when operations exceed 125 mph either the train must not be used if the electric portion of the blended brake is not available, or the train operator must know that the electric portion of the blended brake is not available so he or she can be prepared to use compensating train handling procedures. Further, FRA believes that if the additional heat input to wheels or discs caused by lack of the electric portion of the blended brake causes thermal damage to these braking surfaces, then the electric portion of the blended brake should be considered a required safety feature and, unless it is available, the equipment should not be used.

Paragraph (f) requires the brake system to allow a disabled train's pneumatic brakes to be controlled by a conventional locomotive during rescue operations.

Paragraph (g) requires that Tier II passenger trains be equipped with an independent brake failure detection system that compares brake commands to brake system outputs to determine if a failure has occurred. This paragraph also proposes that the brake failure detection system report failures to the automated monitoring system, which is proposed in § 238.445, thus alerting the train operator to potential brake system degradation so that the operator can take corrective action such as slowing the train.

Paragraph (h) requires that all Tier II passenger equipment be provided with an adhesion control system designed to automatically adjust the braking force on each wheel to prevent sliding during braking. FRA also proposes to require that the train operator be alerted in the event of a failure of this system with a wheel slide alarm that is visual or audible, or both. This proposed feature ties the adhesion control system to the automated monitoring system and prevents dangerous wheel slide flat conditions that can be caused when wheels lock during braking.

§ 238.433 Draft System

FRA is proposing that leading and trailing automatic couplers of Tier II trains be compatible with standard AAR couplers with no special adapters used. FRA believes that compatibility with standard couplers is necessary in order that a conventional locomotive could assist in the rescue of disabled Tier II passenger equipment. In addition, couplers must include an automatic coupling feature as well as an uncoupling device that complies with 49 U.S.C. chapter 203, 49 CFR part 231, and 49 CFR 232.2. FRA believes that automatic uncoupling devices are necessary in order to comply with the intent of the statute so that employees will not have to place themselves between equipment in order to perform coupling or uncoupling operations.

§ 238.435 Interior Fittings and Surfaces

This section contains proposed requirements for interior fittings and surfaces. Once survivable space is ensured by basic vehicle structural strength and crash energy management requirements, the design of interior features becomes an important factor in preventing or mitigating injuries resulting from collisions or derailments. Loose seats, equipment, and luggage are a significant cause of injuries in passenger train collisions and derailments.

Paragraphs (a) through (c) contain requirements for the design of passenger car seats and the strength of their attachment to the car body. These requirements are based on sled tests of passenger coach seats, seat tests conducted for other modes of transportation, and computer modeling to predict the results of passenger train collisions. These provisions include a requirement for shock absorbent material on the backs of seats to cushion the impact of passengers with the seats ahead of them.

Paragraph (d) contains the requirements for strength of attachment of interior fittings and is similar to that proposed in § 238.233(c).

Paragraph (e) contains a special requirement for the ultimate strength of seats and other fittings in the cab of a power car. Due to the extra strength of the cab, its structure is capable of resisting forces caused by accelerations that exceed 10g. As a result, benefit can be gained from a greater longitudinal strength requirement for seat and other interior fitting attachments. FRA is therefore proposing that seats and equipment in the cab be attached to the car body with sufficient strength to resist longitudinal forces caused by an acceleration of 12g. The lateral and vertical requirements remain 4g. This requirement does not apply to equipment located outside the cab.

Paragraphs (f) and (g) contain requirements representing good safety design practice for any type of vehicle.

FRA believes the luggage restraint requirement proposed in paragraph (h) will prevent many of the injuries caused by flying luggage that are typical of passenger train collisions and derailments.

§ 238.437 Emergency Communication

This section requires an emergency communication system within the train with back-up power, and is discussed earlier in the preamble. This safety feature will allow the train crew to provide evacuation and other instructions to passengers. Such a system can help prevent panic that can occur during emergency situations. FRA is proposing that transmission locations be located at both ends of each unit, that the locations be marked with luminescent material, and that clear instructions be provided for the use of the emergency communication system.

§ 238.439 Emergency Window Exits and Roof Hatches

Paragraph (a) contains proposed requirements that apply to emergency window exits on passenger cars. This paragraph is virtually identical to that proposed for Tier I passenger equipment in § 238.235, except for the required size of the emergency window exits. A discussion of emergency window exits and the distinction between proposed requirements for Tier I and Tier II passenger equipment is provided earlier in the preamble.

Paragraph (b) requires either a roof hatch or a clearly marked structural weak point in the roof to provide quick access for properly equipped emergency personnel. One roof hatch or structural weak point is required for each power car cab and two roof hatches or structural weak points for each passenger car. A discussion of roof hatches and structural weak points is also provided earlier in the preamble. Such features should aid in removing passengers and crewmembers from a vehicle that is either on its side or upright in water.

Paragraph (c) is reserved for marking and operating instruction requirements.

§ 238.441 Doors

This section contains the proposed requirements for exterior doors on Tier II passenger cars. This section should be read with the discussion of emergency egress and access earlier in the preamble. The requirements in paragraph (a) are virtually identical to those proposed in § 238.237(b), except that paragraph (a)(2) requires that the status of powered, exterior side doors be displayed to the crew in the operating cab and, if door interlocks are used, the sensors to detect train motion must nominally be set at 3 mph. Such equipment is well within current technology. Paragraph (b) requires that powered, exterior side doors be connected to an emergency back-up power system. Paragraph (c) is identical to that proposed for Tier I passenger equipment in § 238.237(c). Paragraph (d) requires passenger compartment end doors to be equipped with a kick-out panel, pop-out window, or other means of egress in the event the door will not open. As discussed above, FRA considered this requirement for both Tier I and Tier II equipment, but believes such a feature may be dangerous on side doors because passengers could use the feature inappropriately and possibly exit from a moving train. However, this feature has a strong safety benefit for end doors that allow movement from car to car. These doors are not used to exit the train, and using end doors to exit to the next car is the preferred mode of evacuating a car.

Paragraph (e) is reserved for door marking and operating instruction requirements. These requirements are currently being addressed in the proposed rule on passenger train emergency preparedness. *See* 62 FR 8330, Feb. 24, 1997.

§ 238.443 Headlights

Because of the high speeds at which Tier II passenger equipment operates, FRA is proposing that a headlight be directed farther in front of the train to illuminate a person than is currently required for existing equipment under 49 CFR 229.125(a). A Tier II passenger train will travel distances more quickly than a Tier I passenger train, and the train operator will have less time to react thereby necessitating earlier awareness of objects on the track.

§ 238.445 Automated Monitoring

This section contains the proposed requirements for automated monitoring of the status or performance of various safety-related systems. Investigations of past passenger train accidents reveal that many of them were either fully or partly caused by human error. The faster operating speeds of Tier II passenger equipment means that the train operator will have less time to evaluate and react to potentially dangerous situations. The potential for accidents is increased. Automated monitoring systems can decrease the risk of accidents by alerting the operator to abnormal conditions and advising the operator as to necessary corrective action. Such systems can even be designed to take corrective action automatically in certain situations. As a result, FRA is proposing that a Tier II passenger train be equipped with an automated system to monitor various train systems and components.

Paragraph (a) requires the train to be equipped to monitor the performance of a minimum set of safety-related systems and components. The monitoring system can also be used to provide information for trouble-shooting and maintenance and to accumulate reliability data to form the basis for setting required periodic maintenance intervals.

Paragraph (b) requires the operator to be alerted when any of the monitored parameters are out of predetermined limits. FRA does not intend to remove the decision from the operating railroad for when automatic intervention is necessary. However, the operating railroad should have a valid basis for either leaving response in the hands of the train operator or making corrective action automatic.

Paragraph (c) requires the monitoring system to be designed with an automatic self-test feature that notifies the operator that the monitoring capability is functioning correctly and alerts the operator that a system failure has occurred. Because operators can become dependent on automated monitoring systems, they need to know when their vigilance must be heightened to compensate for a malfunction in this automated safety tool.

§ 238.447 Operator's Controls and Cab Layout

In the ANPRM, FRA offered for comment a detailed set of requirements concerning cab control systems and interior safety features for consideration by the industry. However, several members of the Working Group believed that a number of these requirements

involved ergonomic issues which do not directly affect safety. Nonetheless, FRA is proposing in this section extensive requirements for Tier II cab interior features. The speeds at which Tier II equipment will operate will press human reaction time, and such features will contribute to the ability of the crew to operate the train as safely as possible.

Paragraph (g)(1) deserves special mention; it requires that each seat provided for a crewmember be equipped with a single-acting, quick-release lap belt and shoulder harness as defined in § 571.209 of this title. This proposed requirement is mentioned earlier in the preamble discussion of train interior safety features.

Subpart F—Inspection, Testing, and Maintenance Requirements for Tier II Passenger Equipment

Currently, there is no operating history with regard to Tier II equipment, and thus there are no regulations or industry standards establishing detailed testing, inspection, or maintenance procedures, criteria, and intervals for the equipment. The railroads and the rail labor organizations differ on the approach that should be taken in establishing inspection, testing, and maintenance requirements. Railroads have long appealed to FRA to move away from detailed ''command and control'' regulations and instead to provide broad safety performance requirements that afford railroads wide latitude to develop the operational details. Rail labor organizations, on the other hand, believe that specific inspection, testing, and maintenance criteria that cannot be unilaterally changed by railroads are the only way that safe railroad operation can be assured.

FRA believes that the introduction of a new type of passenger train equipment offers the opportunity for a fresh start, where perhaps both of these seemingly conflicting concerns can be resolved. FRA proposes general guidelines on the process to be used by the operating railroad, together with the system developer, to develop an inspection, testing, and maintenance program. The operating railroad and the system developer together have the best information, expertise, and resources necessary to develop the details of an effective inspection, testing, and maintenance program. The operating railroad is thereby granted some latitude to develop the operational details of the program, using the system safety process to justify the safety decisions that are made. However, FRA proposes to exercise final approval of the inspection, testing, and maintenance program proposed by the operating railroad; rail labor organizations will be given an opportunity to discuss their concerns with FRA during the approval process set forth in § 238.505. Tier II equipment must not be used prior to FRA approval of an inspection, testing, and maintenance program. Further, FRA proposes to enforce the safety-critical inspection, testing, and maintenance procedures, criteria, and maintenance intervals that result from the approval process.

§ 238.501 Scope

This subpart contains inspection, testing, and maintenance requirements for passenger equipment that operates at speeds exceeding 125 mph but not exceeding 150 mph.

§ 238.503 Inspection, Testing, and Maintenance Requirements

This section requires the establishment by the railroad of an FRA-approved inspection, testing, and maintenance program based on a daily complete brake system test and mechanical safety inspection of the equipment performed by qualified mechanical inspectors, coupled with a periodic maintenance program based on a system safety analysis. Although paragraph (a) proposes some basic requirements to be included in a program, FRA does not intend to prescribe every detail of what a program must contain. FRA proposes to require the operating railroad to develop and justify the details of any program it adopts based on the specific safety needs and operating environment of the high speed rail system being developed.

Paragraph (b) would make enforceable, subject to civil penalties and other enforcement action, the safety-critical inspection, testing, and maintenance requirements that are identified in the railroad's program and approved by FRA. ''Safety-critical'' requirements are those that, if not fulfilled, increase ''the risk of damage to equipment or personal injury to a passenger, crewmember, or other person.'' *See* § 238.5. Under paragraph (k), the railroad must identify which items in its inspection, testing, and maintenance program are safety-critical. The railroad must submit the program to FRA under the procedures of § 238.505. Once these programs are approved by FRA, this section proposes to make those items identified as safety-critical enforceable by FRA. FRA agrees with labor representatives to the Working Group that safety standards are stronger when they contain specific provisions that can be enforced.

Paragraph (c) requires that the operating railroad develop an inspection, testing, and maintenance program to ensure that all systems and components of Tier II passenger equipment are free of general conditions that endanger the safety of the crew, passengers, or equipment. FRA has identified the various conditions enumerated in paragraph (c) that would need to be addressed in the railroad's program. Consequently, FRA has attempted to define what the inspection, testing, and maintenance program must accomplish, but not how to accomplish it.

Paragraph (d) contains the more specific requirements that any inspection, testing, and maintenance program must incorporate. In paragraph (d)(1), FRA proposes that Tier II equipment receive the equivalent of a Class I brake test, as described in § 238.313, before its departure from an originating terminal and every 1,500 miles after that or once each calendar day the equipment remains in service. The test must be performed by a qualified mechanical inspector. For example, a Tier II train must receive the equivalent of a Class I brake test at its originating terminal and must receive a second Class I equivalent brake test after traveling 1,500 miles from the time of the original Class 1 brake test, whether or not it is the same calendar day. Furthermore, a Tier II train must receive the equivalent of a Class I brake test each calendar day it is used in service even if it has not traveled 1,500 miles since the last Class I equivalent brake test. Due to the speeds at which this equipment is permitted to operate, FRA believes that a comprehensive brake test must be performed prior to the equipment being placed in service.

Paragraph (d)(2) proposes that a complete exterior and interior mechanical inspection be conducted by qualified mechanical inspectors at least once each calendar day that the equipment is used. In order to perform a quality mechanical inspection, railroads must be provided some flexibility in determining the locations where these inspections can best be performed. FRA believes that permitting railroads to conduct these mechanical inspections at any time during the calendar day provides adequate flexibility to move equipment to appropriate locations. Trains that miss a scheduled Class I brake test or mechanical inspection due to a delay en route may proceed to the location where the Class I brake test or mechanical inspection was scheduled to be performed. FRA recognizes that, due to the specialized nature of this

equipment, proper inspections can only be conducted at a limited number of locations. FRA also recognizes that trains become delayed en route due to problems which are not readily foreseeable. Thus, FRA proposes to permit the continued use of such equipment to the location where the required inspection was scheduled to be performed.

Paragraph (e) restates § 238.15 and provides a cross-reference to that section. The paragraph provides that trains developing en route defective, inoperative, or insecure primary brake equipment be moved in accordance with the requirements of that section.

Paragraph (f) restates § 238.17 and adds a narrow exception to that section. The paragraph proposes that Tier II equipment that develops a defective condition not related to the primary brake be moved and handled in accordance with the requirements contained in § 238.17, with one exception. The exception to these requirements applies to a failure of the secondary portion of the brake that occurs en route. In those circumstances, FRA proposes that the train may proceed to the next scheduled equivalent Class I brake test at a speed no greater than the maximum safe operating speed demonstrated through analysis and testing for braking with the friction brake alone. At that location the brake system shall be restored to 100 percent operation before the train continues in service. This proposal allows extensive flexibility for the movement of equipment with defective brakes, but also contains a hard requirement that all brake components be repaired and the brake system, including secondary brakes, be restored at the location of the train's next major brake test. FRA believes that this proposal recognizes the secondary role played by the electric portion of blended brakes. If the railroad has demonstrated that the friction brake alone can stop the train within signal spacing without thermal damage to braking surfaces, then the train may be used at normal maximum speed in the event of an electric brake failure. This proposal essentially limits the use of trains without available secondary braking systems to no more than 48 hours. FRA believes that § 238.17 strikes the correct balance between the need of railroads to transport passengers to their destination and the need to have equipment with defects that could lead to more serious safety problems quickly repaired. This proposed requirement places a heavy responsibility on qualified mechanical inspectors to exercise their judgment on when and how equipment is safe to move.

Paragraph (g) would require that scheduled maintenance intervals be based on the analysis conducted as part of the system safety program and approved by FRA under the procedures of § 238.505. FRA proposes to allow the maintenance intervals for safety-critical components to be changed only when justified by accumulated acceptable operating data. Changes in maintenance cycles of safety-critical components must be based on verifiable data made available to all interested parties and shall be reviewed by FRA. This proposal is another attempt to balance the needs of the operating railroad to run efficiently and the concern of rail labor organizations that railroads have the ability to unilaterally make safety decisions. For a new system with no operating history, a formal system safety analysis is the only justifiable way to set initial maintenance intervals. The proposal recognizes that as time passes and an operating history is developed, a basis for changing maintenance intervals can be established. However, the decision to make these changes must have the participation of all the affected parties.

Paragraph (h) would require that the operating railroad establish a training, qualification, and designation program as defined in the training program plan under § 238.111 to qualify individuals to perform safety inspections, tests, and maintenance on the equipment. If the railroad deems it safety-critical, then only qualified individuals may perform the safety inspection, test, or maintenance of the equipment. FRA does not prescribe a detailed training program or qualification and designation process. Those details are left to the operating railroad, but FRA must approve the program proposed by the operating railroad under procedures of § 238.505.

Under paragraph (i), the operating railroad would be obliged to establish standard procedures for performing all safety-critical inspections, tests, maintenance, or repair. This paragraph proposes various broad requirements relating to the content and enforceability of the standard operating procedures. FRA has drawn on the experiences of other heavy industries and in the military, where inherently dangerous tasks are common, which have proven that standard operating procedures are an effective tool in reducing work-related injuries. Further, standard operating procedures can form the basis for periodic safety refresher training. FRA does not propose to prescribe the detailed procedures to be used. The proposed rule is designed to have the detailed procedures developed by those with most knowledge of how to safely perform the tasks: the operators and employees.

Paragraph (j) proposes to require that the operating railroad establish an inspection, testing, and maintenance quality control program enforced by railroad or contractor supervisors. In essence, this creates the need for the operating railroad to perform spot checks of the work performed by its employee and contract equipment maintainers to ensure that the work is performed in accordance with established procedures and Federal requirements. FRA believes this is an important management function that has a history of being neglected in the railroad industry.

Paragraph (k) requires the operating railroad to identify each inspection and testing procedure and criterion and each maintenance interval that the railroad considers safety-critical.

§ 238.505 Program Approval Procedure

This section contains the procedures a railroad shall follow in securing FRA approval of its program.

Subpart G—Introduction of New Technology to Tier II Passenger Equipment

§ 238.601 Scope

This subpart contains proposed general requirements for introducing new technology that affects safety systems of ''existing Tier II passenger equipment,'' which is defined as Tier II passenger equipment that has been approved for revenue service by FRA under § 238.21. As part of the development of the ANPRM in this docket, FRA discussed extensive requirements for the introduction of new technology. During Working Group meetings, various group members pointed out that the requirements presented by FRA were very similar to the requirements of the system safety program. These members suggested that the proposed rule could be simplified and made more concise if the system safety process were used to introduce new technology to existing Tier II equipment. FRA agrees with this suggestion. FRA may determine that it is best to integrate subpart G with § 238.113. FRA invites comments from interested parties on this possible change.

§ 238.603 Process to Introduce New Technology

Paragraph (a) requires a major upgrade or introduction of new

technology that affects the performance of an existing Tier II passenger equipment safety system to be designed and implemented using the system safety process prescribed in § 238.101. This proposed requirement implements the suggestions of Working Group members.

Paragraph (b) requires railroads to follow the procedures set forth in § 238.21 and obtain FRA's special approval of a pre-revenue service acceptance testing plan for the existing Tier II passenger equipment with the upgrade or new technology containing all the elements prescribed in § 238.113 prior to executing the plan.

Paragraph (c) requires railroads to complete a pre-revenue service demonstration of the existing equipment with the upgrade or new technology in accordance with the FRA approved plan, to fulfill all other requirements of § 238.113, and obtain special approval from FRA pursuant to § 238.21 prior to using the Tier II equipment with the upgrade or new technology in revenue service. FRA considers these requirements extremely important to prevent unknown safety problems from being introduced along with the new technology.

Appendix A—Schedule of Civil Penalties

This appendix is being reserved until the final rule. At that time it will include a schedule of civil penalties to be used in connection with this part. Because such penalty schedules are statements of policy, notice and comment are not required prior to their issuance. *See* 5 U.S.C. 553(b)(3)(A). Nevertheless, commenters are invited to submit suggestions to FRA describing the types of actions or omissions under each regulatory section that would subject a person to the assessment of a civil penalty. Commenters are also invited to recommend what penalties may be appropriate, based upon the relative seriousness of each type of violation.

Regulatory Impact

Executive Order 12866 and DOT Regulatory Policies and Procedures

This proposed rule has been evaluated in accordance with existing policies and procedures and is considered to be significant under both Executive Order 12866 and DOT policies and procedures (44 FR 11034; Feb. 26, 1979). FRA has prepared and placed in the docket a regulatory evaluation of the proposed rule. This evaluation estimates the costs and consequences of the proposed rule as well as its anticipated economic and safety benefits. It may be inspected and photocopied during normal business hours by visiting the FRA Docket Clerk at the Office of Chief Counsel, FRA, Seventh Floor, 1120 Vermont Avenue, N.W., in Washington, D.C. Photocopies may also be obtained by submitting a written request by mail to the FRA Docket Clerk at the Office of Chief Counsel, Federal Railroad Administration, 400 Seventh Street, S.W., Mail Stop 10, Washington, D.C. 20590.

FRA expects that overall the proposed rule will save the passenger rail industry a Net Present Value (NPV) of approximately $41 million over the next 20 years. The estimated NPV of the total 20-year costs associated with the proposed rule is $41,064,095. The estimated NPV of the total 20-year savings (economic benefits) expected to accrue to the industry from the proposed rule is $81,612,874. For some passenger rail operators, the total costs incurred will exceed the total cost savings. For others, the cost savings will outweigh the costs.

The following table contains estimated 20-year costs and savings associated with the proposed requirements.

Requirement category	Cost
System Safety Program/Plan:	
Initial Filing	$ 359,575
Modifications	101,974
Auditability/Tracking	159,611
Fire Protection:	
New equipment	497,509
Existing equipment (see discussion below)	622,486
Inspection, Testing, and Maintenance Program	525,247
Training Course Development	163,844
Training	3,778,176
Pre-Revenue Service Testing	496,281
Total—System Safety	6,704,703
General Design Requirements—Tier I:	
Anti-Climbing Mechanism & Link	65,948
Forward Facing End Structure/Collision Posts	1,745,407
Rollover Strength	60,927
Glazing	244,769
Brakes—ease of inspection	229,390
Interior Fittings	466,449
Emergency Lighting	1,483,162
Side Doors	3,400,297
Total—Design Requirements	7,696,349
Mechanical Inspections:	
Daily Exterior Mechanical Inspections	12,526,320
Daily Interior Mechanical Inspections	1,567,829
Total—Inspections	22,666,895
Brake Inspection, Testing, and Maintenance:	
Periodic MU Brake Maintenance	(20,052,750)
Periodic Coach Brake Maintenance	(5,468,750)
Periodic Cab Car Brake Maintenance	(6,158,448)
1,500-Mile Inspection	(36,019,648)
Class IA Brake Tests	(3,997,281)

Requirement category	Cost
Class II Brake Tests	3,996,147
Total—Brakes	(67,700,730)
Movement of Defective Equipment	(9,915,997)
Total Net Impact	(40,548,780)

The costs of performing fire safety analyses of existing equipment are included in the calculations above. However, the costs of modifying equipment to reduce the risk of personal injuries as required by the proposed rule are not included in the above figures. These costs could total between $8.75 to $14 million. The costs depend on the results of the proposed analyses, which cannot be accurately predicted. Consequently, the total net impact of the proposed rule could be a savings of $26,548,780.

In the last six years there have been at least six passenger train accidents which resulted in more than one train occupant fatality. FRA does not know the severity or number of commuter or intercity passenger train accidents that will occur in the future. Although passenger railroads offer the travelling public one of the safest forms of transportation available—in the five-year period 1991–1995 there were 1.07 passenger fatalities per billion passenger miles—the potential for injuries and loss of life in certain situations is very high. FRA believes that the proposed rule represents a cost-effective approach to providing a reasonable level of protection against known threats to human life. Accordingly, FRA believes that it is reasonable to expect that the measures called for in this proposal would prevent or mitigate the severity of casualties greater in value than the costs of complying with the proposed requirements.

FRA is allowing 60 days for comments and invites public comment on the issue of regulatory impact, and in particular any impact the proposed rule may have on small entities. FRA seeks comments or data, or both, to help identify or quantify other factors that may affect the benefits or costs of the proposal, including alternatives that were not explored by the Working Group and any costs or benefits associated with such alternatives.

Regulatory Flexibility Act

The Regulatory Flexibility Act of 1980 (5 U.S.C. 601 *et seq.*) requires an assessment of the impacts of proposed rules on small entities. FRA has conducted a regulatory flexibility assessment of this rule's impact on small entities, and the assessment has been placed in the public docket for this rulemaking. This proposed rule affects intercity passenger and commuter railroads, and the proposed provisions applicable to private cars may affect other entities as well.

Entities impacted by the proposed rule are principally governmental jurisdictions or transit authorities, which are not small for purposes of the United States Small Business Administration (*i.e.*, no entity operates in a locality with a population of under 50,000 people). Commuter railroads are part of larger transit organizations that receive Federal funds. FRA does not expect that smaller commuter railroads will be affected disproportionately. The level of costs incurred by each organization should vary in proportion to the organization's size. For instance, railroads with fewer employees and passenger equipment will have lower costs associated with employee training and the inspection, testing, and maintenance of passenger equipment.

Tourist, scenic, historic, and excursion railroad operations are excepted from the proposed rule. Entities devoted principally to such operations are smaller railroads. A joint FRA/industry working group formed under RSAC is currently developing recommendations regarding the applicability of FRA regulations, including this one, to tourist, scenic, historic, and excursion railroads. After appropriate consultation with the excursion railroad associations takes place, passenger equipment safety requirements for these operations may be proposed by FRA that are different from those affecting other types of passenger train operations.

A few provisions of the proposed rule apply to private rail cars. These consist of requirements concerning protection against personal injury; rim-stamped straight-plate wheels; suspension system safety; safety appliances; brake system safety; mechanical inspections; and brake inspection, testing, and maintenance. FRA has sought to minimize the burden of the proposed rule on private cars as much as possible, while considering the safety concerns associated with the use of private rail cars in passenger trains operated by railroads subject to the proposed rule. FRA solicits comments or data, or both, to identify the impacts of these provisions to the extent that those affected by such provisions are small entities.

Paperwork Reduction Act

The proposed rule contains information collection requirements. FRA has submitted these information collection requirements to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). The sections that contain the new information collection requirements and the estimated time to fulfill each requirement are as follows:

CFR section	Respondent universe	Total annual responses	Average time per response	Total annual burden hours	Total annual burden cost
216.14—Special notice for repairs—passenger equipment.	17 railroads	12 letters	1 hour	12 hours	$408
238.7—Waivers	17 railroads	12 waivers	2 hours	24 hours	816
238.15—Movement of passenger equipment with power brake defects, and 238.17—Movement of passenger equipment with other than power brake defects.	17 railroads	408 cards/tags	5 minutes	34 hours	1,020
Conditional requirement	17 railroads	200 events	3 minutes	10 hours	300

CFR section	Respondent universe	Total annual responses	Average time per response	Total annual burden hours	Total annual burden cost
238.19—Reporting and tracking defective passenger equipment.	17 railroads	N/A	Usual and customary procedure.	N/A	N/A
List of power brake repair points	1 railroad	1 list	2 hours	2 hours	68
Amendments to list	1 railroad	1update	1 hour	1 hour	34
238.21/238.115/238.223(a)/ 238.309(2)/238.3 11(a)/238.427(2)					
Petitions for special approval of alternative standard.	17 railroads	1 petition	16 hours	16 hours	544
Petitions for special approval of pre-revenue service acceptance testing plan.	17 railroads	1 petition	24 hours	24 hours	816
Statement of interest in reviewing special approvals.	Unknown	2 statements	1 hour	2 hours	68
Comments on the petitions	Unknown	2 comments	1 hour	2 hours	122
238.103—General system safety requirements.	17 railroads	17 plans	433 hours	7,361 hours	355,351
Amendments to System Safety Plan.	17 railroads	17 amendments	11 hours	187 hours	97,801
Traceabillity and Auditability	17 railroads	17 documents	150 hours	2,550 hours	86,700
238.105—Fire protection program 238.115—Fire safety					
Plan	6 equipment manufacturers.	4.8 (5 yr. average)	224 hours	1,075 hours	75,725
Subsequent equipment orders	6 equipment manufacturers.	4.8 (5 yr. average)	60 hours	288 hours	28,800
Preliminary fire safety analysis	17 railroads	17 documents	128 hours	2,184 hours	451,344
Final fire safety analysis	16 railroads	5.3 documents (3 yr. average).	68 hours	795 hours	79,467
Fire safety analysis on equipment transfer.	17 railroads	1 document	8 hours	8 hours	800
Certification	6 equipment manufacturers.	6 certifications	120 hours	720 hours	72,000
238.107—Software safety plan	17 railroads	N/A	Usual and customary procedure.	N/A	N/A
238.109—Inspection, testing, and maintenance program					
Program	17 railroads	N/A	Usual and customary procedure.	N/A	N/A
Maintenance intervals	17 railroads	1 change	88 hours	88 hours	3,208
Standard procedures for safely performing inspection, testing, and maintenance or repairs.	17 railroads	17 procedures	96 hours	1,632	62,832
Subsequent years—new railroads.	1 railroad	1 procedure	96 hours	96 hours	3,696
Subsequent years—railroad annual review and necessary modifications.	17 railroads	17 amendments	19 hours	323 hours	12,359
New equipment purchases	6 equipment manufacturers.	4.8 designs (5 yr. average)	120 hours	576 hours	57,600
238.111 Training, qualification, and designation program					
Training employees to perform brake-related inspections, tests, or maintenance.	17 railroads	N/A	Usual and customary procedure.	N/A	N/A
Training employees to perform daily mechanical inspections.	17 railroads	5,950 employees/235 instructors.	2 hours	12,376 hours	368,900
Development of Training Program.	17 railroads	17 programs	520 hours	8,840 hours	282,880
Record keeping	17 railroads	5,950 records	3 minutes	298 hours	10,132
238.113—Pre-revenue service acceptance testing plan.	6 equipment manufacturers.	4.8 plans (5 yr. average)	200 hours	960 hours	83,328
Subsequent equipment orders	6 equipment manufacturers.	4.8 plans (5 yr. average)	60 hours	288 hours	22,464
Previously used equipment	6 equipment manufacturers.	4.8 plans (5 yr. average)	60 hours	288 hours	22,464
238.231—Brake System					
Identify and mark emergency brake.	N/A	N/A	Usual and customary procedure.	N/A	N/A
238.239—Automated monitoring	17 railroads	17 documents	2 hours	34 hours	1,156

CFR section	Respondent universe	Total annual responses	Average time per response	Total annual burden hours	Total annual burden cost
238.303—Exterior calendar day mechanical inspection of passenger cars and unpowered vehicles used in passenger trains.	N/A	N/A	Usual and customary procedure.	N/A	N/A
238.305—Interior calendar day mechanical inspection of passenger cars					
Stenciling or marking emergency brake valve.	N/A	N/A	Usual and customary procedure.	N/A	N/A
Stenciling or marking high voltage equipment.	N/A	N/A	Usual and customary procedure.	N/A	N/A
Tagging of defective doors	9 railroads	540 tags	1 minute	9 hours	306
238.307—Periodic mechanical inspection of passenger cars.	N/A	N/A	Usual and customary procedure.	N/A	N/A
238.309—Records of periodic maintenance.	N/A	N/A	Usual and customary procedure.	N/A	N/A
238.313—Class I Brake Test	N/A	N/A	Usual and customary procedure.	N/A	N/A
238.403—Crash energy management requirements.	1 railroad	1 analysis	120 hours	120 hours	12,000
238.405—Longitudinal static compressive strength.	17 railroads	1 design	20 hours	20 hours	680
238.421—Gazing					
Marking of glazing material	N/A	N/A	Usual and customary procedure.	N/A	N/A
Stenciling requirement	N/A	N/A	Usual and customary procedure.	N/A	N/A
238.431—Brake System	1 railroad	1 analysis	40 hours	40 hours	1,360
238.437—Emergency communication	3 car manufacturers	3 instructions	1 hour	3 hours	90
238.439—Emergency window exits and roof hatches—Marking.	3 car manufacturers	16 cars marked	15 minutes	4 hours	120
238.503—Inspection, testing, and maintenance requirements					
238.505—Program approval procedures					
Submission of program	1 railroad	1 program	80 hours	80 hours	2,720
Amendments to program	1 railroad	1 amendment	8 hours	8 hours	272
Comments	4 unions/individuals	4 comments	1 hour	4 hours	244
Approval	N/A	N/A	No disapprovals expected at this time.	N/A	N/A
238.603—Process to introduce new technology.	1 railroad	1 plan	100 hours	100 hours	3,400
Appendix B to Part 238—Labeling requirement.	5–6 seat manufacturers.	N/A	Usual and customary procedure.	N/A	N/A

All estimates include the time for reviewing instructions; searching existing data sources; gathering or maintaining the needed data; and reviewing the information. Pursuant to 44 U.S.C. 3506(c)(2)(B), FRA solicits comments concerning: whether these information collection requirements are necessary for the proper performance of the functions of FRA, including whether the information has practical utility; the accuracy of FRA's estimates of the burden of the information collection requirements; the quality, utility, and clarity of the information to be collected; and whether the burden of collection of information on those who are to respond, including through the use of automated collection techniques or other forms of information technology, may be minimized. For information or a copy of the paperwork package submitted to OMB contact Ms. Gloria Swanson Eutsler at 202–632–3318.

Organizations and individuals desiring to submit comments on the collection of information requirements should direct them to the Office of Management and Budget, Attention: Desk Officer for the Federal Railroad Administration, Office of Information and Regulatory Affairs, New Executive Office Building, 726 Jackson Place, N.W., Washington, D.C. 20503, and should also send a copy of their comments to Ms. Gloria Swanson Eutsler, Federal Railroad Administration, 400 Seventh Street, S.W., Washington, D.C. 20590.

OMB is required to make a decision concerning the collection of information requirements contained in this NPRM between 30 and 60 days after publication of this document in the

Federal Register. Therefore, a comment to OMB is best assured of having its full effect if OMB receives it within 30 days of publication. The final rule will respond to any OMB or public comments on the information collection requirements contained in this proposal.

FRA is not authorized to impose a penalty on persons for violating information collection requirements which do not display a current OMB control number, if required. FRA intends to obtain current OMB control numbers for any new information collection requirements resulting from this rulemaking action prior to the effective date of a final rule. The OMB control number, when assigned, will be announced by separate notice in the **Federal Register**.

Environmental Impact

FRA has evaluated these proposed regulations in accordance with its procedures for ensuring full consideration of the environmental impact of FRA actions, as required by the National Environmental Policy Act (42 U.S.C. 4321 *et seq.*), and related directives. This notice meets the criteria that establish this as a non-major action for environmental purposes.

Federalism Implications

This proposed rule has been analyzed in accordance with the principles and criteria contained in Executive Order 12612, and it has been determined that the proposed rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment. The fundamental policy decision providing that Federal regulations should govern aspects of service provided by municipal and public benefit corporations (or agencies) of State governments is embodied in the statute quoted above (49 U.S.C. 20133). Further, FRA has consulted with commuter authorities in developing this proposed rule.

Request for Public Comments

FRA proposes to adopt a new part 238 and to amend parts 216, 223, 229, 231, and 232 of title 49, Code of Federal Regulations, as set forth below. FRA solicits comments on all aspects of the proposed rule whether through written submissions, participation in the public hearing, or both. FRA may make changes in the final rule based on comments received in response to this proposed rule.

List of Subjects

49 CFR Part 216

Railroad safety, Special notice for repairs.

49 CFR Part 223

Railroad safety, Glazing standards.

49 CFR Part 229

Railroad safety, Railroad locomotive safety.

49 CFR Part 231

Railroad safety, Railroad safety appliances.

49 CFR Part 232

Railroad safety, Railroad power brakes.

49 CFR Part 238

Railroad safety, Railroad passenger equipment.

The Proposed Rule

In consideration of the foregoing, FRA proposes to amend chapter II, subtitle B of title 49, Code of Federal Regulations as follows:

PART 216—[AMENDED]

1. The authority citation for part 216 is revised to read as follows:

Authority: 49 U.S.C. 20102–20104, 20133, 20137–20138, 20141, 20143, 20301–20302, 20701–20702, 21301–21302, 21304; 49 CFR 1.49(c), (m).

2. Section 216.1(a) is revised to read as follows:

§ 216.1 Application.

(a) This part applies, according to its terms, to each railroad that uses or operates—

(1) A railroad freight car subject to part 215 of this chapter;

(2) A locomotive subject to 49 U.S.C. chapter 207 (49 U.S.C. 20701–20703); or

(3) Railroad passenger equipment subject to part 238 of this chapter.

* * * * *

3. Section 216.3(b) is amended by removing the phrase ''section 206 of the Federal Railroad Safety Act of 1970 (45 U.S.C. 435)'' and adding in its place the phrase ''49 U.S.C. 20105''.

4. Section 216.5(c) is amended by adding after ''216.13,'': ''216.14,''.

5. The first sentence of § 216.13(a) is amended by removing the phrase ''the FRA Locomotive Inspection Regulations set forth in part 230'' and by adding in its place the phrase ''the FRA Railroad Locomotive Safety Standards set forth in part 229 of this chapter or the FRA Railroad Locomotive Inspection Regulations set forth in part 230 of this chapter''. The third sentence of § 216.13(a) is amended by removing the phrase ''part 230'' and adding in its place the phrase ''parts 229 and 230''.

6. Section 216.14 is added to read as follows:

§ 216.14 Special notice for repairs—passenger equipment.

(a) When an FRA Motive Power and Equipment Inspector or a State Equipment Inspector determines that railroad passenger equipment is not in conformity with one or more of the requirements of the FRA Passenger Equipment Safety Standards set forth in part 238 of this chapter and that it is unsafe for further service, he or she notifies the railroad in writing that the equipment is not in serviceable condition. The Special Notice sets out and describes the defect or defects that cause the equipment to be in unserviceable condition. After receipt of the Special Notice, the railroad shall remove the equipment from service until it is restored to serviceable condition. The equipment may not be deemed in serviceable condition until it complies with all applicable requirements of part 238 of this chapter.

(b) The railroad shall notify in writing the FRA Regional Administrator for the FRA region in which the Special Notice was issued when the equipment is returned to service, specifying the repairs completed.

(c) Railroad passenger equipment subject to a Special Notice may be moved from the place where it was found to be unsafe for further service to the nearest available point where the equipment can be repaired, if such movement is necessary to make the repairs. However, the movement is subject to the further restrictions of §§ 238.15 and 238.17 of this chapter.

§ 216.1 [Amended]

7. Section 216.17(a) is amended as follows:

a. By adding, after ''216.13'', ''216.14,';

b. By adding, after the word ''locomotive,'' in the third sentence, the phrase ''railroad passenger equipment,'; and

c. By revising the fifth sentence to read as follows:

''If upon reinspection, the railroad freight car, locomotive, or passenger equipment is found to be in serviceable condition, or the track is found to comply with the requirements for the class at which it was previously operated by the railroad, the FRA Regional Administrator or his or her agent immediately notifies the railroad, whereupon the restrictions of the Special Notice cease to be effective.''

8. In subpart B of part 216, the phrases ''the FRA Regional Director for Railroad Safety'', ''the FRA Regional Director of Railroad Safety'', ''a Regional Director'' and ''the Regional Director'' are removed, and the phrase ''the FRA Regional Administrator'' is added in their place.

PART 223—[AMENDED]

9. The authority citation for part 223 is revised to read as follows:

Authority: 49 U.S.C. 20102–20103, 20133, 20701–20702, 21301–21302, 21304; 49 CFR 1.49(c), (m).

10. Section 223.3 is amended by adding paragraph (c) to read as follows:

§ 223.3 Application.

* * * * *

(c) Except for § 223.9(d), this part does not apply to Tier II passenger equipment as defined in § 238.5 of this chapter (*i.e.*, passenger equipment operating at speeds exceeding 125 mph but not exceeding 150 mph).

PART 229—[AMENDED]

11. The authority citation for part 229 is revised to read as follows:

Authority: 49 U.S.C. 20102–20103, 20133, 20137–20138, 20143, 20701–20703, 21301–21302, 21304; 49 CFR 1.49(c), (m).

12 . Section 229.3 is amended by revising paragraph (a) and adding new paragraphs (c), (d), and (e) to read as follows:

§ 229.3 Applicability.

(a) Except as provided in paragraphs (b) through (e) of this section, this part applies to all standard gage railroads.

(b) * * *

(c) Paragraphs (a), (b), and (d) through (h) of § 229.125 do not apply to Tier II passenger equipment as defined in § 238.5 of this chapter (*i.e.*, passenger equipment operating at speeds exceeding 125 mph but not exceeding 150 mph).

(d) On or after January 1, 1998, paragraphs (a)(1) and (b)(1) of § 229.141 do not apply to ''passenger equipment'' as defined in § 238.5 of this chapter that is subject to part 238 of this chapter.

(e) Paragraphs (a)(2) through (a)(4), and (b)(2) through (b)(4) of § 229.141 do not apply to ''passenger equipment'' as defined in § 238.5 of this chapter that is subject to part 238 of this chapter and placed in service for the first time on or after January 1, 1998.

PART 231—[AMENDED]

13. The authority citation for part 231 is revised to read as follows:

Authority: 49 U.S.C. 20102–20103, 20131, 20301–20303, 21301–21302, 21304; 49 CFR 1.49 (c), (m).

14. Section 231.0 is amended by redesignating paragraphs (c) through (e) as paragraphs (d) through (f), respectively; by revising paragraph (a); and by adding a new paragraph (c) to read as follows:

§ 231.0 Applicability and penalties.

(a) Except as provided in paragraphs (b) and (c) of this section, this part applies to all standard gage railroads.

(b) * * *

(c) Except for the provisions governing uncoupling devices, this part does not apply to Tier II passenger equipment as defined in § 238.5 of this chapter (*i.e.*, passenger equipment operating at speeds exceeding 125 mph but not exceeding 150 mph).

* * * * *

PART 232—[AMENDED]

15. The authority citation for part 232 is revised to read as follows:

Authority: 49 U.S.C. 20102–20103, 20133, 20141, 20301–20303, 20306, 21301–21302, 21304; 49 CFR 1.49 (c), (m).

16. Section 232.0 is amended by redesignating paragraphs (c) through (e) as paragraphs (d) through (f), respectively; by revising paragraph (a); and by adding a new paragraph (c) to read as follows:

§ 232.0 Applicability and penalties.

(a) Except as provided in paragraphs (b) and (c) of this section, this part applies to all standard gage railroads.

(b) * * *

(c) Except for §§ 232.2 and 232.21 through 232.25, this part does not apply to a ''passenger train'' or ''passenger equipment'' as defined in § 238.5 of this chapter that is subject to part 238 of this chapter.

* * * * *

17. Part 238 is added to read as follows:

PART 238—PASSENGER EQUIPMENT SAFETY STANDARDS

Subpart A—General

Sec.
238.1 Purpose and scope.
238.3 Application.
238.5 Definitions.
238.7 Waivers.
238.9 Responsibility for compliance.
238.11 Civil penalties.
238.13 Preemptive effect.
238.15 Movement of passenger equipment with power brake defects.
238.17 Movement of passenger equipment with other than power brake defects.
238.19 Reporting and tracking defective passenger equipment.
238.21 Special approval procedure.

Subpart B—System Safety and General Requirements

238.101 Scope.

System Safety

238.103 General system safety requirements.
238.105 Fire protection program.
238.107 Software safety program.
238.109 Inspection, testing, and maintenance program.
238.111 Training, qualification, and designation program.
238.113 Pre-revenue service acceptance testing plan.

General Requirements

238.115 Fire safety.
238.117 Protection against personal injury.
238.119 Rim-stamped straight-plate wheels.
238.121 Train system software and hardware.

238.123 Emergency lighting.

Subpart C—Specific Requirements for Tier I Passenger Equipment

238.201 Scope.
238.203 Static end strength.
238.205 Anti-climbing mechanism.
238.207 Link between coupling mechanism and car body.
238.209 Forward-facing end structure of locomotives.
238.211 Collision posts.
238.213 Corner posts.
238.215 Rollover strength.
238.217 Side impact strength.
238.219 Truck-to-car-body attachment.
238.221 Glazing.
238.223 Fuel tanks.
238.225 Electrical system.
238.227 Suspension system.
238.229 Safety appliances.
238.231 Brake system.
238.233 Interior fittings and surfaces.
238.235 Emergency window exits.
238.237 Doors.
238.239 Automated monitoring.

Subpart D—Inspection, Testing, and Maintenance Requirements for Tier I Passenger Equipment

238.301 Scope.
238.303 Exterior calendar day mechanical inspection of passenger cars and unpowered vehicles used in passenger trains.
238.305 Interior calendar day mechanical inspection of passenger cars.
238.307 Periodic mechanical inspection of passenger cars.
238.309 Periodic brake equipment maintenance.
238.311 Single car test.
238.313 Class I brake test.
238.315 Class IA brake test.
238.317 Class II brake test.
238.319 Running brake test.

Subpart E—Specific Requirements for Tier II Passenger Equipment

238.401 Scope.
238.403 Crash energy management requirements.
238.405 Longitudinal static compressive strength.
238.407 Anti-climbing mechanism.
238.409 Forward end structures of power car cabs.
238.411 Rear end structures of power car cabs.
238.413 End structures of trailer cars.
238.415 Rollover strength.

Authority: 49 U.S.C. 20102–20103, 20133, 20141, 20301–20303, 20306, 20701–20702, 21301–21302, 21304; 49 CFR 1.49(c), (m).

Subpart A—General

§ 238.1 Purpose and scope.

(a) The purpose of this part is to:

(1) Prevent accidents involving railroad passenger equipment that cause damage to property, or injury or death to railroad employees, railroad passengers, or the general public; and

(2) Mitigate the consequences of accidents involving railroad passenger equipment, to the extent such accidents cannot be prevented.

(b) This part prescribes minimum Federal safety standards for railroad passenger equipment. This part does not restrict a railroad from adopting and enforcing additional or more stringent requirements not inconsistent with this part.

§ 238.3 Application.

(a) Except as provided in paragraph (c) of this section, this part applies to all:

(1) Railroads that operate intercity or commuter passenger train service on standard gage track which is part of the general railroad system of transportation;

(2) Railroads that provide commuter or other short-haul rail passenger train service in a metropolitan or suburban area as described by 49 U.S.C. 20102(1), including public authorities operating passenger train service; and

(3) Rapid transit operations in an urban area.

(b) Railroads that permit to be used or hauled on their lines passenger equipment subject to this part, in violation of a power brake provision of this part or a safety appliance provision of this part, are subject to the power brake and safety appliance provisions of this part with respect to such operations.

(c) This part does not apply to:

(1) Rapid transit operations in an urban area that are not connected with the general railroad system of transportation;

(2) Circus trains; or

(3) Tourist, scenic, historic, or excursion operations, whether on or off the general railroad system of transportation.

§ 238.5 Definitions.

As used in this part—

AAR means the Association of American Railroads.

Alerter means a device or system installed in the operator cab to promote continuous, active operator attentiveness by monitoring select operator-induced control activities. If fluctuation of a monitored operator control is not detected within a predetermined time, a sequence of audible and visual alarms is activated so as to progressively prompt a response by the operator. Failure by the operator to institute a change of state in a monitored control, or acknowledge the alerter alarm activity through a manual reset provision, results in a penalty brake application, bringing the locomotive or train to a stop.

Anti-climbing mechanism means a device at the ends of adjoining vehicles in a train that is designed to engage when subjected to large buff loads to prevent the override of the vehicles.

Bind means restrict the intended movement of one or more brake system components by reduced clearance, by obstruction, or by increased friction.

Block of cars means one car or multiple cars in a solid unit coupled together for the purpose of being added to, or removed from, a train as a solid unit.

Brake, air or *power brake* means a combination of devices operated by compressed air, arranged in a system, and controlled manually, electrically, or pneumatically, by means of which the motion of a car or locomotive is retarded or arrested.

Brake control system means the components, including software, that either automatically or under the control of the engineer control the retarding force applied to the train by the brake system.

Brake, disc means a retardation system used on some rail vehicles, primarily passenger equipment, that utilizes flat metal discs as the braking surface instead of the wheel tread.

Brake, dynamic means a train braking system whereby the kinetic energy of a moving train is used to generate electric current at the locomotive traction motors, which is then dissipated through banks of resistor grids or back into the catenary or third rail system.

Brake, effective means a brake that is capable of producing its required design retarding force on the train.

Brake indicator means a device, actuated by brake cylinder pressure, which indicates whether brakes are applied or released.

Brake, inoperative means a primary brake that, for any reason, no longer applies or releases as intended or is otherwise ineffective.

Brake, on-tread friction means a braking system that uses a brake shoe that acts on the tread of the wheel to retard the vehicle.

Brake, parking or *hand brake* means a brake that can be applied and released by hand to prevent movement of a stationary car or locomotive.

Brake pipe means the system of piping (including branch pipes, angle cocks, cutout cocks, dirt collectors, hose, and hose couplings) used for connecting locomotives and all cars for the passage of air to control the locomotive and car brakes.

Brake, power means ''air brake'' as that term is defined in this section.

Brake, primary means those components of the train brake system necessary to stop the train within the signal spacing distance without thermal damage to friction braking surfaces.

Brake, secondary means those components of the train brake system which develop supplemental brake retarding force that is not needed to stop the train within signal spacing distances or to prevent thermal damage to wheels.

Brake shoes or pads aligned with tread or disc means that the surface of the brake shoe or pad, respectively, engages the surface of the wheel tread or disc, respectively, with no more than a ¼ inch overhang.

Braking system, blended means a braking system where the primary brake and one or more secondary brakes are

automatically combined to stop the train. If the secondary brakes are unavailable, the blended brake uses the primary brake alone to stop the train.

Calendar day means a time period starting at 12:01 am and ending at midnight on a given date.

Class I brake test means a complete passenger train brake system test (as further specified in § 238.313) performed by a qualified mechanical inspector to ensure that the air brake system is 100 percent effective.

Class IA brake test means a test and inspection (as further specified in § 238.315) of the air brake system on each car in a passenger train to ensure the air brake system is 100 percent effective.

Class II brake test means a test (as further specified in § 238.317) of brake pipe integrity and continuity from the controlling locomotive to the rear unit of a passenger train.

Collision posts means members of the end structures of a vehicle that project upward vertically from the underframe to which they are securely attached, and that provide protection of occupied compartments from an object penetrating the vehicle during a collision.

Control valves means that part of the air brake equipment on each car or locomotive that controls the charging, application, and release of the air brakes, in response to train line commands.

Corner posts means structural members located at the intersection of the front or rear surface with the side surface of a vehicle and which extend vertically from the floor support structure to the roof support structure. Corner posts may be combined with collision posts to become part of the end structure.

Crack means a fracture without complete separation into parts, except that, in a casting, a shrinkage crack or hot tear that does not significantly diminish the strength of the member is not a crack.

Crash energy management means an approach to the design of rail passenger equipment which controls the dissipation of energy during a collision to protect the occupied volumes from crushing and to limit the decelerations on passengers and crewmembers in those volumes. This may be accomplished by designing energy-absorbing structures of low strength in the unoccupied volumes of a rail vehicle or passenger train to collapse in a controlled fashion, while providing higher structural strength in the occupied volumes. Energy deflection can also be part of a crash energy management approach. Crash energy management can be used to help provide anti-climbing resistance and to reduce the risk of train buckling during a collision.

Crash refuge means a volume with extreme structural strength designed to maximize the survivability of crewmembers stationed in the locomotive cab during a collision.

Crewmember means a railroad employee called to perform service covered by 49 U.S.C. 21103 and subject to the railroad's operating rules and program of operational tests and inspections required in §§ 217.9 and 217.11 of this chapter.

Critical buckling stress means minimum stress necessary to initiate buckling of a structural member.

Emergency application means an irretrievable brake application resulting in the maximum retarding force available from the train brake system.

End structure means the main support structure projecting upward from the floor or underframe of a locomotive, passenger car, or other rail vehicle. The end structure is securely attached to the underframe at each end of a rail vehicle.

Foul means restrict the intended movement of one or more brake system components because the component is snagged, entangled, or twisted.

Fuel tank, integral means a fuel containment volume that is integral with some other structural element of the locomotive not designed solely as a fuel container.

Full-height collision post, corner post, or side frame post means any vertical framing member in the car body structure that spans the distance between the underframe and the roof at the car body section where the post is located. For collision posts located at the approximate third points of an end frame, the term ''full-height'' applies to posts that extend and connect to supporting structural members in the roof at the location of the posts, or to a beam connected to the tops of the end-frame and supported by the roof rails (or anti-telescoping plate), or to both.

Full service application means a brake application which results in a brake cylinder pressure at the service limiting valve setting or equivalent.

Glazing, end-facing means a glazing panel located where a line perpendicular to the exterior surface of the panel makes an angle of 50 degrees or less with the longitudinal center line of the rail vehicle in which the panel is installed. A glazing panel that curves so as to meet the definition for both side-facing and end-facing glazing is end-facing glazing.

Glazing, exterior means a glazing panel that is an integral part of the exterior skin of a rail vehicle with a surface exposed to the outside environment.

Glazing frame means the arrangement used to install the glazing into the structure of a rail vehicle.

Glazing, interior means a glazing panel with no surface exposed to the outside environment and which is protected from projectiles by the structure of a rail vehicle.

Glazing, side-facing means a glazing panel located where a line perpendicular to the exterior surface of the panel makes an angle of more than 50 degrees with the longitudinal center line of the rail vehicle in which the panel is installed.

Handrails means safety appliances installed on either side of a rail vehicle's exterior doors to assist passengers and crew to safely board and depart the vehicle.

Head end power means power generated on board the locomotive of a passenger train used for purposes other than propelling the train, such as cooking, heating, illumination, ventilation and air conditioning.

Hunting oscillations means, for purposes of Tier I equipment, lateral oscillations of trucks that could lead to a dangerous instability and, for purposes of Tier II equipment, truck frame lateral oscillations exceeding 0.8g peak-to-peak for six or more consecutive oscillations.

In passenger service, when used in connection with passenger equipment, means passenger equipment subject to this part that is carrying, or available to carry, fare-paying passengers.

In service, when used in connection with passenger equipment, means:

(1) Passenger equipment subject to this part that is in passenger service; and

(2) All other passenger equipment subject to this part, unless the passenger equipment:

(i) Is being handled in accordance with §§ 238.15, 238.17, 238.305(c)(5), or 238.503(f), as applicable;

(ii) Is in a repair shop or on a repair track;

(iii) Is on a storage track and is not carrying passengers; or

(iv) Has been delivered in interchange but has not been accepted by the receiving railroad.

Interior fitting means any auxiliary component in the passenger compartment which is mounted to the floor, ceiling, sidewalls, or end walls and projects into the passenger compartment from the surface or surfaces to which it is mounted. Interior

fittings do not include side and end walls, floors, door pockets, or ceiling lining materials, for example.

Lateral means the horizontal direction perpendicular to the direction of travel of a rail vehicle.

Locomotive means a piece of on-track equipment, other than hi-rail, specialized maintenance, or other similar equipment, which may consist of one or more units operated from a single control stand with one or more propelling motors designed for moving other equipment; with one or more propelling motors designed to transport freight or passenger traffic or both; or without propelling motors but with one or more control stands. This term does not include a locomotive propelled by steam power unless it is used to haul an intercity or commuter passenger train.

Locomotive cab means a compartment or space on board a locomotive where the control stand is located and which is normally occupied by the engineer when the locomotive is being operated.

Locomotive, cab car means a unit of rolling equipment intended to provide transportation for members of the general public that is without propelling motors but with one or more control stands.

Locomotive, controlling means the locomotive from which the engineer exercises control over the train.

Locomotive, MU means a unit of rolling equipment self-propelled by any power source, other than steam, and intended to provide transportation for members of the general public.

Longitudinal means in a direction parallel to the normal direction of travel of a rail vehicle.

Luminescent material means a material that absorbs light energy when ambient levels of light are high and emits this stored energy when ambient levels of light are low, making the material appear to glow in the dark.

L/V ratio means the lateral force that the flange of a vehicle's wheel exerts on the rail, divided by the vertical force that the tread of the same wheel exerts on the rail.

MIL–STD–882C means a military standard issued by the United States Department of Defense to provide uniform requirements for developing and implementing a system safety program to identify and then eliminate the hazards of a system or reduce the associated risk to an acceptable level.

Occupied volume means the spaces of a rail vehicle or passenger train where passengers or crewmembers are normally located during service operation, such as the operating cab and passenger seating and sleeping areas. Vestibules are typically not considered occupied, except when in use as a control cab.

Ordered or *date ordered* means the date on which notice to proceed is given by a procuring railroad to a contractor or supplier for new equipment.

Override means to climb over the normal coupling or side buffers and linking mechanism and impact the end of the adjoining rail vehicle or unit above the underframe.

Passenger car means a unit of rail rolling equipment intended to provide transportation for members of the general public and includes a self-propelled car designed to carry passengers, baggage, mail, or express. This term includes a passenger coach, cab car, and an MU locomotive. This term does not include a private car.

Passenger coach means a unit of rail rolling equipment intended to provide transportation for members of the general public that is without propelling motors and without a control stand.

Passenger equipment means all powered and unpowered passenger cars, locomotives used to haul a passenger car, and any other unit of rail rolling equipment hauled in a train with one or more passenger cars. Passenger equipment includes a—

(1) Passenger coach,

(2) Cab car,

(3) MU locomotive,

(4) Private car,

(5) Locomotive not intended to provide transportation for a member of the general public that is used to power a passenger train, and

(6) Any non-self-propelled vehicle hauled in a passenger train, including a freight car.

Passenger station means a location designated in a railroad's timetable where passengers are regularly scheduled to get on or off any train.

Permanent deformation means the undergoing of a permanent change in shape of a structural member of a rail vehicle.

Piston travel means the amount of linear movement of the air brake hollow rod (or equivalent) or piston rod when forced outward by movement of the piston in the brake cylinder or actuator and limited by the brake shoes being forced against the wheel or disc.

Power car means a rail vehicle that propels a Tier II passenger train or is the lead vehicle in a Tier II passenger train, or both.

Pre-revenue service acceptance testing plan means a document, as further specified in § 238.113, prepared by a railroad that explains in detail how pre-revenue service tests of certain passenger equipment demonstrate that the equipment meets Federal safety standards and the railroad's own safety design requirements.

Private car means historical or antiquated rail rolling equipment that is used only for excursion, recreational, or private transportation businesses. A private car is not a passenger car.

Qualified mechanical inspector means a qualified person who has received, as a part of the training, qualification, and designation program required under § 238.111, instruction and training that includes ''hands-on'' experience (under appropriate supervision or apprenticeship) in one or more of the following functions: troubleshooting, inspection, testing, and maintenance or repair of the specific train brake and other components and systems for which the inspector is assigned responsibility. Further, the mechanical inspector shall be a person whose primary responsibility includes work generally consistent with the above-referenced functions and is designated to—

(1) Conduct Class I brake tests under this part;

(2) Inspect MU locomotives or other passenger cars for compliance with this part; or

(3) Determine whether equipment not in compliance with this part may be moved safely and, if so, under what conditions.

Qualified person means a person determined by a railroad to have the knowledge and skills necessary to perform one or more functions required under this part. The railroad determines the qualifications and competencies for employees designated to perform various functions in the manner set forth in this part.

Railroad means any form of non-highway ground transportation that runs on rails or electromagnetic guideways, including:

(1) Commuter or short-haul rail passenger service in a metropolitan or suburban area and commuter railroad service that was operated by the Consolidated Rail Corporation on January 1, 1979; and

(2) High speed ground transportation systems that connect metropolitan areas, without regard to whether those systems use new technologies not associated with traditional railroads. The term ''railroad'' is also intended to mean a person that provides railroad transportation, whether directly or by contracting out operation of the railroad to another person. The term does not include rapid transit operations in an urban area that are not connected to the general railroad system of transportation.

Rebuilt means equipment undergoing overhaul identified by the railroad as a capital expense under the Surface Transportation Board's accounting standards.

Refresher training means periodic retraining required by a railroad for employees or contractors to remain qualified to perform specific equipment inspection, testing, or maintenance functions.

Repair point means a location designated by a railroad where repairs of the type necessary occur on a regular basis. A repair point has, or should have, the facilities, tools, and qualified mechanical employees required to make the necessary repairs. A repair point need not be staffed continuously.

Respond as intended means to produce the result that a device or system is designed to produce.

Rollover strength means strength needed to protect the structural integrity of a rail vehicle in the event the vehicle leaves the track and impacts the ground on its side or roof.

Roof rail means the longitudinal structural member at the intersection of the side wall and the roof sheathing.

Running brake test means a test (as further specified in § 238.319) of a train system or component while the train is in motion to verify that the system or component functions as intended.

Safety appliance means an appliance required under 49 U.S.C. chapter 203, excluding power brakes. The term includes automatic couplers, hand brakes, sill steps, handholds, handrails, or ladder treads made of steel or a material of equal or greater mechanical strength used by the traveling public or railroad employees that provides a means for safely coupling, uncoupling, or ascending or descending passenger equipment.

Safety-critical component or system means a component or system that, if not available, increases the risk of damage to equipment or injury to a passenger, crewmember, or other person.

Safety-critical task means a task that, if not performed correctly, increases the risk of damage to equipment or injury to a passenger, crewmember, or other person.

Safety inspection criteria means a measurement limit or observation threshold used to trigger the duty under this part to take corrective action to prevent a serious safety problem from developing. Measurements may be taken manually or by reliable sensors.

Semi-permanently coupled means coupled by means of a drawbar or other coupling mechanism that requires tools to perform the uncoupling operation. Coupling and uncoupling of each such unit in a train can be performed safely only while at a maintenance or shop location where personnel can safely get under a unit or between units.

Shear strength means the ability of a structural member to resist forces or components of forces acting perpendicular to compression or tension forces, or both, in the member.

Shock absorbent material means material designed to prevent or mitigate injuries due to impact by yielding and absorbing much of the energy of impact.

Side posts means main vertical structural elements in the sides of a rail vehicle.

Side sills means that portion of the underframe or side at the bottom of the rail vehicle side wall.

Single car test means a comprehensive test (as further specified in § 238.311) of the functioning of all critical brake system components installed on an individual passenger car or unpowered vehicle, other than a passenger car, hauled in a passenger train.

Single car test device means a device capable of controlling the application and release of the brakes on an individual passenger car or an unpowered vehicle, other than a passenger car, hauled in a passenger train through pneumatic or electrical means.

Skin means the outer covering on a fuel tank or the front of a locomotive, including a cab car and an MU locomotive, excluding the windows and forward-facing doors. The skin may be covered with another coating of a material such as fiberglass.

Spall, glazing means small pieces of glazing that fly off the back surface of glazing when an object strikes the front surface.

Spot checks means random checks of train inspections, tests, or maintenance operations conducted by qualified supervisors.

Standard procedures means a description of the step-by-step process to be used to safely accomplish a safety-critical or potentially hazardous task.

System means a composite of equipment, computer programs, people, facilities, procedures, and documentation which are integrated to perform a specific operational function in a specific environment.

System developer means the entity responsible for developing equipment or a system so that it may be approved for use in service.

System safety means the application of design, operating, technical, and management techniques and principles throughout the system's life cycle to reduce hazards and unsafe conditions to the lowest level possible through the most effective use of the available resources.

System safety plan means a document that states in detail the techniques, procedures, and tests to follow to reduce hazards and unsafe conditions to the lowest level possible through the most effective use of available resources. The system safety plan is used as part of the design process for new equipment to ensure that the equipment meets all Federal safety standards and the railroad's own safety requirements.

System safety program means the activities described in the system safety plan to be performed to ensure that the railroad's passenger equipment meets all Federal safety standards and the railroad's own safety design requirements.

Telescope means override an adjoining rail vehicle or unit and penetrate into the interior of that adjoining vehicle or unit because of compressive forces.

Terminal means a starting point or ending point of a single scheduled train trip, where passengers may get on or off a train. Normally the location is a point where the train would reverse direction or change destinations.

Tier I means operating at speeds not exceeding 125 mph.

Tier II means operating at speeds exceeding 125 mph but not exceeding 150 mph.

Tourist, scenic, historic, or excursion operations are railroad operations that carry passengers, often using antiquated equipment, with the conveyance of the passengers to a particular destination not being the principal purpose.

Trailer car means a unit of rail rolling equipment that neither propels a Tier II passenger train nor is the leading unit in a Tier II passenger train. A trailer car is normally without a control stand and is normally occupied by passengers.

Train means a locomotive unit or locomotive units coupled, with or without cars. For the purposes of the provisions of this part related to power brakes, the term ''train'' does not include such equipment when being used in switching movements (as defined in § 231.30(b) of this chapter) of less than one mile.

Train brake communication line means the communication link between the locomotive and cars in a train by which the brake commands are transmitted. This may be a pneumatic pipe, electrical line, or radio signal.

Train, commuter means a passenger train providing commuter service within an urban, suburban, or metropolitan area. The term includes a

passenger train provided by an instrumentality of a State or a political subdivision of a State.

Train, long-distance intercity passenger means a passenger train that provides service between large cities more than 125 miles apart and is not operated exclusively in the National Railroad Passenger Corporation's Northeast Corridor.

Train, passenger means a train that transports or is available to transport members of the general public. If a train is composed of a mixture of passenger and freight equipment, that train is a passenger train for purposes of this part.

Train, short-distance intercity passenger means a passenger train that provides service exclusively on the National Railroad Passenger Corporation's Northeast Corridor or between cities that are not more than 125 miles apart.

Train, Tier II passenger means a short-distance or long-distance intercity passenger train providing service at speeds that include exceeding 125 mph but do not exceed 150 mph.

Trainset, passenger means a passenger train including the locomotive(s) or power car(s) and passenger cars that are semi-permanently coupled to operate as a single unit. The individual components are uncoupled only for emergencies or maintenance.

Transverse means in a direction perpendicular to the normal direction of travel of a railroad vehicle.

Ultimate strength means the load at which a structural member fractures or ceases to resist any load.

Uncoupling mechanism means the arrangement for operating the coupler by any means.

Underframe means the lower horizontal support structure of a car body.

Unit means rail rolling equipment of any type or, in the context of articulated equipment, ''unit'' means a piece of equipment located between two trucks.

Unit body (monocoque) design or unistructure means a type of vehicle construction where the shell or skin acts as a single unit with the supporting frame to resist and transmit the loads acting on the vehicle.

Unoccupied volume means the spaces of a rail vehicle or passenger train which do not contain seating and are not normally occupied by passengers or crewmembers.

Vehicle, rail means a car, locomotive, tender, or similar vehicle.

Vestibule means an area of a passenger car that normally does not contain seating, that leads from the seating area to the side exit doors.

Witness plate means a thin foil placed behind a piece of glazing undergoing an impact test. Any material spalled or broken from the back side of the glazing will dent or mark the witness plate.

Yard means a system of tracks within defined limits provided for the making up of trains, storing of cars, and other purposes.

Yard air test means a train brake system test conducted using a source of compressed air other than a locomotive.

Yield strength means the ability of a structural member to resist a change in length caused by a heavy load. Exceeding the yield strength may cause permanent deformation of the member.

§ 238.7 Waivers.

(a) Any person may petition the Federal Railroad Administration for a waiver of compliance with any requirement prescribed in this part.

(b) Each petition for a waiver under this section shall:

(1) Be filed in the manner required by part 211 of this chapter;

(2) Contain the information required by part 211 of this chapter; and

(3) Provide appropriate data or analysis, or both, establishing that a waiver is warranted under applicable statutory criteria as well as a description of the measures proposed to be taken to provide a level of safety equivalent to that afforded by the provision of this part that is sought to be waived.

§ 238.9 Responsibility for compliance.

(a) A railroad subject to this part shall not—

(1) Use, haul, permit to be used or hauled on its line, offer in interchange, or accept in interchange any train or passenger equipment, while in service,

(i) That has one or more conditions not in compliance with a safety appliance or power brake provision of this part; or

(ii) That has not been inspected and tested as required by a safety appliance or power brake provision of this part; or

(2) Use, haul, offer in interchange, or accept in interchange any train or passenger equipment, while in service,

(i) That has one or more conditions not in compliance with a provision of this part, other than the safety appliance and power brake provisions of this part, if the railroad has actual knowledge of the facts giving rise to the violation, or a reasonable person acting in the circumstances and exercising reasonable care would have that knowledge; or

(ii) That has not been inspected and tested as required by a provision of this part, other than the safety appliance and power brake provisions of this part, if the railroad has actual knowledge of the facts giving rise to the violation, or a reasonable person acting in the circumstances and exercising reasonable care would have that knowledge; or

(3) Violate any other provision of this part.

(b) For purposes of this part, passenger equipment will be considered in use prior to departure but after it has received, or should have received, the inspection required under this part for movement and is deemed ready for service.

(c) Although many of the requirements of this part are stated in terms of the duties of a railroad, when any person (including, but not limited to, a contractor performing safety-related tasks under contract to a railroad subject to this part) performs any function required by this part, that person (whether or not a railroad) is required to perform that function in accordance with this part.

§ 238.11 Civil penalties.

Any person (including but not limited to a railroad; any manager, supervisor, official, or other employee or agent of a railroad; any owner, manufacturer, lessor, or lessee of railroad equipment, track, or facilities; any employee of such owner, manufacturer, lessor, lessee, or independent contractor) who violates any requirement of this part or causes the violation of any such requirement is subject to a civil penalty of at least $500, but not more than $10,000 per violation, except that: Penalties may be assessed against individuals only for willful violations, and, where a grossly negligent violation or a pattern of repeated violations has created an imminent hazard of death or injury to persons, or has caused death or injury, a penalty not to exceed $20,000 per violation may be assessed. Each day a violation continues shall constitute a separate offense. Appendix A to this part contains a schedule of civil penalty amounts used in connection with this part.

§ 238.13 Preemptive effect.

Under 49 U.S.C. 20106, issuance of the regulations in this part preempts any State law, rule, regulation, order, or standard covering the same subject matter, except for a provision directed at an essentially local safety hazard if that provision is consistent with this part and does not impose an undue burden on interstate commerce.

§ 238.15 Movement of passenger equipment with power brake defects.

(a) *General.* This section contains the requirements for moving passenger equipment with a power brake defect

without liability for a civil penalty under this part. Railroads remain liable for the movement of passenger equipment under 49 U.S.C. 20303(c). For purposes of this section, § 238.17, and § 238.503, a ''power brake defect'' is a condition of a power brake component, or other primary brake component, that does not conform with this part. (Passenger cars and other passenger equipment classified as locomotives under part 229 of this chapter are also covered by the movement restrictions contained in § 229.9 of this chapter for those defective conditions covered by part 229 of this chapter.)

(b) *Limitations on movement of passenger equipment containing a power brake defect found during a Class I or IA brake test.* Except as provided in paragraph (c) of this section (dealing with brakes that become defective en route after a Class I or IA brake test was performed), a commuter or passenger train that has in its consist passenger equipment containing a power brake defect found during a Class I or IA brake test (or, for Tier II trains, the equivalent) may only be moved, without civil penalty liability under this part—

(1) If all of the following conditions are met:

(i) The train is moved for purposes of repair, without passengers;

(ii) The applicable operating restrictions in paragraph (d) of this section are observed; and

(iii) The passenger equipment is tagged, or information is recorded, as prescribed in paragraph (c)(2) of this section; or

(2) If the train is moved for purposes of scrapping or sale of the passenger equipment that has the power brake defect, and without passengers; if the movement is at a speed of 15 mph or less; and if the movement conforms with the railroad's air brake or power brake instructions.

(c) *Limitations on movement of passenger equipment in passenger service that becomes defective en route after a Class I or IA brake test.* Passenger equipment hauled or used in service in a commuter or passenger train that develops a power brake defect while en route to another location after receiving a Class I or IA brake test (or, for Tier II trains, the equivalent) may be hauled or used by a railroad for repair, without civil penalty liability under this part, if the applicable operating restrictions set forth in paragraph (d) of this section are complied with and all of the following requisites are satisfied:

(1) *En route defect.* At the time of the train's Class I or IA brake test, the passenger equipment in the train was properly equipped with power brakes that comply with this part. The power brakes on the passenger equipment become defective while it is en route to another location.

(2) *Record.* At the place where the railroad first discovers the defect, a tag or card is placed on both sides of the defective passenger equipment, or an automated tracking system is provided, with the following information about the defective passenger equipment:

(i) The reporting mark and car or locomotive number;

(ii) The name of the inspecting railroad;

(iii) The name of the inspector;

(iv) The inspection location and date;

(v) The nature of each defect;

(vi) The destination of the equipment where it will be repaired; and

(vii) The signature, if possible, and job title of the person reporting the defective condition.

(3) *Conditional requirement.* In addition, if an en route failure causes power brakes to be cut out on passenger equipment, the railroad shall:

(i) Determine the percentage of operative power brakes in the train based on the number of brakes known to be cut out or otherwise inoperative, using the formula specified in paragraph (d)(1) of this section;

(ii) Notify the dispatcher of the percent of operative brakes and movement restrictions on the train imposed by paragraph (d) of this section;

(iii) Notify the mechanical department or desk of the failure; and

(iv) Confirm the percentage of operative brakes by a walking inspection at the next location where the railroad reasonably judges that it is safe to do so.

(d) *Operating restrictions based on percent operative power brakes in train.* (1) *Computation of percent operative power brakes.*—(i) Except as specified in paragraphs (d)(1) (ii) and (iii) of this section, the percentage of operative power brakes in a train shall be determined by dividing the number of axles in the train with operative power brakes by the total number of axles in the train.

(ii) For equipment with tread brake units (TBUs), the percentage of operative power brakes shall be determined by dividing the number of operative TBUs by the total number of TBUs.

(iii) Each cut-out axle on a locomotive that weighs more than 200,000 pounds shall be counted as two cut-out axles for the purposes of calculating the percentage of operative brakes. Unless otherwise specified by the railroad, the friction braking effort over all other axles shall be considered uniform.

(iv) The following brake conditions not in compliance with this part are not considered inoperative power brakes for purposes of this section:

(A) Failure or cutting out of secondary brake systems;

(B) Inoperative or otherwise defective handbrakes or parking brakes;

(C) Excessive piston travel that does not render the power brakes ineffective; and

(D) Power brakes overdue for inspection, testing, maintenance, or stencilling under this part.

(2) *All passenger trains developing 50–74 percent operative power brakes.* A passenger train that develops inoperative power brake equipment resulting in at least 50 percent but less than 75 percent operative power brakes may be used only as follows:

(i) The train may be moved in passenger service only to the next forward passenger station;

(ii) The speed of the train shall be restricted to 20 mph or less;

(iii) After all passengers are discharged, the defective equipment shall be moved directly to the nearest location where the necessary repairs can be made; and

(iv) If the power brakes on the front or rear unit in the train are inoperative, a qualified person shall be stationed at the handbrake on this unit.

(3) *Commuter, short-distance intercity, and short-distance Tier II passenger trains developing 75–99 percent operative power brakes.*

(i) *75–84 percent operative brakes.* Commuter, short-distance intercity, and short-distance Tier II passenger trains which develop inoperative power brake equipment resulting in at least 75 percent but less than 85 percent operative brakes may be used only as follows:

(A) The train may be moved in passenger service only to the next forward terminal;

(B) The speed of the train shall be restricted to 50 percent of the train's maximum allowable speed or 40 mph, whichever is less;

(C) After discharging passengers, the defective equipment shall be moved directly to the nearest location where the necessary repairs can be made; and

(D) If the brakes on the front or rear unit in a train are inoperative, a qualified person shall be stationed at the handbrake on this unit.

(ii) *85–99 percent operative brakes.* Commuter, short-distance intercity, and short-distance Tier II passenger trains which develop inoperative power brake equipment resulting in at least 85

percent but less than 100 percent operative brakes may only be used as follows:

(A) The train may be moved in passenger service only to the next forward terminal;

(B) After all passengers are discharged, the defective cars shall be moved directly to the nearest location where the necessary repairs can be made; and

(C) If the brakes on the front or rear unit in a train are inoperative, a qualified person shall be stationed at the handbrake on this unit.

(4) *Long-distance intercity and long-distance Tier II passenger trains developing 75–99 operative power brakes.*

(i) *75–84 percent operative brakes.* Long-distance intercity and long-distance Tier II passenger trains which develop inoperative power brake equipment resulting in at least 75 percent but less than 85 percent operative brakes may be used only if all of the following restrictions are observed:

(A) The train may be moved in passenger service only to the next forward repair location identified for repair of that equipment by the railroad operating the equipment in the list required by § 238.19(d); however, if the next forward repair location does not have the facilities to handle the safe unloading of passengers, the train may be moved past the designated repair location in service only to the next forward passenger station in order to facilitate the unloading of passengers;

(B) The speed of the train shall be restricted to 50 percent of the train's maximum allowable speed or 40 mph, whichever is less;

(C) After discharging passengers, the defective equipment shall be moved directly to the nearest location where the necessary repairs can be made; and

(D) If the brakes on the front or rear unit in a train are inoperative, a qualified person shall be stationed at the handbrake on this unit.

(ii) *85–99 percent operative brakes.* Long-distance intercity and long-distance Tier II passenger trains which develop inoperative power brake equipment resulting in at least 85 percent but less than 100 percent operative brakes may be used only if all of the following restrictions are observed:

(A) The train may be moved in passenger service only to the next forward repair location identified for repair of that equipment by the railroad operating the equipment in the list required by § 238.19(d); however, if the next forward repair location does not have the facilities to handle the safe unloading of passengers, the train may be moved past the designated repair location in service only to the next forward passenger station in order to facilitate the unloading of passengers;

(B) After passengers are discharged, the defective cars shall be moved directly to the nearest location where the necessary repairs can be made; and

(C) If the brakes on the front or rear unit in a train are inoperative, a qualified person shall be stationed at the handbrake on this unit.

(e) *Special Notice for Repair.* Nothing in this section authorizes the movement of passenger equipment subject to a Special Notice for Repair under part 216 of this chapter unless the movement is made in accordance with the restrictions contained in the Special Notice.

§ 238.17 Movement of passenger equipment with other than power brake defects.

(a) *General.* This section contains the requirements for moving passenger equipment with other than a power brake defect. (Passenger cars and other passenger equipment classified as locomotives under part 229 of this chapter are also covered by the movement restrictions contained in § 229.9 of this chapter for those defective conditions covered by part 229 of this chapter.)

(b) *Limitations on movement of passenger equipment containing defects found at time of calendar day inspection.* Except as provided in § 238.305(c)(5), passenger equipment containing a condition not in conformance with this part at the time of its calendar day mechanical inspection may be moved from that location for repair if all of the following conditions are satisfied:

(1) When the defective equipment is moved, it is not in passenger service and is in a non-revenue train;

(2) The requirements of paragraphs (c)(2) and (c)(3) of this section are met;

(3) The special requirements of paragraph (d) of this section, if applicable, are met.

(c) *Usual limitations on movement of passenger equipment that develops defects en route.* Except as provided in § 238.503(f), passenger equipment that develops en route to its destination, after its calendar day inspection was performed and before its next calendar day mechanical inspection was performed, any defect not in compliance with this part, other than a power brake defect, may be moved only if the railroad complies with all of the following requirements and, if applicable, the special requirements in paragraph (d) of this section:

(1) Prior to movement of the defective equipment, a qualified mechanical inspector shall determine if it is safe to move the equipment in passenger service and, if so, the maximum speed and other restrictions necessary for safely conducting the movement. If appropriate, these determinations may be made based upon a description of the defective condition provided by a crewmember.

(2) Prior to movement of the defective equipment, the qualified mechanical inspector shall notify the crewmember in charge of the movement of the defective equipment, who in turn shall inform all other crewmembers of the presence of the defective condition(s) and the maximum speed and other restrictions determined under paragraph (c)(1) of this section. The movement shall be made in conformance with such restrictions.

(3) The railroad shall maintain a record of all defects reported and their subsequent repair in the defect tracking system required in § 238.19. In addition, prior to movement of the defective equipment, a tag or card placed on both sides of the defective equipment, or an automated tracking system, shall record the following information about the defective equipment:

(i) The reporting mark and car or locomotive number;

(ii) The name of the inspecting railroad;

(iii) The name of the inspector, inspection location, and date;

(iv) The nature of each defect;

(v) Movement restrictions and safety restrictions, if any;

(vi) The destination of the equipment where it will be repaired; and

(vii) The signature, if possible, as well as the job title and location of the person making the determinations required by this section.

(4) At the first location possible, a qualified mechanical inspector shall perform a physical inspection of the defective equipment to verify the description of the defect provided by the crew. After a qualified mechanical inspector verifies that the defective equipment is safe to remain in service, the defective equipment that develops a condition not in compliance with this part while en route may continue in passenger service not later than the next calendar day mechanical inspection, if the requirements of this paragraph are otherwise fully met.

(d) *Special requisites for movement of passenger equipment with safety appliance defects.* Consistent with 49 U.S.C. 20303, passenger equipment with

a safety appliance not in compliance with this part or with part 231 of this chapter, if applicable, may be moved—

(1) If necessary to effect repair of the safety appliance;

(2) From the point where the safety appliance defect was first discovered by the railroad to the nearest available location on the railroad where the necessary repairs required to bring the passenger equipment into compliance can be made or, at the option of the receiving railroad, the equipment may be received and hauled for repair to a point on the receiving railroad's line no farther than the point on the delivering railroad's line where the repair of the defect could have been made; and

(3) If a tag placed on both sides of the passenger equipment or an automated tracking system contains the information required under paragraph (c)(3) of this section.

(e) *Special Notice for Repair.* Nothing in this section authorizes the movement of equipment subject to a Special Notice for Repair under part 216 of this chapter unless the movement is made in accordance with the restrictions contained in the Special Notice.

§ 238.19 Reporting and tracking defective passenger equipment.

(a) *General.* Each railroad shall have in place a reporting and tracking system for passenger equipment with a defect not in conformance with this part that:

(1) Records the identification number of the defective equipment;

(2) Records the date the defect occurred;

(3) Records the nature of the defect;

(4) Records the determination made by a qualified mechanical inspector on whether the equipment is safe to run;

(5) Records the name of the qualified mechanical inspector making such a determination;

(6) Records any operating restrictions placed on the equipment; and

(7) Records repairs made and the date that they were made.

(b) *Retention of records.* At a minimum, each railroad shall keep the records described in paragraph (a) of this section for one periodic maintenance interval for each specific type of equipment as described in the railroad's system safety plan. FRA strongly encourages railroads to keep these records for longer periods of time because they form the basis for future reliability-driven decisions concerning test and maintenance intervals.

(c) *Availability of records.* Railroads shall make defect reporting and tracking records available to FRA upon request.

(d) *List of power brake repair points.* Railroads operating long-distance intercity and long-distance Tier II passenger equipment shall designate locations, in writing, where repairs to passenger equipment with a power brake defect will be made and shall provide the list to FRA's Associate Administrator for Safety and make it available to FRA for inspection and copying upon request. Railroads operating these trains shall designate a sufficient number of repair locations to ensure the safe and timely repair of passenger equipment. These designations shall not be changed without at least 30 days' written notice to FRA's Associate Administrator for Safety.

§ 238.21 Special approval procedure.

(a) *General.* The following procedures govern consideration and action upon requests for special approval of alternative standards under §§ 238.115, 238.223, 238.309, 238.311, 238.405, or 238.427 and for special approval of pre-revenue service acceptance testing plans under § 238.113 or § 238.603. (Requests for approval of programs for the inspection, testing, and maintenance of Tier II passenger equipment are governed by § 238.505.)

(b) *Petitions for special approval of alternative standard.* Each petition for special approval of an alternative standard shall contain—

(1) The name, title, address, and telephone number of the primary person to be contacted with regard to review of the petition;

(2) The alternative proposed, in detail, to be substituted for the particular requirements of this part;

(3) Appropriate data or analysis, or both, establishing that the alternative will provide an equivalent level of safety; and

(4) A statement affirming that the railroad has served a copy of the petition on designated representatives of railroad employees, together with a list of the names and addresses of the persons served.

(c) *Petitions for special approval of pre-revenue service acceptance testing plan.* Each petition for special approval of a pre-revenue service acceptance testing plan shall contain—

(1) The name, title, address, and telephone number of the primary person to be contacted with regard to review of the petition; and

(2) The elements prescribed in § 238.113.

(d) *Service.* (1) Each petition for special approval under paragraph (b) or (c) of this section shall be submitted in triplicate to the Associate Administrator for Safety, Federal Railroad Administration, 400 7th Street, S.W., Washington, D.C. 20590.

(2)(i) Service of each petition for special approval of an alternative standard under paragraph (b) of this section shall be made on the following:

(A) Designated employee representatives responsible for the equipment's operation, inspection, testing, and maintenance under this part;

(B) Any organizations or bodies that either issued the standard incorporated in the section(s) of this part to which the special approval pertains or issued the alternative standard that is proposed in the petition; and

(C) Any other person who has filed with FRA a current statement of interest in reviewing special approvals under the particular requirement of this part at least 30 days but not more than 5 years prior to the filing of the petition.

(ii) If filed, a statement of interest shall be filed with FRA's Associate Administrator for Safety and shall reference the specific section(s) of this part in which the person has an interest.

(e) *Federal Register notice.* FRA will publish a notice in the **Federal Register** concerning each petition under paragraph (b) of this section.

(f) *Comment.* Not later than 30 days from the date of publication of the notice in the **Federal Register** concerning a petition under paragraph (b) of this section, any person may comment on the petition.

(1) Each comment shall set forth specifically the basis upon which it is made, and contain a concise statement of the interest of the commenter in the proceeding.

(2) Three copies of each comment shall be submitted to the Associate Administrator for Safety, Federal Railroad Administration, 400 7th Street, S.W., Washington, D.C. 20590.

(3) The commenter shall certify that a copy of the comment was served on each petitioner.

(g) *Disposition of petitions.* (1) If FRA finds that the petition complies with the requirements of this section and that the proposed plan is acceptable or changes are justified, the petition will be granted, normally within 90 days of its receipt. If the petition is neither granted nor denied within 90 days, the petition remains pending for decision. FRA may attach special conditions to the approval of the petition. Following the approval of a petition, FRA may reopen consideration of the petition for cause stated.

(2) If FRA finds that the petition does not comply with the requirements of this section and that the proposed plan is not acceptable or that the proposed

changes are not justified, the petition will be denied, normally within 90 days of its receipt.

(3) When FRA grants or denies a petition, or reopens consideration of the petition, written notice is sent to the petitioner and other interested parties.

Subpart B—System Safety and General Requirements

§ 238.101 Scope.

This subpart contains system safety requirements for each railroad that operates passenger equipment and general requirements for the safety of all railroad passenger equipment subject to this part.

System Safety

§ 238.103 General system safety requirements.

(a) By the dates specified in paragraph (g) of this section, each railroad operating passenger equipment subject to this part shall adopt a written system safety plan that describes the railroad's system safety program, using MIL–STD–882(C) as a guide. The system safety plan shall be updated annually.

(b) For the procurement of new passenger equipment, the system safety plan shall describe the system safety program to be conducted as part of the equipment design and development process to ensure that all safety issues and Federal safety requirements are identified, addressed, and documented. The documentation shall include certification in writing by the manufacturer that the passenger equipment meets the design requirements of this part. The system safety plan shall also describe the system safety program to be conducted as part of the maintenance, overhaul, and operation of all passenger equipment by that railroad. The system safety program should ensure that safety issues are considered as important as cost and performance issues in the design, development, maintenance, overhaul, and operation of the equipment.

(c) The system safety plan shall be the principal safety document. It shall be used as guidance or, as applicable, requirements for the development and operation of equipment and subsystems. At a minimum, the system safety plan shall address:

(1) Fire protection;

(2) Software safety;

(3) Inspection, testing, and maintenance;

(4) Training and qualifications; and

(5) Pre-revenue service acceptance testing.

(d) The system safety plan shall describe the approaches and processes to be used to:

(1) Identify all safety requirements, including Federal requirements governing the design of passenger equipment and its supporting systems;

(2) Evaluate the total system, including hardware, software, testing, and support activities, to identify known or potential safety hazards over the life cycle of the equipment;

(3) Identify safety issues during design reviews;

(4) Eliminate or reduce the risk posed by the hazards identified;

(5) Monitor and track the progress made toward resolving safety issues, reducing hazards, and meeting safety requirements; and

(6) Develop a program of testing or analysis, or both, to demonstrate that safety requirements have been met.

(e) As part of the system safety program, adequate documentation shall be maintained to audit how the design and operation of new equipment meets safety requirements and to track how safety issues are raised and resolved.

(f) The system safety plan shall address how operational limitations may be imposed on the use of equipment if the equipment design cannot meet certain safety requirements.

(g) *Dates.* (1) The portion of the system safety plan applicable to existing passenger equipment shall be adopted no later than [one year after the effective date of the final rule].

(2) The portion of the system safety plan applicable to passenger equipment to be procured by the railroad that is already in the design and development process before the effective date of the final rule shall be adopted no later than [one year after the effective date of the final rule].

(3) The portion of the system safety plan applicable to passenger equipment to be procured by the railroad that is not yet in the design and development process on [the effective date of the final rule] shall be adopted before commencing the design and development of new equipment.

(h) The railroad's system safety plan and documentation required by paragraph (e) of this section shall be available for inspection and copying by FRA.

§ 238.105 Fire protection program.

(a) The operating railroad shall include in its system safety program fire safety considerations and features in the design of new passenger equipment that reduce the risk of equipment damage and personal injuries due to fires to an acceptable level as defined in MIL–STD–882(C).

(b) As part of the system safety program, each railroad operating passenger equipment subject to this part shall complete a thorough written analysis of the fire protection problem. In conducting this analysis, the railroad shall—

(1) Ensure that good fire protection practice is used as part of the equipment design process.

(2) Take effective steps to design equipment to be sufficiently fire resistant to detect a fire and allow the evacuation of equipment before fire, smoke, or toxic fumes cause injury to a passenger or crewmember.

(3) Identify, analyze, and prioritize the fire hazards inherent in the design of equipment.

(4) Document and explain how safety issues were resolved in relation to cost and performance issues in the design of equipment to minimize the risk of each fire hazard.

(5) Describe the analysis and tests necessary to demonstrate how the fire protection approach taken in the design of equipment will enable a train to meet the fire protection standards of this part and of the railroad's system safety plan.

(6) Describe the analysis and tests necessary to select materials which provide sufficient fire resistance to reasonably ensure adequate time to detect a fire and safely evacuate a train.

(7) Reasonably ensure that a ventilation system does not contribute to the lethality of a fire.

(8) Identify in writing which train components are at risk of being a source of fire and which require overheat protection. As prescribed in § 238.115(c), overheat detectors shall be installed in all components where the analysis determines that such equipment is necessary. If overheat protection is not provided for a component at risk of being a source of fire, the written rationale and justification for the decision shall be included as part of the system safety program documentation.

(9) Identify in writing all unoccupied train compartments that contain equipment or material posing a fire hazard, and analyze the benefit provided by including a fire or smoke detection system in each compartment identified. As prescribed in § 238.115(d), fire or smoke detectors shall be installed in unoccupied compartments where the analysis determines that such equipment is necessary to ensure sufficient time for the safe evacuation of a train. The written analysis shall explain why a fire or smoke detector is not necessary, if the decision is made not to install one in

any of the unoccupied compartments identified as a potential source of fire.

(10) Perform an analysis of the occupied and unoccupied spaces which require portable fire extinguishers. The analysis shall include the proper type and size of fire extinguisher for each location.

(11) Identify in writing all unoccupied train compartments that contain equipment or material which poses a fire hazard. On a case-by-case basis, the benefit provided by including a fixed, automatic fire-suppression system in each compartment identified shall be analyzed. The type and size of the automatic fire-suppression system for each necessary application shall be determined. As prescribed in § 238.115(e), a fixed, automatic fire suppression system shall be installed in unoccupied compartments where the analysis determines it is necessary and practical to ensure sufficient time for the safe evacuation of the train. The analysis shall provide the reasoning why a fixed, automatic fire-suppression system is not necessary or practical if the decision is made not to install one in any of the unoccupied compartments identified in the plan.

(12) Develop and adopt written procedures for the inspection, testing, and maintenance of all fire safety systems and equipment. As prescribed in § 238.115(f), the railroad shall comply with those procedures that it designates as mandatory.

(c) The operating railroad shall reasonably ensure in its contracts for the purchase of new equipment that the system developer follows the design criteria and performs the tests required by the fire protection part of the railroad's system safety plan and program.

(d)(1) Not later than 365 days following [the effective date of the final rule] each passenger railroad shall complete a preliminary fire safety analysis for each category of existing rail equipment and current rail service.

(2) Not later than 730 days following [the effective date of the final] rule each such railroad shall—

(i) Complete a final fire safety analysis (equivalent to that required for new equipment in this section) for any category of existing equipment and service evaluated during the preliminary fire safety analysis as likely presenting an unacceptable risk of personal injury, including consideration of the extent to which interior materials comply with the test performance criteria for flammability and smoke emission characteristics contained in Appendix B to this part or alternative standards approved by FRA under this part; and

(ii) Take remedial action to reduce the risk of personal injuries to an acceptable level in any such category.

(3) Within 1460 days following the effective date of the final rule, the railroad shall complete a fire safety analysis for all categories of equipment and service. In completing this analysis, the railroad shall, to the extent practicable, determine the extent to which remaining interior materials comply with the test performance criteria for flammability and smoke emission characteristics contained in Appendix B to this part or alternative standards approved by FRA under this part and, based on the fire safety analysis, take remedial action to reduce the risk of personal injuries to an acceptable level in any such category.

(4) Where possible prior to transferring existing equipment to a new category of service, but in no case more than 90 days following such a transfer, the passenger railroad shall complete a new fire safety analysis taking into consideration the change in railroad operations and shall effect prompt action to reduce any identified risk to an acceptable level.

(5) As used in this paragraph, ''category of rail equipment and current rail service'' shall be determined by the railroad based on relevant fire safety risks, including available ignition sources, presence or absence of heat/smoke detection systems, known variations from required interior material test performance criteria or alternative standards approved by FRA, and availability of rapid and safe egress to the exterior of the vehicle under conditions secure from fire, smoke, and other hazards.

§ 238.107 Software safety program.

(a) The operating railroad shall develop and maintain a software safety program to guide the design, development, testing, integration, and verification of computer programs used to control or monitor equipment safety functions.

(b) The software safety program shall:

(1) Treat system software that controls or monitors safety functions as safety-critical unless a completely redundant, failsafe, non-software means to provide the same function is provided; and

(2) Include a description of how the following tasks will be accomplished, or objectives achieved, to ensure safe, reliable system software used to monitor or perform safety functions:

(i) The software design process used;

(ii) The software design documentation to be produced;

(iii) A software hazard analysis;

(iv) Software safety reviews;

(v) Software hazard monitoring and tracking;

(vi) Hardware and software integration safety tests; and

(vii) Demonstration of overall software safety as part of the pre-revenue service tests of equipment.

(c) The operating railroad shall ensure that the system developer follows the design criteria and performs the tests required by the software safety part of the system safety program. To fulfill this obligation in part, the operating railroad shall include software safety requirements in each of its contracts for the purchase of new equipment or new components of existing equipment that contain safety-critical software.

(d) The operating railroad shall follow the software safety procedures required by the software safety part of the system safety program.

§ 238.109 Inspection, testing, and maintenance program.

With respect to Tier II passenger equipment operated by a railroad, fulfillment of the requirements of § 238.503 to file an inspection, testing, and maintenance program with FRA satisfies the requirement of § 238.103(c)(3) to address the railroad's inspection, testing, and maintenance program for such equipment in the railroad's system safety plan.

The following provisions of this section apply only to Tier I equipment operated by the railroad.

(a) *General.* Each railroad shall provide to FRA, upon request, detailed information, consistent with the requirements of this part, on the inspection, testing, and maintenance procedures necessary for the railroad to safely operate Tier I equipment. This information shall include a detailed description of:

(1) Safety inspection procedures, intervals, and criteria;

(2) Test procedures and intervals;

(3) Scheduled preventive maintenance intervals;

(4) Maintenance procedures; and

(5) Special testing equipment or measuring devices required to perform safety inspections and tests.

(b) *General inspection, testing, and maintenance procedures.* The inspection, testing, and maintenance program shall contain procedures reasonably to ensure that all systems and components of the equipment are free of all general conditions that endanger the safety of the crew, passengers, or equipment, including procedures to ensure that all systems and components of the equipment are

free of the following conditions that endanger the safety of the crew, passengers, or equipment:

(1) A continuous accumulation of oil or grease;

(2) Improper functioning of a component;

(3) A crack, break, excessive wear, structural defect, or weakness of a component;

(4) A leak;

(5) Use of a component or system under a condition that exceeds that for which the component or system is designed to operate; and

(6) Insecure attachment of a component.

(c) *Maintenance intervals.* Initial scheduled maintenance intervals should be based on analysis completed as part of the system safety program. The intervals should be changed only when justified by accumulated, verifiable operating data.

(d) *Standard procedures for safely performing inspection, testing, and maintenance, or repairs.* Each railroad shall establish written standard procedures for performing all safety-critical or potentially hazardous equipment inspection, test, maintenance, or repair tasks. These standard procedures shall be available to FRA upon request and shall:

(1) Describe in detail each step required to safely perform the task;

(2) Describe the knowledge necessary to safely perform the task;

(3) Describe any precautions that shall be taken to safely perform the task;

(4) Describe the use of any safety equipment necessary to perform the task;

(5) Be approved by the railroad's chief mechanical officer;

(6) Be approved by the railroad's official responsible for safety;

(7) Be enforced by supervisors with responsibility for accomplishing the tasks; and

(8) Be reviewed annually by the railroad.

§ 238.111 Training, qualification, and designation program.

(a) Each railroad shall adopt and comply with a training, qualification, and designation program for employees and contractors that perform safety-related inspections, tests, or maintenance of passenger equipment. For purposes of this section, a ''contractor'' is defined as a person under contract with the railroad or an employee of a person under contract with the railroad.

(b) As part of this program, the railroad shall, at a minimum:

(1) Identify the safety-related tasks that must be performed on each type of equipment that the railroad operates;

(2) Develop written procedures for the performance of the tasks identified;

(3) Identify the skills and knowledge necessary to perform each task;

(4) Develop a training course that includes classroom and ''hands-on'' lessons designed to impart the skills and knowledge identified as necessary to perform each task;

(5) Require all employees and contractors to successfully complete the training course that covers the equipment and tasks for which they are responsible;

(6) Require all employees and contractors to pass a written examination covering the equipment and tasks for which they are responsible;

(7) Require all employees and contractors to demonstrate ''hands-on'' capability to perform their assigned tasks on the type equipment to which they are assigned;

(8) Require supervisors to complete the program that covers the employees that they supervise;

(9) Require supervisors to exercise oversight to ensure that all the identified tasks are performed in accordance with the railroad's written procedures;

(10) Designate in writing that each employee and contractor has the knowledge and skills necessary to perform the safety-related tasks that are part of his or her job;

(11) Require periodic refresher training at an interval not to exceed three years that includes classroom and ''hands-on'' training, as well as testing;

(12) Add new equipment to the qualification and designation program prior to its introduction to revenue service; and

(13) Maintain records adequate to demonstrate that each employee and contractor performing safety-related tasks on passenger equipment is currently qualified to do so. These records shall be adequate to distinguish the qualifications of the employee or contractor as a qualified person or as a qualified mechanical inspector.

§ 238.113 Pre-revenue service acceptance testing plan.

(a) Except as provided in paragraph (f), before using passenger equipment for the first time on its system the operating railroad shall submit a pre-revenue service acceptance testing plan containing the information required by paragraph (e) of this section and obtain the approval of the FRA Associate Administrator for Safety, under the procedures specified in § 238.21.

(b) After receiving FRA approval of the pre-revenue service testing plan and before introducing the passenger equipment into revenue service, the operating railroad shall:

(1) Adopt and comply with such FRA-approved plan, including fully executing the tests required by the plan;

(2) Report to the FRA Associate Administrator for Safety the results of the pre-revenue service acceptance tests;

(3) Correct any safety deficiencies identified by FRA in the design of the equipment or in the inspection, testing, and maintenance procedures or, if safety deficiencies cannot be corrected by design changes, agree to comply with any operational limitations that may be imposed by the Associate Administrator for Safety on the revenue service operation of the equipment; and

(4) Obtain FRA approval to place the equipment in revenue service.

(c) The operating railroad shall comply with any such operational limitations imposed by the Associate Administrator for Safety.

(d) The plan shall be made available to FRA for inspection and copying upon request.

(e) The plan shall include all of the following elements:

(1) An identification of any waivers of FRA or other Federal safety regulations required for the tests or for revenue service operation of the equipment.

(2) A clear statement of the test objectives. One of the principal test objectives shall be to demonstrate that the equipment meets the safety design and performance requirements specified in this part when operated in the environment in which it is to be used.

(3) A planned schedule for conducting the tests.

(4) A description of the railroad property or facilities to be used to conduct the tests.

(5) A detailed description of how the tests are to be conducted. This description shall include:

(i) An identification of the equipment to be tested;

(ii) The method by which the equipment is to be tested;

(iii) The criteria to be used to evaluate the equipment's performance; and

(iv) The means by which the test results are to be reported to FRA.

(6) A description of any special instrumentation to be used during the tests.

(7) A description of the information or data to be obtained.

(8) A description of how the information or data obtained is to be analyzed or used.

(9) A clear description of any criteria to be used as safety limits during the testing.

(10) A description of the criteria to be used to measure or determine the success or failure of the tests. If acceptance is to be based on extrapolation of less than full level testing results, the analysis to be done to justify the validity of the extrapolation shall be described.

(11) A description of any special safety precautions to be observed during the testing.

(12) A written set of standard operating procedures to be used to ensure that the testing is done safely.

(13) Quality control procedures to ensure that the inspection, testing, and maintenance procedures are followed.

(14) Criteria to be used for the revenue service operation of the equipment.

(15) A description of any testing of the equipment that has previously been performed.

(f) For passenger equipment that has previously been used in revenue service in the United States, the railroad shall test the equipment on its system, prior to placing it in revenue service, to ensure the compatibility of the equipment with the operating system (track, signals, etc.) of the railroad. A description of such testing shall be retained by the railroad and made available to FRA for inspection and copying upon request.

General Requirements

§ 238.115 Fire safety.

(a)(1) All materials used in constructing the interior of both a passenger car and a cab of a locomotive ordered on or after January 1, 1999, or placed in service for the first time on or after January 1, 2001, shall meet the test performance criteria for flammability and smoke emission characteristics contained in Appendix B to this part or alternative standards issued or recognized by an expert consensus organization after special approval of FRA's Associate Administrator for Safety under § 238.21.

(2) On or after [the effective date of the final rule], all materials used in refurbishing the interior of a passenger car and a locomotive cab shall meet the test performance criteria for flammability and smoke emission characteristics contained in Appendix B to this part or alternative standards issued or recognized by an expert consensus organization after special approval of FRA's Associate Administrator for Safety under § 238.21. Refurbishing includes replacing an individual component such as a seat cushion.

(3) For purposes of this section the interior of a passenger car and a locomotive cab includes walls, floors, ceilings, seats, doors, windows, electrical conduits, air ducts, and any other internal equipment.

(b) A railroad shall require certification that combustible materials to be used in constructing or refurbishing passenger car and locomotive cab interiors have been tested by a recognized independent testing laboratory and that the results comply with the requirements of paragraph (a) of this section.

(c) Overheat detectors shall be installed in all components of passenger equipment where the written analysis required by § 238.105(b)(8) determines that such equipment is necessary.

(d) Fire or smoke detectors shall be installed in unoccupied compartments of a train if the analysis required by § 238.105(b)(9) determines that such equipment is necessary to ensure sufficient time for the safe evacuation of the train.

(e) A fixed, automatic fire suppression system shall be installed in unoccupied compartments of a train if the analysis required by § 238.105(b)(11) determines that such a system is necessary and practical to ensure sufficient time for the safe evacuation of the train.

(f) The railroad shall comply with those elements of its written procedures, under § 238.105(b)(12), for the inspection, testing, and maintenance of all fire safety systems and equipment that it has designated as mandatory.

(g) After completing each fire safety analysis required by § 238.105(d), the railroad shall take action to reduce the risk of personal injuries as provided in that paragraph.

§ 238.117 Protection against personal injury.

On or after January 1, 1998, all moving parts, high voltage equipment, electrical conductors and switches, and pipes carrying hot fluids or gases on all passenger equipment shall be appropriately equipped with interlocks or guards to minimize the chance of personal injury.

§ 238.119 Rim-stamped straight-plate wheels.

(a) On or after January 1, 1998, no railroad shall place or continue in service any vehicle equipped with a rim-stamped straight-plate wheel, except for a private car.

(b) A rim-stamped straight-plate wheel shall not be used as a replacement wheel on a private car operated in a passenger train.

§ 238.121 Train system software and hardware.

Electrical and electronic systems, including software components, used to control safety functions of passenger equipment shall be treated as safety-critical by the operating railroad. Safety-critical systems utilized in equipment ordered on or after January 1, 1999, and such systems implemented or materially modified for new or existing equipment on or after January 1, 2001, shall conform with the following requirements:

(a) A formal safety methodology shall be used to develop electrical and electronic control systems that control safety functions for computer hardware and software. The safety methodology shall include a Failure Modes, Effects, Criticality Analysis (FMECA) and verification tests for all components of the control system and its interfaces for computer hardware and software.

(b) A comprehensive hardware and software integration program for safety-critical systems shall be adopted and complied with to ensure that the software functions as intended when installed in a hardware system identical to that to be used in service.

(c) Safety-related control systems driven by computer software shall include hardware and software design features that result in a safe condition in the event of a computer hardware or software failure.

§ 238.123 Emergency lighting.

(a) This section applies to each locomotive and passenger car ordered or rebuilt on or after January 1, 1999, or placed in service for the first time on or after January 1, 2001. This section applies to each level of a bi-level unit.

(b) Emergency lighting shall be provided and shall include the following:

(1) An illumination level of a minimum of 5 foot-candles at floor level for all potential passenger and crew evacuation routes from the equipment; and

(2) A back-up power system capable of:

(i) Operating in all equipment orientations within 45 degrees of vertical;

(ii) Operating after the initial shock of a collision or derailment resulting in the following individually applied accelerations:

(A) Longitudinal: 8g;

(B) Lateral: 4g; and

(C) Vertical: 4g; and

(iii) Operating all emergency lighting for a period of at least two hours.

Subpart C—Specific Requirements for Tier I Passenger Equipment

§ 238.201 Scope.

This subpart contains requirements for railroad passenger equipment operating at speeds not exceeding 125 miles per hour. As stated in § 238.229, all such passenger equipment remains subject to the safety appliance requirements contained in Federal statute at 49 U.S.C. chapter 203 and in FRA regulations at part 231 and § 232.2 of this chapter. Unless otherwise specified, these requirements only apply to passenger equipment ordered on or after January 1, 1999, or placed in service for the first time on or after January 1, 2001.

§ 238.203 Static end strength.

(a) Except as further specified in this paragraph and paragraph (b) of this section, on or after January 1, 1998, all passenger equipment shall have a minimum static end strength of 800,000 pounds without permanent deformation of the car body structure. This requirement does not apply to either—

(1) A private car or

(2) A vehicle of special design that operates at the rear of a passenger train and is used solely to transport freight, such as an auto-carrier or a RoadRailer.

(b) On or after January 1, 1998, each locomotive and passenger car shall have a minimum static end strength of 800,000 pounds on the line of draft at the ends of occupied volumes without permanent deformation of the car body structure. The static end strength of unoccupied volumes may be less than 800,000 pounds if a crash energy management design is used.

(c) When overloaded in compression, the car body structure of passenger equipment shall be designed, to the maximum extent possible, to fail by buckling or crushing, or both, of structural members rather than by fracture of structural members or failure of structural connections.

§ 238.205 Anti-climbing mechanism.

(a) Except as provided in paragraph (b) of this section, all passenger equipment placed in service for the first time on or after January 1, 1998, shall have at both the forward and rear ends an anti-climbing mechanism capable of resisting an upward or downward vertical force of 100,000 pounds without failure. When coupled together in any combination to join two vehicles, AAR Type H and Type F tight-lock couplers satisfy this requirement.

(b) Each locomotive ordered on or after January 1, 1999, or placed in service for the first time on or after January 1, 2001, shall have an anti-climbing mechanism at its forward end capable of resisting an upward or downward vertical force of 200,000 pounds without failure, in lieu of the forward end anti-climbing mechanism requirements described in paragraph (a) of this section.

§ 238.207 Link between coupling mechanism and car body.

All passenger equipment placed in service for the first time on or after January 1, 1998, shall have a coupler carrier designed to resist a vertical downward thrust from the coupler shank of 100,000 pounds for any normal horizontal position of the coupler, without permanent deformation.

§ 238.209 Forward-facing end structure of locomotives.

The skin covering the forward-facing end of each locomotive shall be:

(a) Equivalent to a ½-inch steel plate with a 25,000 pounds-per-square-inch yield strength—material of a higher yield strength may be used to decrease the required thickness of the material provided an equivalent level of strength is maintained;

(b) Designed to inhibit the entry of fluids into the occupied cab area of the equipment; and

(c) Be affixed to the collision posts or other main vertical structural members of the forward-facing end structure so as to add to the strength of the end structure.

§ 238.211 Collision posts.

(a) Except as further specified in this paragraph and paragraphs (b) and (c) of this section—

(1) All passenger equipment placed in service for the first time on or after January 1, 1998, shall have either:

(i) Two full-height collision posts, located at approximately the one-third points laterally, at each end where coupling and uncoupling are expected. Each collision post shall have an ultimate longitudinal shear strength of not less than 300,000 pounds at a point even with the top of the underframe member to which it is attached. If reinforcement is used to provide the shear value, the reinforcement shall have full value for a distance of 18 inches up from the underframe connection and then taper to a point approximately 30 inches above the underframe connection; or

(ii) An equivalent end structure that can withstand the sum of forces that each collision post is required to withstand. For analysis purposes, the required forces may be assumed to be evenly distributed at the end structure at the underframe joint.

(2) This paragraph does not apply to a vehicle of special design that operates at the rear of a passenger train and is used solely to transport freight, such as an auto-carrier or a RoadRailer.

(b) Each locomotive, including a cab car and an MU locomotive, ordered on or after January 1, 1999, or placed in service for the first time on or after January 1, 2001, shall have at its forward end, in lieu of the structural protection described in paragraph (a) of this section, either:

(1) Two forward collision posts, located at approximately the one-third points laterally, each capable of withstanding:

(i) A 500,000-pound longitudinal force at the point even with the top of the underframe, without exceeding the ultimate strength of the joint; and

(ii) A 200,000-pound longitudinal force exerted 30 inches above the joint of the post to the underframe, without exceeding the ultimate strength; or

(2) An equivalent end structure that can withstand the sum of the forces that each collision post is required to withstand.

(c) If a vehicle consists of articulated units, the end structural protection requirements in paragraphs (a) and (b) of this section apply only to the ends of the permanently joined assembly of units, not to each end of each unit so joined.

§ 238.213 Corner posts.

(a) Each passenger car shall have at each end of the vehicle two full-height corner posts capable of resisting without failure a horizontal load of 150,000 pounds at the point of attachment to the underframe and a load of 20,000 pounds at the point of attachment to the roof structure. The orientation of the applied horizontal loads shall range from longitudinal inward to transverse inward. The corner posts may be positioned near the occupied volume of the rail vehicle to provide protection or structural strength to the occupied volume.

(b) Each corner post shall resist a horizontal load of 30,000 pounds applied 18 inches above the top of the floor without permanent deformation. The orientation of the applied horizontal loads shall range from longitudinal inward to transverse inward.

§ 238.215 Rollover strength.

(a) Each passenger car shall be designed to rest on its side and be uniformly supported at the top (''roof rail''), the bottom (''side sill'') chords of the side frame, and, if bi-level, the intermediate floor rail. The allowable

stress for occupied volumes for this condition shall be one-half yield or one-half the critical buckling stress, whichever is less.

(b) Each passenger car shall also be designed to rest on its roof so that any damage in occupied areas is limited to roof sheathing and framing. Deformation to the roof sheathing and framing is allowed to the extent necessary to permit the vehicle to be supported directly on the top chords of the side frames and end frames. Other than roof sheathing and framing, the allowable stress for occupied volumes for this condition shall be one-half yield or one-half the critical buckling stress, whichever is less.

§ 238.217 Side impact strength.

Each passenger car shall comply with the following:

(a) *Side posts and corner braces.* (1) For ''modified girder,'' ''semi-monocoque,'' or truss construction, the sum of the section moduli—about a longitudinal axis, taken at the weakest horizontal section between the side sill and side plate—of all posts and braces on each side of the car located between the body corner posts shall be not less than 0.30 multiplied by the distance in feet between the centers of end panels.

(2) For ''modified girder'' or ''semi-monocoque'' construction only, the sum of the section moduli—about a transverse axis, taken at the weakest horizontal section between side sill and side plate—of all posts, braces and pier panels, to the extent available, on each side of the car located between body corner posts shall be not less than 0.20 multiplied by the distance in feet between the centers of end panels.

(3) The center of an end panel is the point midway between the center of the body corner post and the center of the adjacent side post.

(b) *Sheathing.* (1) Outside sheathing of mild, open-hearth steel when used flat, without reinforcement (other than side posts) in a side frame of ''modified girder'' or ''semi-monocoque'' shall not be less than ⅛ inch nominal thickness. Other metals may be used of a thickness in inverse proportion to their yield strengths.

(2) Outside metal sheathing of less than ⅛ inch thickness may be used only if it is reinforced so as to produce at least an equivalent sectional area at a right angle to reinforcements as that of the flat sheathing specified in paragraph (b)(1) of this section.

(3) When the sheathing used for truss construction serves no load-carrying function, the minimum thickness of that sheathing shall be not less than 40 percent of that specified in paragraph (b)(1) of this section.

§ 238.219 Truck-to-car-body attachment.

Passenger equipment shall have a truck-to-car-body attachment with an ultimate strength sufficient to resist without failure a force of 2g vertical on the mass of the truck and a force of 250,000 pounds in any horizontal direction. For purposes of this section, the mass of the truck includes axles, wheels, bearings, the truck-mounted brake system, suspension system components, and any other components attached to the truck by design.

§ 238.221 Glazing.

(a) Passenger equipment shall comply with the applicable Safety Glazing Standards contained in part 223 of this chapter, if required by that part.

(b) Glazing securement components shall hold the glazing in place against all forces described in part 223 of this chapter. Securement components shall remain held to the car body structure against these same forces.

(c) Glazing securement components shall be designed to resist the forces due to air pressure differences caused when two trains pass at the minimum separation for two adjacent tracks, while traveling in opposite directions, each train traveling at the maximum authorized speed.

§ 238.223 Fuel tanks.

(a) *External fuel tanks.* External locomotive fuel tanks shall comply with AAR Recommended Practice-506, Performance Requirements for Diesel Electric Locomotive Fuel Tanks (as adopted July 1, 1995), or an industry standard providing at least equivalent safety if approved by FRA's Associate Administrator for Safety under § 238.21.

(b) *Integral fuel tanks.* Integral fuel tanks shall be positioned in a manner to reduce the likelihood of accidental penetration from roadway debris or collision.

(1) The vent system spill protection systems of integral fuel tanks shall be designed to prevent them from becoming a path of fuel loss for any tank orientation due to a locomotive overturning.

(2) The bulkheads and skin of integral fuel tanks shall at a minimum be made of steel plate 3/8 of an inch thick with a 25,000-lb yield strength, or made of material with an equivalent strength. Skid plates are not required. Higher yield strength material may be used to decrease the thickness of the material as long as an equivalent strength is maintained.

§ 238.225 Electrical system.

All passenger equipment shall comply with the following:

(a) *Conductors.* Conductor sizes shall be selected on the basis of current-carrying capacity, mechanical strength, temperature, flexibility requirements, and maximum allowable voltage drop. Current-carrying capacity shall be derated for grouping and for operating temperature.

(b) *Main battery system.* (1) The main battery compartment shall be isolated from the cab and passenger seating areas by a non-combustible barrier.

(2) Battery chargers shall be designed to protect against overcharging.

(3) If batteries are of the type to potentially vent explosive gases, the battery compartment shall be adequately ventilated to prevent the accumulation of explosive concentrations of these gases.

(c) *Power dissipation resistors.* (1) Power dissipating resistors shall be adequately ventilated to prevent overheating under worst-case operating conditions as determined by each railroad.

(2) Power dissipation grids shall be designed and installed with sufficient isolation to prevent combustion.

(3) Resistor elements shall be electrically insulated from resistor frames, and the frames shall be electrically insulated from the supports that hold them.

(d) *Electromagnetic interference and compatibility.* (1) The operating railroad shall ensure electromagnetic compatibility of the safety-critical equipment systems with their environment. Electromagnetic compatibility may be achieved through equipment design or changes to the operating environment.

(2) The electronic equipment shall not produce electrical noise that affects the safe performance of train line control and communications or wayside signaling systems.

(3) To contain electromagnetic interference emissions, suppression of transients shall be at the source wherever possible.

(4) All electronic equipment shall be self-protected from damage or improper operation, or both, due to high voltage transients and long-term over-voltage or under-voltage conditions. This includes protection from both power frequency and harmonic effects as well as protection from radio frequency signals into the microwave frequency range.

§ 238.227 Suspension system.

On or after January 1, 1998—

(a) All passenger equipment shall exhibit freedom from hunting oscillations at all speeds.

(b) All passenger equipment intended for service above 110 mph shall demonstrate stable operation during pre-revenue service qualification tests at all speeds up to 5 mph in excess of the maximum intended operating speed under worst-case conditions—including component wear—as determined by the operating railroad.

§ 238.229 Safety appliances.

All passenger equipment continues to be subject to the safety appliance requirements contained in Federal statute at 49 U.S.C. chapter 203 and in FRA regulations at part 231 and § 232.2 of this chapter.

§ 238.231 Brake system.

Except as otherwise provided in this section, on or after January 1, 1998, the following requirements apply to all passenger equipment and passenger trains.

(a) A passenger train's primary brake system shall be capable of stopping the train with a service application from its maximum authorized operating speed within the signal spacing existing on the track over which the train is operating.

(b) The brake system design of passenger equipment ordered on or after January 1, 1999, or placed in service for the first time on or after January 1, 2001, shall not require an inspector to place himself or herself on, under, or between components of the equipment to observe brake actuation or release.

(c) Passenger equipment shall be provided with an emergency application feature that produces an irretrievable stop, using a brake rate consistent with prevailing adhesion, passenger safety, and brake system thermal capacity. An emergency application shall be available at any time, and shall be initiated by an unintentional parting of the train.

(d) A passenger train brake system shall respond as intended to signals from train brake control line or lines. Control lines shall be designed so that failure or breakage of a control line will cause the brakes to apply or will result in a default to control lines that meet this requirement.

(e) Introduction of alcohol or other chemicals into the air brake system of passenger equipment is prohibited.

(f) The operating railroad shall require that the design and operation of the brake system results in wheels that are free of condemnable cracks.

(g) Disc brakes shall be designed and operated to produce a surface temperature no greater than the safe operating temperature recommended by the disc manufacturer and verified by testing or previous service.

(h) Except for a locomotive that is ordered before January 1, 1999, and placed in service for the first time before January 1, 2001, and except for a private car, all passenger equipment shall be equipped with a hand or parking brake that shall be:

(1) Capable of application or activation by hand;

(2) Capable of release by hand; and

(3) Capable of holding the loaded unit on the maximum grade anticipated by the operating railroad.

(i) Passenger cars shall be equipped with a means to apply the emergency brake that is accessible to passengers and located in the vestibule or passenger compartment. The emergency brake shall be clearly identified and marked.

(j) Locomotives equipped with blended brakes shall be designed so that:

(1) The blending of friction and dynamic brake to obtain the correct retarding force is automatic;

(2) Loss of power or failure of the dynamic brake does not result in exceeding the allowable stop distance;

(3) The friction brake alone is adequate to safely stop the train under all operating conditions; and

(4) Operation of the friction brake alone does not result in thermal damage to wheels or disc rotor surface temperatures exceeding the manufacturer's recommendation.

(k) For new designs of braking systems, the design process shall include computer modeling or dynamometer simulation of train braking that shows compliance with paragraphs (f) and (g) of this section over the range of equipment operating speeds. Changes in operating parameters shall require a new simulation prior to implementing the changes.

(l) Locomotives ordered on or after January 1, 1999, or placed in service for the first time on or after January 1, 2001, shall be equipped with effective air coolers or dryers that provide air to the main reservoir with a dew point at least 10 degrees F. below ambient temperature.

§ 238.233 Interior fittings and surfaces.

(a) Each seat in a passenger car shall be securely fastened to the car body so as to withstand an individually applied acceleration of 4g acting in the vertical and in the lateral direction on the deadweight of the seat or seats, if a tandem unit. A seat attachment shall have an ultimate strength capable of resisting the longitudinal inertial force of 8g acting on the mass of the seat plus the impact force of the mass of a 95th-percentile male occupant(s) being decelerated from a relative speed of 25 mph and striking the seat from behind.

(b) Overhead storage racks in a passenger car shall provide longitudinal and lateral restraint for stowed articles. Overhead storage racks shall be attached to the car body with sufficient strength to resist loads due to the following individually applied accelerations acting on the mass of the luggage stowed as determined by the railroad:

(1) Longitudinal: 8g;

(2) Vertical: 4g; and

(3) Lateral: 4g.

(c) Other interior fittings within a passenger car shall be attached to the car body with sufficient strength to withstand the following individually applied accelerations acting on the mass of the fitting:

(1) Longitudinal: 8g;

(2) Vertical: 4g; and

(3) Lateral: 4g.

(d) To the extent possible, all interior fittings in a passenger car, except seats, shall be recessed or flush-mounted.

(e) Sharp edges and corners in a locomotive cab and a passenger car shall be either avoided or padded to mitigate the consequences of an impact with such surfaces.

(f) Each floor-mounted seat provided exclusively for a crewmember assigned to occupy the cab of a locomotive shall be secured to the car body with an attachment having an ultimate strength capable of withstanding the loads due to the following individually applied accelerations acting on the mass of the seat and the crewmember (ranging from a 5th-percentile female to a 95th-percentile male) occupying it:

(1) Longitudinal: 8g;

(2) Lateral: 4g; and

(3) Vertical: 4g.

§ 238.235 Emergency window exits.

Except as provided in paragraph (b), the following requirements apply to all passenger cars on or after January 1, 1998—

(a) Except as provided in paragraphs (d) and (e) of this section, each passenger car shall have a minimum of four emergency window exits, either in a staggered configuration or with one located at each end of each side of the car.

(b) Each emergency window exit in a passenger car placed in service for the first time on or after January 1, 1998, shall have a minimum unobstructed opening with dimensions of 24 inches horizontally by 18 inches vertically.

(c) Each emergency window exit shall be easily operable by a 5th-percentile female without requiring the use of a tool or other implement.

(d) If the car is bi-level, each main level shall have a minimum of four emergency window exits, either in a staggered configuration or with one located at each end of each side of the car.

(e) Each passenger car of special design, such as a sleeping car, shall have at least one emergency window exit in each compartment.

(f) *Marking and instructions.* [Reserved]

§ 238.237 Doors.

(a) Within 2 years of the effective date of the final rule, each powered, exterior side door in a vestibule that is partitioned from the passenger compartment of a passenger car shall be equipped with a manual override that is:

(1) Capable of opening the door without power from inside the car;

(2) Located adjacent to the door which it controls; and

(3) Designed and maintained so that a person may access the override device from inside the car without requiring the use of a tool or other implement.

(b) Each passenger car ordered on or after January 1, 1999, or placed in service for the first time on or after January 1, 2001, shall have a minimum of four side doors, or the functional equivalent of four side doors, each permitting at least one 95th-percentile male to pass through at a single time.[1] Each powered, exterior side door shall be equipped with a manual override that is:

(1) Capable of opening the door without power from both inside and outside the car;

(2) Located adjacent to the door which it controls; and

(3) Designed and maintained so that a person may access the override device from both inside and outside the car without requiring the use of a tool or other implement.

(c) A railroad may protect a manual override device used to open a powered, exterior door with a cover or a screen capable of removal by a 5th-percentile female without requiring the use of a tool or other implement. If the method of removing the protective cover or screen entails breaking or shattering it, the cover or screen shall be scored, perforated, or otherwise weakened so that a 5th-percentile female can penetrate the cover or screen with a single blow of her fist without injury to her hand.

[1] The Americans with Disabilities Act (ADA) Accessibility Specifications for Transportation Vehicles also contain requirements for doorway clearance (See Title 49 Code of Federal Regulations Part 38).

(d) *Marking and instructions.* [Reserved]

§ 238.239 Automated monitoring.

(a) Except as further specified in this paragraph, on or after January 1, 1998, a working alerter or deadman control shall be provided in the controlling locomotive of each passenger train operating in other than cab signal, automatic train control, or automatic train stop territory. If the controlling locomotive is ordered on or after January 1, 1999, or placed into service for the first time on or after January 1, 2001, a working alerter shall be provided.

(b) Alerter or deadman control timing shall be set by the operating railroad taking into consideration maximum train speed and capabilities of the signal system. The railroad shall document the basis for setting alerter or deadman control timing and make this documentation available to FRA upon request.

(c) If the train operator does not respond to the alerter or maintain proper contact with the deadman control, it shall initiate a penalty brake application.

(d) The following procedures apply if the alerter or deadman control fails en route:

(1) A second person qualified on the signal system and brake application procedures shall be stationed in the cab; or

(2) The engineer shall be in constant communication with a second crewmember until the train reaches the next terminal.

Subpart D—Inspection, Testing, and Maintenance Requirements for Tier I Passenger Equipment

§ 238.301 Scope.

This subpart contains requirements pertaining to the inspection, testing, and maintenance of passenger equipment operating at speeds not exceeding 125 miles per hour. The requirements in this subpart address the inspection, testing, and maintenance of the brake system as well as other mechanical and electrical components covered by this part.

§ 238.303 Exterior calendar day mechanical inspection of passenger cars and unpowered vehicles used in passenger trains.

(a) Except as provided in paragraph (d) of this section, each passenger car and each unpowered vehicle used in a passenger train shall receive an exterior mechanical safety inspection at least once each calendar day that the equipment is placed in service. (Note: The exterior inspection of a passenger car classified as a locomotive under part 229 of this chapter shall be in accordance with this part as well as part 229 of this chapter.)

(b) The exterior calendar day mechanical safety inspection shall be performed by a qualified mechanical inspector as defined in § 238.5.

(c) As part of the exterior inspection, the railroad shall verify conformity with the following conditions, and nonconformity with any such condition renders the passenger car or unpowered vehicle used in a passenger train defective whenever discovered in service:

(1) Products of combustion are released entirely outside the cab and other compartments.

(2) All battery containers are vented and all batteries are kept from gassing excessively.

(3) Each coupler is in the following condition:

(i) The distance between the guard arm and the knuckle nose is not more than 5⅛ inches on standard type couplers (MCB contour 1904) or more than 5$\frac{5}{16}$ inches on D&E couplers;

(ii) Sidewall or pin bearing bosses and the pulling face of the knuckles are not broken or cracked;

(iii) The coupler assembly is equipped with anti-creep protection;

(iv) The free slack in the coupler or drawbar not absorbed by friction devices or draft gears is not more than ½ inch;

(v) The coupler carrier is not broken or cracked;

(vi) The yoke is not broken or cracked; and

(vii) The draft gear is not broken.

(4) A device is provided under the lower end of all drawbar pins and articulated connection pins to prevent the pin from falling out of place in case of breakage.

(5) The suspension system, including the spring rigging, is in the following condition:

(i) Protective construction or safety hangers are provided to prevent spring planks, spring seats, or bolsters from dropping to the track structure in event of a hanger or spring failure;

(ii) The top (long) leaf or any of the other three leaves of the elliptical spring is not broken, except when a spring is part of a nest of three or more springs and none of the other springs in the nest has its top leaf or any of the other three leaves broken;

(iii) The outer coil spring or saddle is not broken;

(iv) The equalizers, hangers, bolts, gibs, or pins are not cracked or broken;

(v) The coil spring is not fully compressed when the car is at rest;

(vi) The shock absorber is not broken or leaking clearly formed droplets of oil or other fluid; and

(vii) Air bags or other pneumatic suspension system components inflate or deflate, as applicable, correctly and otherwise operate as intended.

(6) All trucks are in the following condition:

(i) Equipped with a device or securing arrangement to prevent the truck and car body from separating in case of derailment;

(ii) All tie bars are not loose;

(iii) All center castings, motor suspension lugs, equalizers, hangers, gibs, or pins are not cracked or broken; and

(iv) The truck frame is not broken and is not cracked in a stress area that may affect its structural integrity.

(7) All side bearings are in the following condition:

(i) All friction side bearings with springs designed to carry weight do not have more than 25 percent of the springs in any one nest broken;

(ii) All friction side bearings do not run in contact unless designed to carry weight; and

(iii) The maximum clearance of all side bearings does not exceed the manufacturer's recommendation.

(8) All wheels do not have any of the following conditions:

(i) A single flat spot that is 2½ inches or more in length, or two adjoining spots that are each two or more inches in length;

(ii) A gouge or chip in the flange that is more than 1½ inches in length and ½ inch in width;

(iii) A broken rim, if the tread, measured from the flange at a point ⅝ of an inch above the tread, is less than 3¾ inches in width.

(iv) A shelled-out spot 2½ inches or more in length, or two adjoining spots that are each two or more inches in length;

(v) A seam running lengthwise that is within 3¾ inches of the flange;

(vi) A flange worn to a ⅞ inch thickness or less, gauged at a point ⅜ of an inch above the tread;

(vii) A tread worn hollow 5/16 inch or more;

(viii) A flange height of 1½ inches or more measured from the tread to the top of the flange;

(ix) A rim less than 1 inch thick;

(x) A crack or break in the flange, tread, rim, plate, or hub;

(xi) A loose wheel; or

(xii) A weld.

(9) No part or appliance of a passenger coach, except the wheels, is less than 2½ inches above the top of the rail.

(10) All unguarded, noncurrent-carrying metal parts subject to becoming charged are grounded or thoroughly insulated.

(11) All jumpers and cable connections are in the following condition:

(i) All jumpers and cable connections between coaches, between locomotives, or between a locomotive and a coach are located and guarded in a manner that provides sufficient vertical clearance. Jumpers and cable connections may not hang with one end free;

(ii) The insulation is not broken or badly chafed;

(iii) No plug, receptacle, or terminal is broken; and

(iv) No strand of wire is broken or protruding.

(12) All doors and cover plates guarding high voltage equipment are marked ''Danger—High Voltage'' or with the word ''Danger'' and the normal voltage carried by the parts so protected.

(13) All buffer plates are in place.

(14) If so equipped, all diaphragms are in place and properly aligned.

(15) All secondary braking systems are working.

(d) A long-distance intercity passenger train that misses a scheduled exterior calendar day mechanical inspection due to a delay en route may continue in service to the location where the inspection was scheduled to be performed. At that point, an exterior calendar day mechanical inspection shall be performed prior to returning the equipment to service. This flexibility applies only to the exterior mechanical safety inspections required by this section, and does not relieve the railroad of the responsibility to perform a calendar day inspection on a unit classified as a ''locomotive'' under part 229 of this chapter as required by § 229.21 of this chapter.

(e) Cars requiring a single car test in accordance with § 238.311 that are being moved in service to a location where the single car test can be performed shall have the single car test completed prior to, or as a part of, the calendar day mechanical inspection.

§ 238.305 Interior calendar day mechanical inspection of passenger cars.

(a) Except as provided in paragraph (d) of this section, each passenger car shall receive an interior mechanical safety inspection at least once each calendar day that it is placed in service.

(b) The interior daily mechanical inspection shall be performed by a qualified person or a qualified mechanical inspector.

(c) As part of the daily interior mechanical inspection, the railroad shall verify conformity with the following conditions, and nonconformity with any such condition renders the car defective whenever discovered in service, except as provided in paragraph (c)(5) of this section:

(1) All fan openings, exposed gears and pinions, exposed moving parts of mechanisms, pipes carrying hot gases and high-voltage equipment, switches, circuit breakers, contactors, relays, grid resistors, and fuses are in non-hazardous locations or equipped with guards to prevent personal injury.

(2) The words ''Emergency Brake Valve'' are legibly stenciled or marked near each brake pipe valve or shown on an adjacent badge plate.

(3) All doors and cover plates guarding high voltage equipment are marked ''Danger—High Voltage'' or with the word ''Danger'' and the normal voltage carried by the parts so protected.

(4) All trap doors safely operate and securely latch in place in both the up and down position.

(5) All end doors and side doors operate safely and as intended. If all of the following conditions are satisfied, the car may remain in passenger service until the next interior calendar day mechanical inspection is due at which time the appropriate repairs shall be made:

(i) A qualified person or a qualified mechanical inspector determines that the repairs necessary to bring a door into compliance cannot be performed at the time the interior mechanical inspection is conducted;

(ii) A qualified person or a qualified mechanical inspector determines that it is safe to move the equipment in passenger service; and

(iii) A tag is prominently displayed on the door indicating that the door is defective.

(6) All safety-related signage is in place and legible.

(7) All vestibule steps are illuminated.

(8) All manual door releases are in place based on a visual inspection.

(d) A long-distance intercity passenger train that misses a scheduled calendar day interior mechanical inspection due to a delay en route may continue in service to the location where the inspection was scheduled to be performed. At that point, an interior calendar day mechanical inspection shall be performed prior to returning the equipment to service.

§ 238.307 Periodic mechanical inspection of passenger cars.

(a) Railroads shall conduct periodic inspections of passenger cars as required by this section and as warranted by data developed under §§ 238.103 and 238.109. A periodic

inspection conducted under part 229 of this chapter satisfies the requirement of this section with respect to the features inspected.

(b) The periodic inspection program shall specifically include the following interior features, which shall be inspected not less frequently than each 180 days. At a minimum, this inspection shall determine that:

(1) Floors of passageways and compartments are free from oil, water, waste, or any obstruction that creates a slipping, tripping, or fire hazard, and floors are properly treated to provide secure footing.

(2) Emergency lighting systems are operational.

(3) With regard to switches:

(i) All hand-operated switches carrying currents with a potential of more than 150 volts that may be operated while under load are covered and are operative from the outside of the cover;

(ii) A means is provided to display whether the switches are open or closed; and

(iii) Switches not designed to be operated safely while under load are legibly marked with the voltage carried and the words ''must not be operated under load''.

(4) Seats and seat attachments are not broken or loose.

(5) Luggage racks are not broken or loose.

(6) All beds and bunks are not broken or loose, and all restraints or safety latches and straps are in place and function as intended.

(7) A representative sample of emergency window exits on its cars properly operate, in accordance with the requirements of § 239.107 of this chapter.

(8) All manual door releases operate as intended.

(c) Nonconformity with any of the conditions set forth in this section renders the car defective whenever discovered in service.

§ 238.309 Periodic brake equipment maintenance.

(a) *General.* (1) This section contains the minimum intervals at which the brake equipment on various types of passenger equipment shall be periodically cleaned, repaired, and tested. This maintenance procedure requires that all of the equipment's brake system pneumatic components that contain moving parts and are sealed against air leaks be removed from the equipment, disassembled, cleaned, and lubricated and that the parts that can deteriorate with age be replaced.

(2) A railroad may petition FRA's Associate Administrator for Safety to approve alternative maintenance procedures providing equivalent safety, in lieu of the requirements of this section. The petition shall be filed as provided in § 238.21.

(b) *MU locomotives.* The brake equipment of each MU locomotive shall be cleaned, repaired, and tested at intervals in accordance with the following schedule:

(1) Every 736 days if the MU locomotive is part of a fleet that is not 100 percent equipped with air dryers.

(2) Every 1,104 days if the MU locomotive is part of a fleet that is 100 percent equipped with air dryers and is equipped with PS–68, 26–C, 26–L, PS–90, CS–1, RT–5A, GRB–1, CS–2, or 26–R brake systems. (This listing of brake system types is intended to subsume all brake systems using 26 type, ABD, or ABDW control valves and PS68, PS–90, 26B–1, 26C, 26CE, 26–Bl, 30CDW, or 30ECDW engineer's brake valves.)

(3) Every 736 days for all other MU locomotives.

(c) *Conventional locomotives.* The brake equipment of each conventional locomotive shall be cleaned, repaired, and tested at intervals in accordance with following schedule:

(1) Every 1,104 days for a locomotive equipped with a 26–L or equivalent brake system.

(2) Every 736 days for a locomotive equipped with other than a 26–L or equivalent brake system.

(d) *Passenger coaches and other unpowered vehicles.* The brake equipment on each passenger coach and each other unpowered vehicle used in a passenger train shall be cleaned, repaired, and tested at intervals in accordance with following schedule:

(1) Every 1,476 days for a coach or vehicle equipped with a 26–C or equivalent brake system.

(2) Every 1,104 days for a coach or vehicle equipped with other than a 26–C or equivalent brake system.

(e) *Cab cars.* The brake equipment of each cab car shall be cleaned, repaired, and tested in accordance with the following schedule:

(1) Every 1,476 days for that portion of the cab car brake system using brake valves that are identical to the passenger coach 26–C brake system;

(2) Every 1,104 days for that portion of the cab car brake system using brake valves that are identical to the locomotive 26–L brake system; and

(3) Every 732 days for all other types of cab car brake valves.

(f) *Records of periodic maintenance.* The date and place of the cleaning, repairing, and testing required by this section shall be recorded on Form FRA 6180–49A or a similar form developed by the railroad containing the same information, and the person performing the work and that person's supervisor shall sign the form. Alternatively, the railroad may stencil the vehicle with the date and place of the cleaning, repairing, and testing and maintain an electronic record of the person performing the work and that person's supervisor. A record of the parts of the air brake system that are cleaned, repaired, and tested shall be kept in the railroad's files, the cab of the locomotive, or a designated location in the passenger car until the next such periodic test is performed.

§ 238.311 Single car test.

(a) Single car tests of all passenger cars and all unpowered vehicles used in passenger trains shall be performed in accordance with the AAR Standard S–044 contained in AAR ''Instruction Pamphlet 5039–4, Supplement 3'' (April 1991), or an alternative procedure approved by FRA's Associate Administrator for Safety under § 238.21.

(b) A railroad shall perform a single car test of the brake system of a car or vehicle described in paragraph (a) of this section when the car or vehicle is found with one or more of the following wheel defects:

(1) Built-up tread;

(2) Slid flat wheel;

(3) Thermal cracks;

(4) Overheated wheel; or

(5) Shelling.

(c) Except as provided in paragraph (e) of this section, a railroad shall perform a single car test of the brake system of a car or vehicle described in paragraph (a) of this section when:

(1) The car or vehicle is placed in service after having been out of service for 30 days or more;

(2) The trainline is repaired; or

(3) One or more of the following conventional air brake equipment items is removed, repaired, or replaced:

(i) Brake reservoir;

(ii) Brake cylinder;

(iii) Piston assembly;

(iv) Vent valve;

(v) Quick service valve;

(vi) Brake cylinder release valve;

(vii) Modulating valve or slack adjuster;

(viii) Relay valve;

(ix) Angle cock or cutout cock;

(x) Service portion;

(xi) Emergency portion; or

(xii) Pipe bracket.

(d) Each single car test required by this section shall be performed by a qualified mechanical inspector.

(e) If the single car test cannot be made at the point where repairs are made, the car may be moved in

passenger service to the next forward location where the test can be made. The single car test shall be completed prior to, or as a part of, the car's next calendar day mechanical inspection.

§ 238.313 Class I brake test.

(a) Each commuter and short-distance intercity passenger train shall receive a Class I brake test once each calendar day that the train is placed or remains in passenger service.

(b) Except as provided in paragraph (h) of this section, each long-distance intercity passenger train shall receive a Class I brake test:

(1) Prior to the train's departure from an originating terminal; and

(2) Every 1,500 miles or once each additional calendar day, whichever occurs first, that the train remains in continuous passenger service.

(c) Each Class I brake test shall be performed by a qualified mechanical inspector.

(d) Each Class I brake test may be performed either separately or in conjunction with the calendar day mechanical inspection required under § 238.303.

(e) Except as provided in § 238.15(b), a railroad shall not use or haul a passenger train in passenger service from a location where a Class I brake test has been performed, or was required by this part to have been performed, with less than 100 percent operative brakes.

(f) A Class I brake test shall determine and ensure that:

(1) The friction brakes apply and remain applied on each car in the train until a release of the brakes has been initiated on each car in response to train line electric, pneumatic, or other signals. This test shall include a verification that each side of each car's brake system responds properly to application and release signals;

(2) The brake shoes or pads are firmly seated against the wheel or disk with the brakes applied;

(3) Piston travel is within prescribed limits, either by direct observation, observation of an actuator, or by observation of the clearance between the brake shoe and the wheel with the brakes released;

(4) The communicating signal system is tested and known to be operating as intended;

(5) Each brake shoe is securely fastened and aligned in relation to the wheel;

(6) The engineer's brake valve or controller will cause the proper train line commands for each position or brake level setting;

(7) Brake pipe leakage does not exceed 5 pounds-per-square-inch per minute if leakage will affect service performance;

(8) The emergency brake application and deadman pedal or other emergency control devices function as intended;

(9) Each brake shoe or pad is not below the minimum thickness established by the railroad. This thickness shall not be less than the minimum thickness necessary to safely travel the maximum distance allowed between Class I brake system tests;

(10) Each angle cock and cutout cock is properly positioned;

(11) Brake rigging does not bind or foul so as to impede the force delivered to a brake shoe, impede the release of a brake shoe, or otherwise adversely affect the operation of brake system;

(12) If the train is equipped with electropneumatic brakes, an electropneumatic application of the brakes is made and that the train is walked to determine that the brakes on each car in the train properly apply;

(13) Each brake disc is free of cracks;

(14) If the equipment is provided with a brake indicator, the brake indicator operates as intended; and

(15) The communication of brake pipe pressure changes at the rear of the train is verified.

(g) A qualified mechanical inspector that performs a Class I brake test on a train shall place in the cab of the controlling locomotive of the train a written statement, which shall be retained in the cab until the next Class I brake test is performed and which shall contain the following information:

(1) Date and time the Class I brake test was performed;

(2) Location where the test was performed; and

(3) The number of the controlling locomotive of the train.

(h) A long-distance, intercity passenger train that misses a scheduled calendar day Class I brake test due to a delay en route may proceed to the point where the Class I brake test was scheduled to be performed. A Class I brake test shall be completed at that point prior to placing the train back in service.

§ 238.315 Class IA brake test.

(a) Except as provided in paragraph (b)(1) of this section, either a Class I or Class IA brake test shall be performed:

(1) Prior to the first morning departure of each commuter or short-distance intercity passenger train; and

(2) Prior to placing a train in service that has been off a source of compressed air for more than four hours.

(b) A commuter or short-distance intercity passenger train that provides continuing late night service that began prior to midnight may complete its daily operating cycle after midnight without performing another Class I or Class IA brake test. A Class I or Class IA brake test shall be performed on such a train before it starts a new daily operating cycle.

(c) A Class I or Class IA test may be performed at a shop or yard site and need not be repeated at the first passenger terminal if the train remains on a source of compressed air and in the custody of the train crew.

(d) The Class IA test shall be performed by either a qualified person or a qualified mechanical inspector as defined in § 238.5.

(e) Except as provided in § 238.15(b), a railroad shall not use or haul a passenger train in passenger service from a location where a Class IA brake test has been performed, or was required by this part to have been performed, with less than 100 percent operative brakes.

(f) In performing a Class IA brake test, it shall be determined that:

(1) Brake pipe leakage does not exceed 5 pounds-per-square-inch per minute if brake pipe leakage will affect service performance;

(2) Each brake sets and releases by inspecting in the manner described in paragraph (g) of this section;

(3) The emergency brake application and the deadman pedal or other emergency control devices function as intended;

(4) Each angle cock and cutout cock is properly set;

(5) To the extent determinable, piston travel is within the nominal range for the type of brake equipment; and

(6) Brake pipe pressure changes at the rear of the train are properly communicated to the controlling locomotive.

(g) In determining whether each brake sets and releases—

(1) The inspection of the set and release of the brakes shall be completed by walking the train to directly observe the set and release of each brake, if the railroad determines that such a procedure is safe.

(2) If the railroad determines that operating conditions pose a safety hazard to an inspector walking the brakes, brake indicators may be used to verify the set and release on cars so equipped. However, the observation of the brake indicators shall not be made from the cab of the locomotive. The inspector shall position himself or herself to be able to accurately observe the indicators.

§ 238.317 Class II brake test.

(a) A Class II brake test shall be performed on a passenger train when any of the following events occur:

(1) Whenever the control stand used to control the train is changed;

(2) When previously tested units are added to or removed from the train; and

(3) When an operator first takes charge of the train, except for face-to-face relief.

(b) A Class II brake test shall be performed by a qualified person or a qualified mechanical inspector.

(c) A railroad shall not use or haul a passenger train in passenger service from a terminal or yard where a Class II brake test has been performed, or was required by this part to have been performed, with any of the brakes known to be cutout, inoperative, or defective.

(d) In performing a Class II brake test on a train, a railroad shall determine that:

(1) The brakes on the rear unit of the train apply and release in response to a signal from the engineer's brake valve or controller of the leading or controlling unit;

(2) The emergency brake application and deadman pedal or other emergency control devices function as intended; and

(3) Brake pipe pressure changes are properly communicated at the rear of the train.

§ 238.319 Running brake test.

(a) As soon as conditions safely permit, a running brake test shall be performed on each passenger train after the train has received, or was required under this part to have received, either a Class I, Class IA, or Class II brake test.

(b) The running brake test shall be conducted in accordance with the railroad's established operating rules, and shall be made by applying brakes in a manner that allows the engineer to ascertain whether the brakes are operating properly.

(c) If the engineer determines that the brakes are not operating properly, the engineer shall stop the train and follow the procedures provided in § 238.15.

Subpart E—Specific Requirements for Tier II Passenger Equipment

§ 238.401 Scope.

This subpart contains specific requirements for railroad passenger equipment operating at speeds exceeding 125 mph but not exceeding 150 mph. As stated in § 238.433(b), all such passenger equipment remains subject to the requirements concerning couplers and uncoupling devices contained in Federal statute at 49 U.S.C. chapter 203 and in FRA regulations at part 231 and § 232.2 of this chapter. The requirements of this subpart are effective on the effective date of the final rule.

§ 238.403 Crash energy management requirements.

(a) Each power car and trailer car shall be designed with a crash energy management system to dissipate kinetic energy during a collision. The rash energy management system shall provide a controlled deformation and collapse of designated sections within the unoccupied volumes to absorb collision energy and to reduce the decelerations on passengers and crewmembers resulting from dynamic forces transmitted to occupied volumes.

(b) The design of each unit shall consist of an occupied volume located between two normally unoccupied volumes. Where practical, sections within the unoccupied volumes shall be designed to be structurally weaker than the occupied volume. During a collision, the designated sections within the unoccupied volumes shall start to deform and eventually collapse in a controlled fashion to dissipate energy before any structural damage occurs to the occupied volume.

(c) At a minimum, the train shall be designed to meet the following requirements:

(1) Thirteen megajoules (MJ) shall be absorbed at each end of the train through the controlled crushing of unoccupied or occasionally occupied spaces, and of this amount a minimum of 5 MJ shall be absorbed outboard of the operator's cab in each power car;

(2) A minimum of an additional 3 MJ shall be absorbed by the power car structure between the operator's cab and the first trailer car; and

(3) The end of the first trailer car adjacent to each power car shall absorb a minimum of 5 MJ through controlled crushing.

(d) For a 30-mph collision of a train on tangent, level track with an identical stationary train:

(1) The deceleration of the occupied compartments of each trailer car shall not exceed 10g; and

(2) When seated anywhere in the train, the velocity at which a 50th-percentile male contacts the seat back ahead of him shall not exceed 25 mph.

(e) Compliance with paragraphs (a) through (d) of this section shall be demonstrated by analysis using a dynamic collision computer model. For the purpose of demonstrating compliance, the following assumptions shall be made:

(1) The train remains upright, in-line, and with all wheels on the track throughout the collision; and

(2) Resistance to structural crushing following the force-versus-distance function determined during the structural analysis required under § 238.103 as part of the design of the train.

(f) Passenger searing shall not be permitted in the leading unit of a Tier II train.

§ 238.405 Longitudinal static compressive strength.

(a) To form an effective crash refuge for crewmembers occupying the cab of a power car, the longitudinal ultimate compressive strength of the underframe of the cab of a power car shall be a minimum of 2,100,000 pounds unless equivalent protection to crewmembers is provided under an alternate design approach, validated through analysis and testing, approved by the FRA Associate Administrator for Safety under the provisions of § 238.21.

(b) The longitudinal compressive strength of the underframe of the occupied volume of each trailer car shall be a minimum of 800,000 pounds without deformation. To demonstrate compliance with this requirement, the 800,000-pound load shall be applied to the underframe of the occupied volume as it would be transmitted to the underframe by the full structure of the vehicle.

(c) Unoccupied or lightly occupied volumes of a power car or a trailer car designed to crush as part of the crash energy management design are not subject to the requirements of this section.

§ 238.407 Anti-climbing mechanism.

(a) Each power car shall have an anti-climbing mechanism at its forward end capable of resisting an upward or downward static vertical force of 200,000 pounds. A power car constructed with a crash energy management design is permitted to crush in a controlled manner before the anti-climbing mechanism fully engages.

(b) Interior train coupling points between units, including between units of articulated cars or other permanently joined units of cars, shall have an anti-climbing mechanism capable of resisting an upward or downward vertical force of 100,000 pounds.

(c) The forward coupler of a power car shall be attached to the car body to resist a vertical downward force of 100,000 pounds for any horizontal position of the coupler without yielding.

§ 238.409 Forward end structures of power car cabs.

This section contains the design requirements for the forward end structure of the cab of a power car. (A conceptual implementation of this end structure is provided in Figure 1.)

(a) *Center collision post.* The forward end structure shall have a full-height center collision post, or its structural equivalent, capable of withstanding the following:

(1) A shear load of 500,000 pounds at its joint with the underframe without exceeding the ultimate strength of the joint;

(2) A shear load of 150,000 pounds at its joint with the roof without exceeding the ultimate strength of the joint; and

(3) A horizontal, longitudinal force of 300,000 pounds applied at a point on level with the bottom of the windshield without exceeding the yield or the critical buckling stress.

(b) *Side collision posts.* The forward end structure shall have two side collision posts, or their structural equivalent, located at approximately the one-third points laterally, each capable of withstanding the following:

(1) A shear load of 500,000 pounds at its joint with the underframe without exceeding the ultimate strength of the joint; and

(2) A horizontal, longitudinal force of 300,000 pounds, applied at a point on level with the bottom of the windshield, without exceeding the yield or the critical buckling stress.

(c) *Corner posts.* The forward end structure shall have two full-height corner posts, or their structural equivalent, each capable of withstanding the following:

(1) A horizontal, longitudinal or lateral shear load of 300,000 pounds at its joint with the underframe, without exceeding the ultimate strength of the joint;

(2) A horizontal, lateral force of 100,000 pounds applied at a point 30 inches up from the underframe attachment, without exceeding the yield or the critical buckling stress; and

(3) A horizontal, longitudinal or lateral shear load of 150,000 pounds at its joint with the roof, without exceeding the ultimate strength of the joint.

(d) *Skin.* The skin covering the forward-facing end of each power car shall be:

(1) Equivalent to a ½-inch steel plate with a 25,000 pounds-per-square-inch yield strength—material of a higher yield strength may be used to decrease the required thickness of the material provided an equivalent level of strength is maintained.

(2) Securely attached to the end structure.

(3) Sealed to prevent the entry of fluids into the occupied cab area of the equipment.

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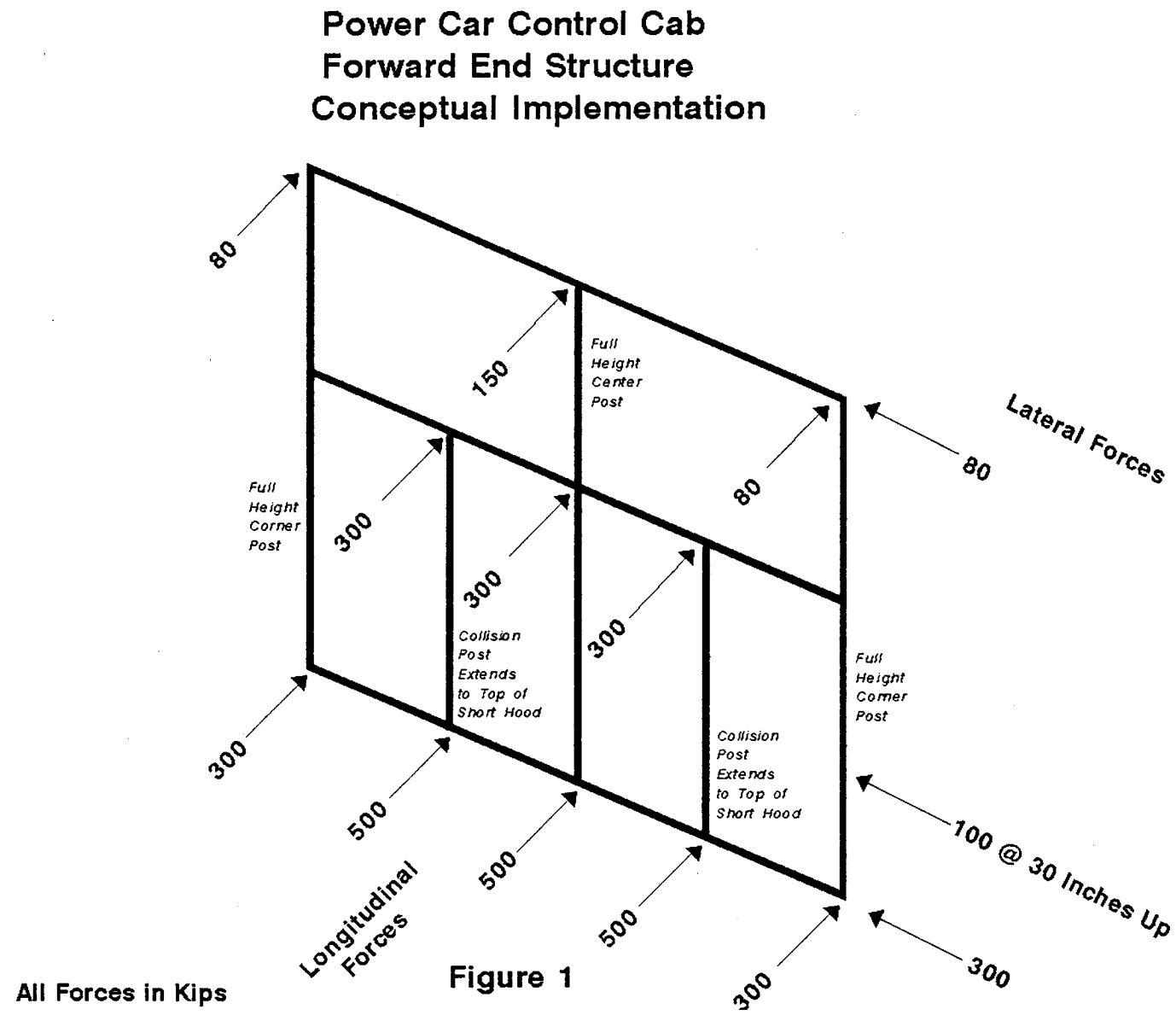

Figure 1

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§ 238.411 Rear end structures of power car cabs.

This section contains design requirements for the rear end structure of the cab of a power car. (A conceptual implementation of this end structure is provided in Figure 2.)

(a) *Corner posts.* The rear end structure shall have two full-height corner posts, or their structural equivalent, each capable of withstanding the following:

(1) A horizontal, longitudinal or lateral shear load of 300,000 pounds at its joint with the underframe without exceeding the ultimate strength of the joint; and

(2) A horizontal, longitudinal or lateral shear load of 80,000 pounds at its joint with the roof without exceeding the ultimate strength of the joint.

Collision posts. The rear end structure shall have two full-height collision posts, or their structural equivalent, each capable of withstanding the following:

(1) A horizontal, longitudinal shear load of 750,000 pounds at its joint with the underframe without exceeding the ultimate strength of the joint; and

(2) A horizontal, longitudinal shear lead of 75,000 pounds at its joint with the roof without exceeding the ultimate strength of the joint.

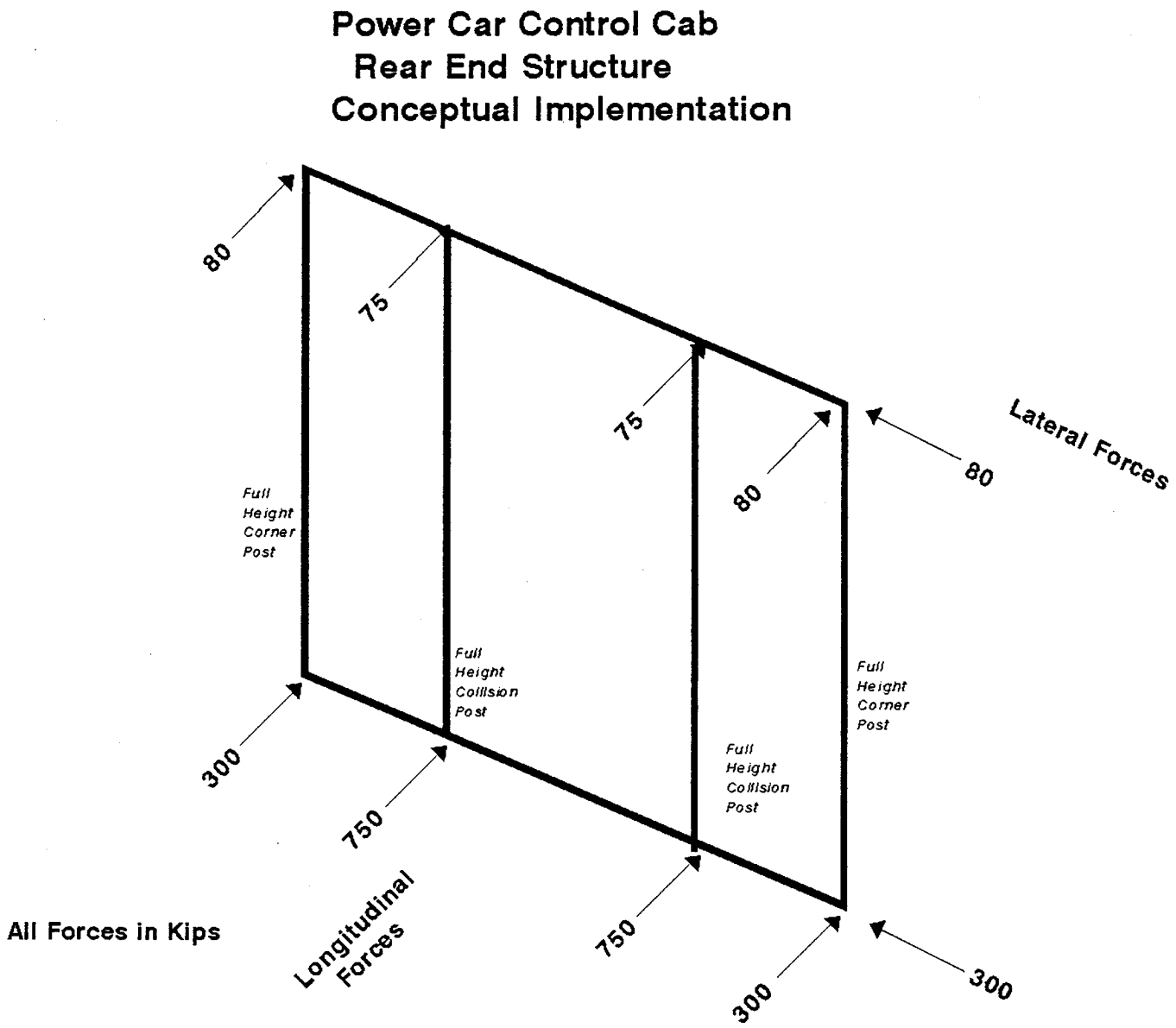

Figure 2

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§ 238.413 End structures of trailer cars.

(a) Except as provided in paragraphs (b) and (c) of this section, the end structure of a trailer car shall be designed to include the following elements, or their structural equivalent. (A conceptual implementation of this end structure is provided in Figure 3.)

(1) *Corner posts.* Two full-height corner posts, each capable of withstanding the following:

(i) A horizontal, longitudinal shear load of 150,000 pounds at its joint with the underframe without exceeding the ultimate strength of the joint;

(ii) A horizontal, longitudinal or lateral force of 30,000 pounds applied at a point 30 inches up from the underframe attachment without exceeding the yield or the critical buckling stress; and

(iii) A horizontal, longitudinal or lateral shear load of 20,000 pounds at its joint with the roof without exceeding the ultimate strength of the joint.

(2) *Collision posts.* Two full-height collision posts each capable of withstanding the following:

(i) A horizontal, longitudinal shear load of 300,000 pounds at its joint with the underframe without exceeding the ultimate strength of the joint; and

(ii) A horizontal, longitudinal shear load of 60,000 pounds at its joint with the roof without exceeding the ultimate strength of the joint.

(b) If the trailer car consists of multiple articulated units not designed for uncoupling other than in a maintenance shop, the end structure requirements of paragraph (a) of this section apply only to the ends of the entire car, not to the ends of each unit comprising the multi-unit car.

(c) If the trailer car is designed with a vestibule, the vestibule inboard end structure shall be designed with two full-height corner posts, or their structural equivalent, each capable of withstanding the following (A conceptual implementation of this end structure is provided in Figure 4.):

(1) A horizontal, longitudinal shear load of 200,000 pounds at its joint with the underframe without exceeding the ultimate strength of the joint;

(2) A horizontal, lateral force of 30,000 pounds applied at a point 30 inches up from the underframe attachment without exceeding the yield or the critical buckling stress;

(3) A horizontal, longitudinal force of 50,000 pounds applied at a point 30 inches up from the underframe attachment without exceeding the yield or the critical buckling stress; and

(4) A horizontal, longitudinal or lateral shear load of 20,000 pounds at its joint with the roof without exceeding the ultimate strength of the joint.

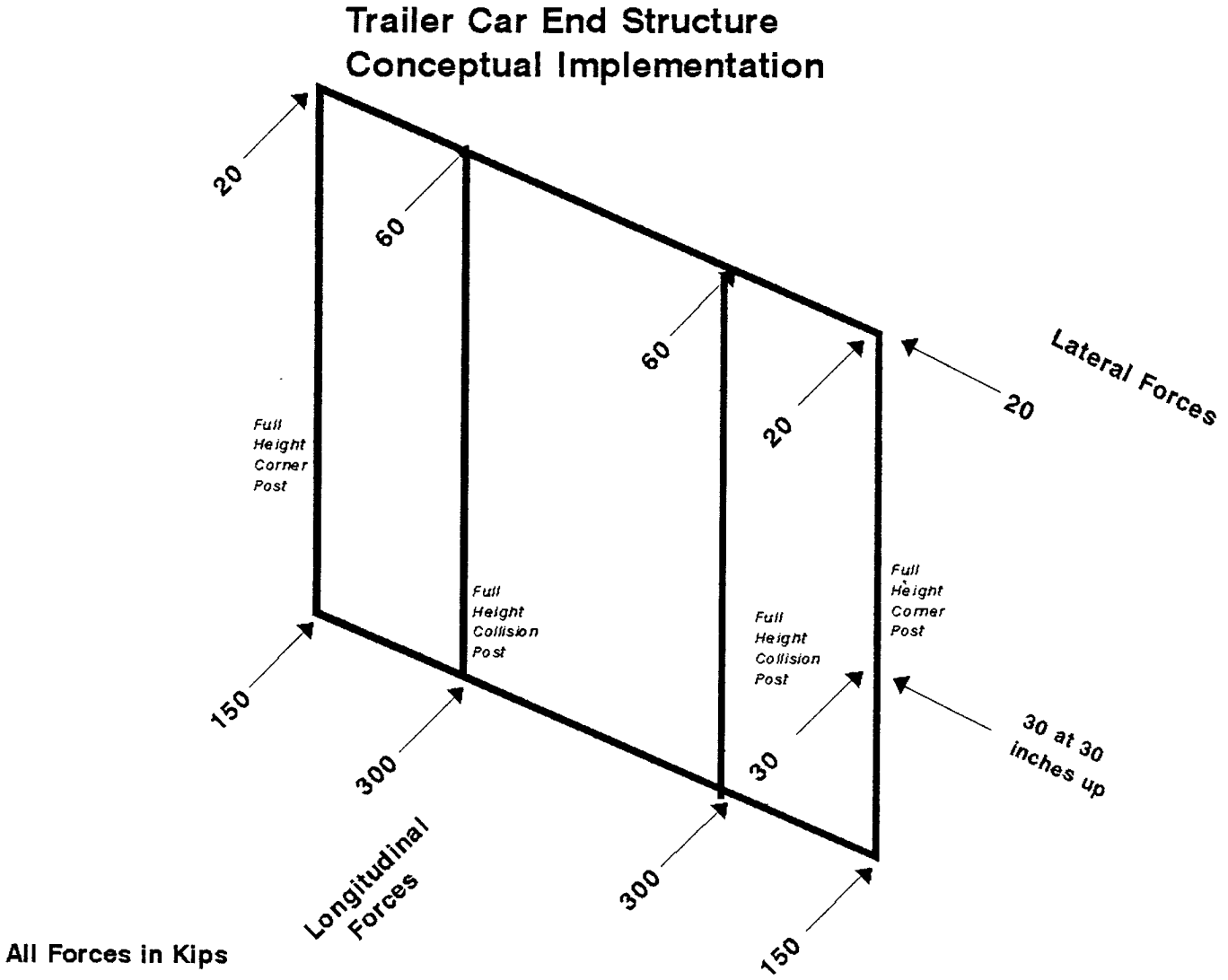

Figure 3

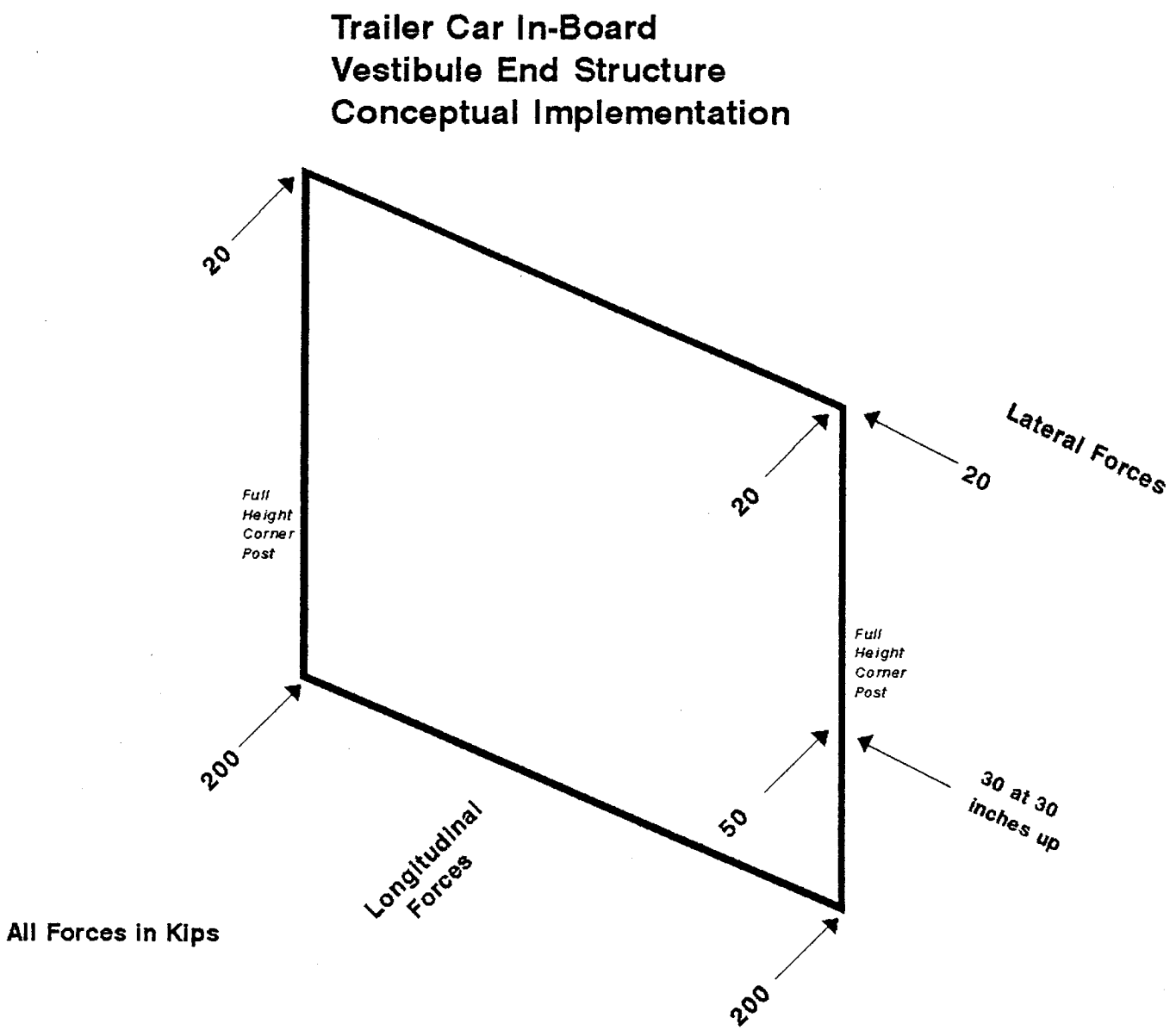

Figure 4

BILLING CODE 4910–06–C

§ 238.415 Rollover strength.

(a) Each power car shall be designed to rest on its side and be uniformly supported at the top (''roof rail'') and the bottom (''side sill'') chords of the side frame. The allowable stress for occupied volumes for this condition shall be one-half yield or one-half the critical buckling stress, whichever is less.

(b) Each passenger car and power car shall also be designed to rest on its roof so that any damage in occupied areas is limited to roof sheathing and framing. Deformation to the roof sheathing and framing is allowed to the extent necessary to permit the vehicle to be supported directly on the top chords of the side frames and end frames. Other than roof sheathing and framing, the allowable stress for occupied volumes for this condition shall be one-half yield or one-half the critical buckling stress, whichever is less.

§ 238.417 Side loads.

(a) The single-level passenger car body structure shall be designed to resist an inward transverse load of 80,000 pounds of force applied to the side sill and 10,000 pounds of force applied to the belt rail (horizontal members at the bottom of the window opening in the side frame).

(b) These loads shall be considered to be applied separately over the full vertical dimension of the specified member for a distance of 8 feet in the direction of the length of the car.

(c) The allowable stress shall be the lesser of the yield stress or the critical buckling stress with local yielding of the side skin allowed.

(d) The connections of the side frame to the roof and underframe shall support these loads.

§ 238.419 Truck-to-car-body and truck component attachment.

(a) The ultimate strength of the truck-to-car-body attachment for each unit in a train shall be sufficient to resist without failure a vertical force equivalent to 2g acting on the mass of the truck and a force of 250,000 pounds acting in any horizontal direction.

(b) Each component of a truck (which include axles, wheels, bearings, the truck-mounted brake system, suspension system components, and any other components attached to the truck by design) shall remain attached to the truck when a force equivalent to 2g acting on the mass of the component is exerted in any direction on that component.

§ 238.421 Glazing.

(a) Each power car and trailer car shall be equipped with certified glazing meeting the following requirements:

(1) End-facing exterior glazing shall resist the impact of a 12-pound solid steel sphere at the maximum speed at which the vehicle will operate, at an angle equal to the angle between the glazing surface as installed and the direction of travel, with no penetration or spall.

(2) Side-facing exterior glazing shall resist the impact of a:

(i) 12-pound solid steel sphere at 15 mph, at an angle of 90 degrees to the surface of the glazing, with no penetration or spall; and

(ii) A granite ballast stone weighing a minimum of 0.5 pounds, traveling at 75 mph and impacting at a 90-degree angle to the glazing surface, with no penetration or spall.

(3) All exterior glazing shall:

(i) Resist a single impact of a 9-mm, 147-grain bullet traveling at an impact velocity of 900 feet per second, with no bullet penetration or spall; and

(ii) Demonstrate anti-spalling performance by the use of a .001 aluminum witness plate, placed 12 inches from the glazing surface during all impact tests. The witness plate shall contain no marks from spalled glazing particles after any impact test.

(b) Each individual unit of glazing material shall be permanently marked, prior to installation, in such a manner that the marking is clearly visible after the material has been installed. The marking shall include:

(1) The words ''FRA TYPE IH'' for end-facing glazing or ''FRA TYPE IIH'' for side-facing glazing, to indicate that the material has successfully passed the testing requirements of paragraph (a) of this section;

(2) The name of the manufacturer; and

(3) The type or brand identification of the material.

(c) Glazing securement components shall hold the glazing in place against the forces described in paragraphs (a)(1) through (a)(3) of this section.

(d) Glazing securement components shall be designed to resist the forces due to air pressure differences caused when two trains pass at the minimum separation for two adjacent tracks, while traveling in opposite directions, each train traveling at the maximum authorized speed.

(e) Interior equipment glazing shall meet the minimum requirements of AS1 type laminated glass as defined in American National Standard ''Safety Code for Glazing Materials for Glazing Motor Vehicles Operating on Land Highways,'' ASA Standard Z26.1–1966.

(f) Each vehicle that is fully equipped with glazing materials that meet the requirements of paragraphs (a) through (e) of this section shall be stencilled on an interior wall as follows: ''Fully Equipped with FRA Part 238 Glazing'' or similar words conveying that meaning, in letters at least ⅜ of an inch high.

§ 238.423 Fuel tanks.

(a) *External fuel tanks.* (1) With all locomotive wheels resting on the ties beside the rail, the lowest point of an external fuel tank shall clear an 8½-inch combined height of the tie plate and rail by a minimum of 1½ inches. (This requirement results in a minimum 10-inch vertical distance from the lowest point on the wheel tread to the lowest point on the external fuel tank.)

(2) The end bulkheads of external fuel tanks shall at a minimum be equivalent to a 1-inch thick steel plate with a 25,000 pounds-per-square-inch yield strength—material of a higher yield strength may be used to decrease the required thickness of the material provided an equivalent level of strength is maintained.

(3) The skin of external fuel tanks shall at a minimum be equivalent to a ½-inch thick steel plate with a 25,000 pounds-per-square-inch yield strength—material of a higher yield strength may be used to decrease the required thickness of the material provided an equivalent level of strength is maintained.

(4) The material used for construction of external fuel tank exterior surfaces shall not exhibit a decrease in yield strength or penetration resistance in the temperature range of 0 to 160 degrees F.

(5) External fuel tank vent systems shall be designed to prevent them from becoming a path of fuel loss in the event a tank is placed in any orientation due to a locomotive overturning.

(6) The bottom surface of an external fuel tank shall be equipped with skid surfaces to prevent sliding contact with the rail or the ground from easily wearing through the tank.

(7) The structural strength of an external fuel tank shall be adequate to support 1½ times the dead weight of the locomotive without deformation of the tank.

(b) *Internal fuel tanks.* (1) Internal fuel tanks shall have their lowest point at least 18 inches above the lowest point on the locomotive wheel tread and shall be enclosed by, or shall be part of, the locomotive structure.

(2) Internal fuel tank vent systems shall be designed to prevent them from becoming a path of fuel loss in the event a tank is placed in any orientation due to a locomotive overturning.

(3) Internal fuel tank bulkheads and skin shall at a minimum be equivalent to a ⅜-inch thick steel plate with a 25,000-pound yield strength—material of a higher yield strength may be used to decrease the required thickness of the material provided an equivalent level of strength is maintained. Skid plates are not required.

§ 238.425 Electrical system.

(a) *Circuit protection.* (1) The main propulsion power line shall be protected with a lightning arrestor, automatic circuit breaker, and overload relay. The lightning arrestor shall be run by the most direct path possible to ground with a connection to ground of not less than No. 6 AWG. These overload protection devices shall be housed in an enclosure designed specifically for that purpose with the arc chute vented directly to outside air.

(2) Head end power, including trainline power distribution, shall be provided with both overload and ground fault protection.

(3) Circuits used for purposes other than propelling the equipment shall be connected to their power source through circuit breakers or equivalent current-limiting devices.

(4) Each auxiliary circuit shall be provided with a circuit breaker located as near as practical to the point of connection to the source of power for that circuit; however, such protection may be omitted from circuits controlling safety-critical devices.

(b) *Main battery system.* (1) The main batteries shall be isolated from the cab and passenger seating areas by a non-combustible barrier.

(2) Battery chargers shall be designed to protect against overcharging.

(3) Battery circuits shall include an emergency battery cut-off switch to completely disconnect the energy stored in the batteries from the load.

(4) If batteries are of the type to potentially vent explosive gases, the batteries shall be adequately ventilated to prevent accumulation of explosive concentrations of these gases.

(c) *Power dissipation resistors.* (1) Power dissipating resistors shall be

adequately ventilated to prevent overheating under worst-case operating conditions.

(2) Power dissipation grids shall be designed and installed with sufficient isolation to prevent combustion between resistor elements and combustible material.

(3) Power dissipation resistor circuits shall incorporate warning or protective devices for low ventilation air flow, over-temperature, and short circuit failures.

(4) Resistor elements shall be electrically insulated from resistor frames, and the frames shall be electrically insulated from the supports that hold them.

(d) *Electromagnetic interference and compatibility.* (1) The operating railroad shall ensure electromagnetic compatibility of the systems critical to the safety of equipment with their environment. Electromagnetic compatibility can be achieved through equipment design or changes to the operating environment.

(2) The electronic equipment shall not produce electrical noise that interferes with trainline control and communications or with wayside signaling systems.

(3) To contain electromagnetic interference emissions, suppression of transients shall be at the source wherever possible.

(4) Electrical and electronic systems of equipment shall be capable of operation in the presence of external electromagnetic noise sources.

(5) All electronic equipment shall be self-protected from damage or improper operation, or both, due to high voltage transients and long-term over-voltage or under-voltage conditions.

§ 238.427 Suspension system.

(a) *General requirements.* (1) Suspension systems shall be designed to reasonably prevent wheel climb, wheel lift, rail rollover, rail shift, and a vehicle from overturning to ensure safe, stable performance and ride quality. These requirements shall be met in all operating environments, and under all track conditions and loading conditions as determined by the operating railroad. These requirements shall be met at all track speeds and over all track qualities of track consistent with the Track Safety Standards in part 213 of this chapter, up to the maximum operating speed and maximum cant deficiency of the equipment.

(2) Passenger equipment shall meet the safety performance standards for suspension systems contained in Appendix C to this part or alternative standards providing equivalent safety if approved by the FRA Associate Administrator for Safety under the provisions of § 238.21.

(b) *Lateral accelerations.* Passenger cars shall not operate under conditions that result in a steady-state lateral acceleration of 0.1g (measured parallel to the car floor inside the passenger compartment) or greater.

(c) *Hunting oscillations.* Each truck shall be equipped with a permanently installed lateral accelerometer mounted on the truck frame. The accelerometer output signals shall be calibrated and filtered, and shall pass through signal conditioning circuitry designed to determine if hunting oscillations of the truck are occurring. If hunting oscillations are detected, the train monitoring system shall provide an alarm to the operator, and the train shall be slowed to a speed 5 mph less than the speed at which the hunting oscillations stopped.

(d) *Ride vibration (quality).* While traveling at the maximum operating speed over the intended route, the train suspension system shall be designed to:

(1) Limit the vertical acceleration, as measured by a vertical accelerometer mounted on the car floor, to no greater than 0.55g single event, peak-to-peak;

(2) Limit the lateral acceleration, as measured by a lateral accelerometer mounted on the car floor, to no greater than 0.3g single event, peak-to-peak; and

(3) Limit the combination of lateral acceleration (L) and vertical acceleration (V) occurring within any time period of 2 consecutive seconds as expressed by the square root of $(V^{2}+L^{2})$ to no greater than 0.604, where L may not exceed 0.3g and V may not exceed 0.55g.

(e) *Compliance.* Compliance with the requirements contained in paragraph (d) of this section shall be demonstrated during the equipment pre-revenue service acceptance tests required under § 238.113 and [proposed] § 213.345 of this chapter.

(f) *Overheat sensors.* Overheat sensors for each equipment bearing shall be provided. The sensors may be on board or placed at reasonable wayside intervals.

§ 238.429 Safety appliances.

(a) *Couplers.* (1) The leading and the trailing ends of semi-permanently coupled trainsets shall be equipped with an automatic coupler that couples on impact and uncouples by either activation of a traditional uncoupling lever or some other type of uncoupling mechanism that does not require a person to go between the equipment units.

(2) Automatic couplers and uncoupling devices on the leading and trailing ends of semi-permanently coupled trainsets may be stored within a removable shrouded housing.

(3) If the units in a train are not semi-permanently coupled, both ends of each unit shall be equipped with an automatic coupler, that couples on impact and uncouples by either activation of a traditional uncoupling lever or some other type of uncoupling mechanism that does not require a person to go between the equipment units.

(b) *Hand brakes.* Except as provided in paragraph (f) of this section, Tier II trains shall be equipped with a parking or hand brake that can be applied and released manually that is capable of holding the train on a 3-percent grade.

(c) *Safety appliance mechanical strength and fasteners.*

(1) All handrails, handholds, and sill steps shall be made of 1-inch diameter steel pipe or ⅝-inch thickness steel or a material of equal or greater mechanical strength.

(2) All safety appliances shall be securely fastened to the car body structure with mechanical fasteners that have mechanical strength greater than or equal to that of a ½-inch diameter SAE steel bolt mechanical fastener.

(i) Safety appliance mechanical fasteners shall have mechanical strength and fatigue resistance equal to or greater than a ½-inch diameter SAE steel bolt.

(ii) Mechanical fasteners shall be installed with a positive means to prevent unauthorized removal. Self-locking threaded fasteners do not meet this requirement.

(iii) Mechanical fasteners shall be installed to facilitate inspection.

(d) *Handrails and handholds.* Except as provided in paragraph (f) of this section:

(1) Handrails shall be provided for passengers on both sides of all steps used to board or depart the train.

(2) Exits on a power vehicle shall be equipped with handrails and handholds so that crewmembers can get on and off the vehicle safely.

(3) Throughout their entire length, handrails and handholds shall be a contrasting color to the surrounding vehicle body.

(4) The maximum distance above the top of the rail to the bottom of vertical handrails and handholds shall be 51 inches and the minimum distance shall be 21 inches.

(5) Vertical handrails and handholds shall be installed to continue to a point at least equal to the height of the top edge of the control cab door.

(6) The minimum hand clearance distance between a vertical handrail or handhold and the vehicle body shall be 2½ inches for the entire length.

(7) All vertical handrails and handholds shall be securely fastened to the vehicle body.

(8) If the length of the handrail exceeds 60 inches, it shall be securely fastened to the power vehicle body with two fasteners at each end.

(e) *Sill steps.* Except as provided in paragraph (f) of this section:

(1) Each power vehicle shall be equipped with a sill step below each exterior door as follows:

(i) The sill step shall have a minimum cross-sectional area of ½ by 3 inches.

(ii) The sill step shall be made of steel or a material of equal or greater strength and fatigue resistance.

(iii) The minimum tread length of the sill step shall be 10 inches.

(iv) The minimum clear depth of the sill step shall be 8 inches.

(v) The outside edge of the tread of the sill step shall be flush with the side of the car body structure.

(vi) Sill steps shall not have a vertical rise between treads exceeding 18 inches.

(vii) The lowest sill step tread shall be not more than 20 inches above the top of the track rail.

(viii) Sill steps shall be a color which contrasts with the surrounding power vehicle body color.

(ix) Sill steps shall be securely fastened.

(x) At least 50 percent of the tread surface area of each sill step shall be open space.

(xi) The portion of the tread surface area of each sill step which is not open space and is normally contacted by the foot shall be treated with an anti-skid material.

(f) Exceptions.

(1) If the units of the equipment are semi-permanently coupled, with uncoupling done only at maintenance facilities, the equipment units that are not required by paragraph (a) of this section to be equipped with automatic couplers need not be equipped with sill steps or end or side handholds that would normally be used to safely perform coupling and uncoupling operations.

(2) If the units of the equipment are not semi-permanently coupled, the units shall be equipped with hand brakes, sill steps, end handholds, and side handholds that meet the requirements contained in § 231.14 of this chapter.

(3) If two trainsets are coupled to form a single train that is not semi-permanently coupled (i.e., that is coupled by an automatic coupler), the automatically coupled ends shall be equipped with hand brakes, sill steps, end handholds, and side handholds that meet the requirements contained in § 231.14 of this chapter. If the trainsets are semi-permanently coupled, these safety appliances are not required.

(g) *Optional safety appliances.* Safety appliances installed at the option of the railroad shall be firmly attached with mechanical fasteners and shall meet the design and installation requirements provided in this section.

§ 238.431 Brake system.

(a) A passenger train's brake system shall be capable of stopping the train from its maximum operating speed within the signal spacing existing on the track over which the train is operating under worst-case adhesion conditions.

(b) The brake system shall be designed to allow an inspector to determine that the brake system is functioning properly without having to place himself or herself in a dangerous position on, under, or between the equipment.

(c) Passenger equipment shall be provided with an emergency application feature that produces an irretrievable stop, using a brake rate consistent with prevailing adhesion, passenger safety, and brake system thermal capacity. An emergency application shall be available at any time, and shall be initiated by an unintentional parting of the train. A means to initiate an emergency brake application shall be provided at two locations in each unit of the train.

(d) The brake system shall be designed to prevent thermal damage to wheels and brake discs. The operating railroad shall demonstrate through analysis and test that no thermal damage results to the wheels or brake discs under conditions resulting in maximum braking effort being exerted on the wheels or discs.

(e) The following requirements apply to blended braking systems:

(1) Loss of power or failure of the dynamic brake does not result in exceeding the allowable stop distance;

(2) The friction brake alone is adequate to safely stop the train under all operating conditions;

(3) The operational status of the electric portion of the brake system shall be displayed for the train operator in the control cab; and

(4) The operating railroad shall demonstrate through analysis and testing the maximum operating speed for safe operation of the train using only the friction brake portion of the blended brake with no thermal damage to wheels or discs.

(f) The brake system design shall allow a disabled train's pneumatic brakes to be controlled by a conventional locomotive, during rescue operation, through brake pipe control alone.

(g) An independent failure-detection system shall compare brake commands with brake system output to determine if a failure has occurred. The failure detection system shall report brake system failures to the automated train monitoring system.

(h) Passenger equipment shall be provided with an adhesion control system designed to automatically adjust the braking force on each wheel to prevent sliding during braking. In the event of a failure of this system to prevent wheel slide within preset parameters, a wheel slide alarm that is visual or audible, or both, shall alert the train operator in the cab of the controlling power car to wheel-slide conditions on any axle of the train.

§ 238.433 Draft system.

(a) Leading and trailing automatic couplers of trains shall be compatible with standard AAR couplers with no special adapters used.

(b) All passenger equipment continues to be subject to the requirements concerning couplers and uncoupling devices contained in Federal Statute at 49 U.S.C. chapter 203 and in FRA regulations at part 231 and § 232.2 of this chapter.

§ 238.435 Interior fittings and surfaces.

(a) The seat back in a passenger car shall be designed to withstand, with deflection but without total failure, the load of a seat occupant who is a 95th-percentile male accelerated at 8g impacting the seat back.

(b) The seat back in a passenger car shall include shock-absorbent material to cushion the impact of occupants with the seat ahead of them.

(c) The ultimate strength of a seat attachment to a passenger car body shall be of sufficient strength to withstand the following individually applied accelerations acting on the mass of the seat plus the mass of a seat occupant who is a 95th-percentile male:

(1) Longitudinal: 8g;

(2) Lateral: 4g; and

(3) Vertical: 4g.

(d) Other interior fittings shall be attached to the passenger car body with sufficient strength to withstand the following individually applied accelerations acting on the mass of the fitting:

(1) Longitudinal: 8g;

(2) Lateral: 4g; and

(3) Vertical: 4g.

Fittings that can be expected to be impacted by a person during a collision, such as tables between facing seats, shall be designed for the mass of the fitting plus the mass of the number of occupants who are 95th-percentile males that could be expected to strike the fitting.

(e) The ultimate strength of the interior fittings and equipment in power car control cabs shall be sufficient to resist without failure loads due to the following individually applied accelerations acting on the mass of the fitting or equipment:

(1) Longitudinal: 12g;

(2) Lateral: 4g; and

(3) Vertical: 4g.

(f) To the extent possible, interior fittings, except seats, shall be recessed or flush-mounted. Corners and sharp edges shall be avoided or otherwise padded.

(g) Energy-absorbent material shall be used to pad surfaces likely to be impacted by occupants during collisions or derailments.

(h) Luggage stowage compartments shall be of the enclosed, aircraft type with ultimate strength sufficient to resist loads due to the following individually applied accelerations acting on the mass of the luggage that the compartments are designed to accommodate:

(1) Longitudinal: 8g;

(2) Lateral: 4g; and

(3) Vertical: 4g.

§ 238.437 Emergency communication.

A means of emergency communication throughout a train shall be provided and shall include the following:

(a) Transmission locations that are clearly marked with luminescent material at each end of each unit adjacent to the unit end doors;

(b) Clear and understandable operating instructions at or near each transmission location; and

(c) Back-up power for a minimum time period of two hours.

§ 238.439 Emergency window exits and roof hatches.

(a) *Emergency window exits.* Except as provided in paragraphs (a)(3) and (a)(4) of this section, each passenger car shall have a minimum of four emergency window exits, either in a staggered configuration or with one located at each end of each side of a passenger car.

(1) Each sealed emergency window exit on a passenger coach shall have a minimum free opening of 30 inches horizontally by 30 inches vertically.

(2) Each emergency window exit shall be easily operable by a 5th-percentile female without requiring the use of a tool or other implement.

(3) If the passenger car is bi-level, each main level shall have a minimum of four emergency window exits, either in a staggered configuration or with one located at each end of each side on each level.

(4) Each passenger car of special design, such as a sleeping car, shall have at least one emergency window exit in each compartment.

(b) *Roof hatches.* (1) Each power car cab shall have a minimum of one roof hatch emergency entrance location with either a minimum opening of 18 inches by 24 inches or a clearly marked structural weak point in the roof to provide a minimum opening of the same dimensions to provide quick access for properly equipped emergency personnel.

(2) Each passenger car shall be equipped with a minimum of two roof hatch emergency entrance locations with either a minimum opening of 18 inches by 24 inches or two clearly marked structural weak points in the roof to provide a minimum opening of the same dimensions to provide quick access for properly equipped emergency personnel.

(c) *Marking and instructions.* [Reserved]

§ 238.441 Doors.

(a) Each passenger car shall have a minimum of four side doors, or the functional equivalent of four side doors, each permitting at least one 95th-percentile male to pass through at a single time.[2]

(1) Each powered, exterior side door shall be equipped with a manual override that is:

(i) Capable of opening the door without power from both inside and outside the car;

(ii) Located adjacent to the door which it controls; and

(iii) Designed and maintained so that a person may access the override device from both inside and outside the car without the use of any tool or other implement.

(2) The status of each powered, exterior side door shall be displayed to the crew in the operating cab. If door interlocks are used, the sensors used to detect train motion shall be nominally set to operate at 3 mph.

(b) Each powered, exterior side door shall be connected to an emergency back-up power system.

(c) A railroad may protect a manual override device used to open a powered, exterior door with a cover or a screen capable of removal by a 5th-percentile female without requiring the use of a tool or other implement. If the method of removing the protective cover or screen entails breaking or shattering it, the cover or screen shall be scored, perforated, or otherwise weakened so that a 5th-percentile female can penetrate the cover or screen with a single blow of her fist without injury to her hand.

(d) Passenger compartment end doors shall be equipped with a kick-out panel, pop-out window, or other similar means of egress in the event the door will not open.

(e) *Marking and instructions.* [Reserved]

§ 238.443 Headlights.

Each power car shall be equipped with at least two headlights. Each headlight shall produce no less than 200,000 candela. One headlight shall be focused to illuminate a person standing between the rails at 800 feet under clear weather conditions. The other headlight shall be focused to illuminate a person standing between the rails at 1500 feet under clear weather conditions.

§ 238.445 Automated monitoring.

(a) Each passenger train shall be equipped to monitor the performance of the following systems or components:

(1) Reception of cab signals and train control signals;

(2) Truck hunting;

(3) Dynamic brake status;

(4) Friction brake status;

(5) Fire detection systems;

(6) Head end power status;

(7) Alerter or deadman control;

(8) Horn and bell;

(9) Wheel slide;

(10) Tilt system, if so equipped; and

(11) On-board bearing-temperature sensors, if so equipped.

(b) The operator shall be alerted when any of the monitored parameters are out of predetermined limits. In situations where the system safety analysis indicates that operator-reaction time is crucial to safety, immediate automatic corrective action such as limiting the speed of the train shall be taken.

(c) The monitoring system shall be designed with an automatic self-test feature that notifies the operator that the monitoring capability is functioning correctly and alerts the operator that a system failure has occurred.

§ 238.447 Operator's controls and cab layout.

(a) Operator controls in the power vehicle or control cab shall be arranged

[2] The Americans with Disabilities Act (ADA) Accessibility Specifications for Transportation Vehicles also contain requirements for doorway clearance (See Title 49 Code of Federal Regulations Part 38).

to be comfortably within view and within easy reach when the operator is seated in the normal train control position.

(b) The control panels shall be laid out to minimize the chance of human error.

(c) Control panel buttons, switches, levers, knobs, and the like shall be distinguishable by sight and by touch.

(d) An alerter shall be provided. If not acknowledged, the alerter shall cause a brake application to stop the train.

(e) Cab information displays shall be designed with the following characteristics:

(1) Simplicity and standardization shall be the driving criteria for design of formats for the display of information in the cab;

(2) Essential, safety-critical information shall be displayed as a default condition;

(3) Operator selection shall be required to display other than default information;

(4) Cab or train control signals shall be displayed for the operator; and

(5) Displays shall be readable from the operators's normal position under all lighting conditions.

(f) The cab layout shall be arranged to meet the following requirements:

(1) The crew has an effective field of view in the forward direction and to the right and left of the direction of travel;

(2) Field-of-view obstructions due to required structural members are minimized; and

(3) The crew's position in the cab is located to permit the crew to be able to directly observe traffic approaching the train from either side of the train.

(g) Each seat provided for a crewmember shall be:

(1) Equipped with a single acting, quick-release lap belt and shoulder harness as defined in § 571.209 of this title;

(2) Secured to the car body with an attachment having an ultimate strength capable of withstanding the loads due to the following individually applied accelerations acting on the mass of the seat and the crewmember occupying it:

(i) Longitudinal: 12g;

(ii) Lateral: 4g; and

(iii) Vertical: 4g;

(3) Designed so all adjustments have the range necessary to accommodate a 5th-percentile female to a 95th-percentile male;

(4) Equipped with lumbar support that is adjustable from the seated position;

(5) Equipped with force-assisted, vertical-height adjustment, operated from the seated position;

(6) Equipped with a manually reclining seat back, adjustable from the seated position;

(7) Equipped with an adjustable headrest; and

(8) Equipped with folding, padded armrests.

(h) Sharp edges and corners shall be eliminated from the interior of the cab, and interior surfaces of the cab likely to be impacted by a crewmember during a collision or derailment shall be padded with shock-absorbent material.

Subpart F—Inspection, Testing, and Maintenance Requirements for Tier II Passenger Equipment

§ 238.501 Scope.

This subpart contains inspection, testing, and maintenance requirements for railroad passenger equipment that operates at speeds exceeding 125 mph but not exceeding 150 mph.

§ 238.503 Inspection, testing, and maintenance requirements.

(a) *General.* Under the procedures provided in § 238.505, each railroad shall obtain FRA approval of a written inspection, testing, and maintenance program for Tier II passenger equipment prior to implementation of that program and prior to commencing passenger operations using that equipment. As further specified in this section, the program shall describe in detail the procedures, equipment, and other means necessary for the safe operation of the passenger equipment, including:

(1) Safety inspection procedures, intervals, and criteria;

(2) Testing procedures and intervals;

(3) Scheduled preventive-maintenance intervals;

(4) Maintenance procedures;

(5) Special testing equipment or measuring devices required to perform safety inspections and tests; and

(6) The training, qualification, and designation of employees and contractors to perform safety inspections, tests, and maintenance.

(b) *Compliance.* After the railroad's inspection, testing, and maintenance program is approved by FRA under § 238.505, the railroad shall adopt the program and shall perform—

(1) The inspections and tests of power brakes and other primary brakes as described in the program;

(2) The other inspections and tests described in the program in accordance with the procedures and criteria that the railroad identified as safety-critical; and

(3) The maintenance tasks described in the program in accordance with the procedures and intervals that the railroad identified as safety-critical.

(c) *General safety inspection, testing, and maintenance procedures.* The inspection, testing, and maintenance program under paragraph (a) of this section shall contain the railroad's written procedures to ensure that all systems and components of in service equipment are free of any general condition that endangers the safety of the crew, passengers, or equipment. These procedures shall protect against:

(1) A continuous accumulation of oil or grease;

(2) Improper functioning of a component;

(3) A crack, break, excessive wear, structural defect, or weakness of a component;

(4) A leak;

(5) Use of a component or system under a condition that exceeds that for which the component or system is designed to operate; and

(6) Insecure attachment of a component.

(d) *Specific safety inspections.* The program under paragraph (a) of this section shall specify that all Tier II passenger equipment shall receive thorough safety inspections in accordance with the following standards:

(1) Except as provided in paragraph (d)(3) of this section, the equivalent of a Class I brake test contained in § 238.313 shall be conducted prior to a train's departure from an originating terminal and every 1,500 miles or once each calendar day, whichever comes first, that the train remains in continuous service.

(i) Class I equivalent brake tests shall be performed by qualified mechanical inspectors.

(ii) Except as provided in § 238.15(b), a railroad shall not use or haul a Tier II passenger train in passenger service from a location where a Class I equivalent brake test has been performed, or was required by this part to have been performed, with less than 100 percent operative brakes.

(2) Except as provided in paragraph (d)(3) of this section, a complete safety exterior and interior mechanical inspection, in accordance with the railroad's inspection program, shall be conducted by qualified mechanical inspectors at least once during each calendar day the equipment is used in service.

(3) Trains that miss a scheduled Class I brake test or mechanical inspection due to a delay en route may proceed to the point where the Class I brake test or mechanical inspection was scheduled to be performed.

(e) *Movement of trains with power brake defects.* Movement of trains with

a power brake defect as defined in § 238.15 (any primary brake defect) shall be governed by § 238.15.

(f) *Movement of trains with other defects.* Movement of trains that with a defect other than a power brake defect shall be conducted in accordance with § 238.17, with the following exception. When a failure of the secondary brake on a Tier II passenger train occurs en route, that train may remain in service until its next scheduled calendar day Class I brake test equivalent at a speed no greater than the maximum safe operating speed demonstrated through analysis and testing for braking with the friction brake alone. The brake system shall be restored to 100 percent operation before the train departs that inspection location.

(g) *Maintenance intervals.* The program under paragraph (a) of this section shall include the railroad's initial scheduled maintenance intervals for Tier II equipment based on an analysis completed as part of the system safety program. The maintenance interval of a safety-critical component shall be changed only when justified by accumulated, verifiable operating data and approved by FRA's Associate Administrator for Safety under § 238.505 before the change takes effect.

(h) *Training, qualification, and designation program.* The program under paragraph (a) of this section shall describe the training, qualification, and designation program, as defined in the training program plan under § 238.111, established by the railroad to qualify individuals to inspect, test, and maintain the equipment.

(1) If the railroad deems it safety-critical, then only qualified individuals shall inspect, test, and maintain the equipment.

(2) Knowledge of the standard procedures described in paragraph (i) of this section shall be required to qualify an employee or contractor to perform an inspection, testing, or maintenance task under this part.

(i) *Standard procedures for safely performing inspection, testing, maintenance, or repairs.* The program under paragraph (a) of this section shall include the railroad's written standard procedures for performing all safety-critical equipment inspection, testing, maintenance, or repair tasks. These standard procedures shall:

(1) Describe in detail each step required to safely perform the task;

(2) Describe the knowledge necessary to safely perform the task;

(3) Describe any precautions that must be taken to safely perform the task;

(4) Describe the use of any safety equipment necessary to perform the task;

(5) Be approved by the railroad's chief mechanical officer;

(6) Be approved by the railroad's official responsible for safety;

(7) Be enforced by supervisors with responsibility for accomplishing the tasks; and

(8) Be reviewed annually by the railroad.

(j) *Quality control program.* Each railroad shall establish an inspection, testing, and maintenance quality control program enforced by railroad or contractor supervisors to reasonably ensure that inspections, tests, and maintenance are performed in accordance with Federal safety standards and the procedures established by the railroad.

(k) *Identification of safety-critical items.* In the program under paragraph (a) of this section, the railroad shall identify all inspection and testing procedures and criteria as well as all maintenance intervals that the railroad deems to be safety-critical.

§ 238.505 Program approval procedure.

(a) *Submission.* Not less than 90 days prior to commencing passenger operations using Tier II passenger equipment, each railroad to which this subpart applies shall submit for approval an inspection, testing, and maintenance program for that equipment meeting the requirements of this subpart with the Associate Administrator for Safety, Federal Railroad Administration, 400 7th Street, S.W., Washington, D.C. 20590. If a railroad seeks to amend an approved program, the railroad shall file with FRA's Associate Administrator for Safety a petition for approval of such amendment not less than 60 days prior to the proposed effective date of the amendment. A program responsive to the requirements of this subpart or any amendment to the program shall not be implemented prior to FRA approval.

(1) Each program or amendment under § 238.503 shall contain:

(i) The information prescribed in § 238.503 for such program or amendment;

(ii) The name, title, address, and telephone number of the primary person to be contacted with regard to review of the program or amendment; and

(iii) A statement affirming that the railroad has served a copy of the program or amendment on designated representatives of railroad employees, together with a list of the names and addresses of persons served.

(2) Each railroad shall serve a copy of each submission to FRA on designated representatives of railroad employees responsible for the equipment's operation, inspection, testing, and maintenance under this subpart.

(b) *Comment.* Not later than 45 days from the date of filing the program or amendment, any person may comment on the program or amendment.

(1) Each comment shall set forth specifically the basis upon which it is made, and contain a concise statement of the interest of the commenter in the proceeding.

(2) Three copies of each comment shall be submitted to the Associate Administrator for Safety, Federal Railroad Administration, 400 7th Street, S.W., Washington, D.C. 20590.

(3) The commenter shall certify that a copy of the comment was served on the railroad.

(c) *Approval.* (1) Within 60 days of receipt of each initial inspection, testing, and maintenance program, FRA will conduct a formal review of the program. FRA will then notify the primary railroad contact person and the designated employee representatives in writing whether the inspection, testing, and maintenance program is approved and, if not approved, the specific points in which the program is deficient. If a program is not approved by FRA, the railroad shall amend its program to correct all deficiencies and resubmit its program with the required revisions not later than 45 days prior to commencing passenger operations.

(2) FRA will review each proposed amendment to the program within 45 days of receipt. FRA will then notify the primary railroad contact person and the designated employee representatives in writing whether the proposed amendment has been approved by FRA and, if not approved, the specific points in which the proposed amendment is deficient. The railroad shall correct any deficiencies and file the corrected amendment prior to implementing the amendment.

(3) Following initial approval of a program or amendment, FRA may reopen consideration of the program or amendment for cause stated.

Subpart G—Introduction of New Technology to Tier II Passenger Equipment

§ 238.601 Scope.

This subpart contains general requirements for introducing new technology that affects a safety system of existing Tier II passenger equipment. For purposes of this subpart, ''existing Tier II passenger equipment'' is Tier II

passenger equipment that has been approved for revenue service by the FRA Associate Administrator for Safety under the procedures of § 238.21.

§ 238.603 Process to introduce new technology.

(a) If a railroad plans a major upgrade or introduction of new technology on existing Tier II passenger equipment, as defined in § 238.601, that affects the performance of a safety system on such equipment, such major upgrade or introduction of new technology shall be designed and implemented using the system safety process prescribed in § 238.101.

(b) Under the procedures of § 238.21, each railroad shall obtain special approval from the FRA Associate Administrator for Safety of a pre-revenue service acceptance testing plan, under § 238.113, for existing Tier II passenger equipment with a major upgrade or new technology that affects the performance of a safety system on such equipment, prior to implementing the plan. ''New passenger equipment,'' for purposes of § 238.113, includes existing Tier II passenger equipment with such a major upgrade or new technology.

(c) Each railroad shall complete a pre-revenue service demonstration of such passenger equipment described in paragraph (b) of this section in accordance with the approved plan, shall fulfill all of the other requirements prescribed in § 238.113, and shall obtain special approval from the FRA Associate Administrator for Safety under the procedures of § 238.21 prior to using such passenger equipment in revenue service.

Appendix A to Part 238—Schedule of Civil Penalties [Reserved]

Appendix B to Part 238—Test Performance Criteria for the Flammability and Smoke Emission Characteristics of Materials Used in Constructing or Refurbishing Locomotive Cab and Passenger Car Interiors

This appendix provides the performance standards for testing the flammability and smoke emission characteristics of materials used in constructing or refurbishing locomotive cab and passenger car interiors, in accordance with the requirements of § 238.115.

(a) *Definitions.*

Critical radiant flux (CRF) means, as defined in ASTM E–648, a measure of the behavior of horizontally-mounted floor covering systems exposed to a flaming ignition source in a graded radiant heat energy environment in a test chamber.

Flame spread index (I_s) means, as defined in ASTM E–162, a factor derived from the rate of progress of the flame front (F_s) and the rate of heat liberation by the material under test (Q), such that $I_s = F_s \times Q$.

Specific optical density (D_s) means, as defined in ASTM E–662, the optical density measured over unit path length within a chamber of unit volume, produced from a specimen of unit surface area, that is irradiated by a heat flux of 2.5 watts/cm^2 for a specified period of time.

Surface flammability means the rate at which flames will travel along surfaces.

Flaming running means continuous flaming material leaving the site of material burning or material installation.

Flaming dripping means periodic dripping of flaming material from the site of material burning or material installation.

(b) *Required test procedures and performance criteria.*

The materials used in locomotive cabs and passenger cars shall be tested according to the procedures and performance criteria set forth in the following table. In all instances, the most recent version of the test procedures or the revision in effect at the time a vehicle is ordered should be employed in the evaluation of the materials specified.

Category	Function of material	Test procedure	Performance criteria
Passenger seats, Sleeping and dining car components.	Cushions, Mattresses [1, 2, 5, 9]	ASTM D–3675	$I_S \leq 25$
		ASTM E–662	D_S (1.5) ≤ 100; D_S (4.0) ≤ 175
	Seat and/or Mattress Frame [1, 5, 8]	ASTM E–162	$I_S \leq 35$
		ASTM E–662	D_S (1.5) ≤ 100; D_S (4.0) ≤ 200
	Seat and Toilet Shroud, Food Trays [1, 5]	ASTM E–162	$I_S \leq 35$
		ASTM E–662	D_S (1.5) ≤ 100; D_S (4.0) ≤ 200
	Seat Upholstery, Mattress Ticking and Covers, Curtains [1, 2, 3, 5].	FAR 25.853 (Vertical)	Flame Time ≤ 10 sec.; Burn length ≤ 6 inch
		ASTM E–662	D_S (4.0) ≤ 250 coated; D_S (4.0) ≤ 100 uncoated
Panels	Wall [1, 5, 10]	ASTM E–162	$I_S \leq 35$
		ASTM E–662	D_S (1.5) ≤ 100; D_S (4.0) ≤ 200
	Ceiling [1, 5, 10]	ASTM E–162	$I_S \leq 35$
		ASTM E–662	D_S (1.5) ≤ 100; D_S (4.0) ≤ 200
	Partition, Tables and Shelves [1, 5]	ASTM E–162	$I_S \leq 35$
		ASTM E–662	D_S (1.5) ≤ 100; D_S (4.0) ≤ 200
	Windscreen [1, 5]	ASTM E–162	$I_S \leq 35$
		ASTM E–662	D_S (1.5) ≤ 100; D_S (4.0) ≤ 200
	HVAC Ducting [1, 5]	ASTM E–162	$I_S \leq 35$
		ASTM E–662	D_S (1.5) ≤ 100
	Window [4, 5]	ASTM E–162	$I_S \leq 100$
		ASTM E–662	D_S (1.5) ≤ 100; D_S (4.0) ≤ 200
	Light Diffuser [5]	ASTM E–162	$I_S \leq 100$
		ASTM E–662	D_S (1.5) ≤ 100; D_S (4.0) ≤ 200
Flooring	Structural [6]	ASTM E–119	Pass
	Covering [7, 10]	ASTM E–648	CRF ≤ 0.5 w/cm^2
		ASTM E–662	D_S (1.5) ≤ 100; D_S (4.0) ≤ 200
Insulation	Thermal [1, 2, 5]	ASTM E–162	$I_S \leq 25$
		ASTM E–662	D_S (1.5) ≤ 100
	Acoustic [1, 2, 5]	ASTM E–162	$I_S \leq 25$
		ASTM E–662	D_S (1.5) ≤ 100
Elastomers	Window Gaskets, Door Nosing, Diaphragms, Roof Mat. [1].	ASTM C–542	Pass
		ASTM E–662	D_S (1.5) ≤ 100; D_S (4.0) ≤ 200
Exterior Plastic Components	End Cap, Roof Housings [1, 5]	ASTM E–162	$I_S \leq 35$
		ASTM E–662	D_S (1.5) ≤ 100; D_S (4.0) ≤ 200

Category	Function of material	Test procedure	Performance criteria
Component Box Covers	Interior, Exterior Boxes[1, 3, 5]	ASTM E–162 ASTM E–662	$I_S \leq 35$ D_S (1.5) ≤ 100; D_S (4.0) ≤ 200

1. Materials tested for surface flammability must not exhibit any flaming running or flaming dripping.

2. The surface flammability and smoke emission characteristics must be demonstrated to be permanent by washing, if appropriate, according to FED–STD–191A Textile Test Method 5830.

3. The surface flammability and smoke emission characteristics must be demonstrated to be permanent by dry-cleaning, if appropriate, according to ASTM D-2724. Materials that cannot be washed or dry cleaned must be so labeled and meet the applicable performance criteria after being cleaned as recommended by the manufacturer.

4. For double window glazing, only the interior glazing must meet the materials requirements specified herein; the exterior need not meet those requirements.

5. ASTM E–662 maximum test limits for smoke emission (specified optical density) must be measured in either the flaming or non-flaming mode, depending on which mode generates the most smoke.

6. Structural flooring assemblies must meet the performance criteria during a nominal test period determined by the railroad property. The nominal test period must be twice the maximum expected period of time, under normal circumstances, for a vehicle to come to a complete, safe stop from maximum speed, plus the time necessary to evacuate all passengers from a vehicle to a safe area. The nominal test period must not be less than 15 minutes. Only one specimen need be tested. A proportional reduction may be made in the dimensions of the specimen provided that it represents a true test of its ability to perform as a barrier against under-car fires. Penetrations (ducts, etc.) must be designed against acting as passageways for fire and smoke.

7. Floor covering must be tested in accordance with ASTM E–648 with its padding, if the padding is used in actual installation.

8. Arm rests, if foamed plastic, are tested as cushions and, if hard material, are tested as a seat back shroud.

9. Testing is performed without upholstery.

10. Carpeting on walls and ceilings is to be considered wall and ceiling panel materials, respectively.

(c) *The sources of test procedures specified in the table are as follows:*

(1) Leaching Resistance of Cloth, FED–STD–191A–Textile Test Method 5830. (Available from: General Services Administration Specifications Division, Building 197 Washington Navy Yard, Washington, D.C. 20407.)

(2) Federal Aviation Administration Vertical Burn Test, FAR–25.853.

(3) American Society for Testing Materials (ASTM):

(i) Specification for Gaskets, ASTM C–542.

(ii) Surface Flammability of Flexible Cellular Materials Using a Radiant Heat Energy Source, ASTM D–3675.

(iii) Fire Tests of Building Construction and Materials, ASTM E–119.

(iv) Surface Flammability of Materials Using a Radiant Heat Energy Source, STM E–162.

(v) Bonded and Laminated Apparel Fabrics, ASTM D–2724.

(vi) Critical Radiant Flux of Floor Covering Systems Using a Radiant Heat Energy Source, ASTM E–648.

(vii) Specific Optical Density of Smoke Generated by Solid Materials, STM E–662.

(Available from: American Society for Testing Materials, 1916 Race Street, Philadelphia, Pennsylvania 19103.)

Appendix C to Part 238—Suspension System Safety Performance Standards

This appendix contains the minimum suspension system safety performance standards for Tier II passenger equipment as required by § 238.427. These requirements shall be the basis for evaluating suspension system safety performance until an industry standard acceptable to FRA is developed and approved under the procedures provided in § 238.21.

Passenger equipment suspension systems shall be designed to limit the lateral and vertical forces and lateral to vertical (L/V) ratios, for the time duration required to travel six feet at any operating speed or over any class of track, under all operating conditions as determined by the railroad, as follows:

1. The maximum single wheel lateral to vertical force (L/V) ratio shall not exceed Nadal's limit as follows:

$$\text{Wheel L / V} \leq \frac{\tan(\delta) - \mu}{1 + \mu \tan(\delta)} \qquad \text{(for positive angle of attack)}$$

where: δ=flange angle (deg).
μ=coefficient of friction of 0.5.

2. The net axle lateral force shall not exceed 0.5 times the static vertical axle load.

3. The vertical wheel/rail force shall be greater than 10 percent of the static vertical wheel load.

4. The sum of the vertical wheel loads on one side of any truck shall be greater than 20 percent of the static vertical axle load. This shall include the effect of a crosswind allowance as specified by the railroad for the intended service.

5. The maximum truck side L/V ratio shall not exceed 0.5.

6. When stopped on track with a uniform 6-inch superelevation, vertical wheel loads, at all wheels, shall be greater than 60 percent of the nominal vertical wheel load on level track.

Issued in Washington, D.C., on September 12, 1997.

Jolene M. Molitoris,

Federal Railroad Administrator.

[FR Doc. 97–24713 Filed 9–22–97; 8:45 am]

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Federal Register

Tuesday
September 23, 1997

Part III

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 101 Chapter I, and Part, 190 Food Labeling Regulation, Amendments; Food Regulation Uniform Compliance Date; and New Dietary Ingredient Premarket Notification; Final Rules

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket Nos. 95N–0245 and 94P–0110]

RIN 0910–AA59

Food Labeling; Statement of Identity, Nutrition Labeling and Ingredient Labeling of Dietary Supplements; Compliance Policy Guide, Revocation

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its food labeling regulations to establish requirements for the identification of dietary supplements and for their nutrition labeling and ingredient labeling in response to the Dietary Supplement Health and Education Act of 1994 (the DSHEA). FDA is also responding to a citizen petition from the Council for Responsible Nutrition on type size requirements for these products. In addition, FDA is announcing the revocation of Compliance Policy Guide 530.400 (CPG 7121.02) entitled ''Vitamin Products for Human Use—Low Potency'' to eliminate inconsistencies with the new labeling requirements.

DATES: The regulation is effective March 23, 1999. The Director of the Office of the Federal Register approves the incorporations by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 of certain publications in 21 CFR 101.4(h), effective March 23, 1999.

FOR FURTHER INFORMATION CONTACT: Susan Thompson, Center for Food Safety and Applied Nutrition (HFS–165), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5587.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of December 28, 1995 (60 FR 67194), FDA published a proposed rule entitled ''Food Labeling; Statement of Identity, Nutrition Labeling and Ingredient Labeling of Dietary Supplements'' (hereinafter identified as ''the December 1995 proposal''). This document, which specifically responds to the DSHEA, superseded earlier documents responding to the Nutrition Labeling and Education Act of 1990 (the 1990 amendments)(Pub. L. 101–535) and the Dietary Supplement Act of 1992 (the DS act) (Pub. L. 102–571) with respect to dietary supplements.

The 1990 amendments amended the Federal Food, Drug, and Cosmetic Act (the act) in a number of important ways. One of the notable aspects of the 1990 amendments is that they added section 403(q) to the act (21 U.S.C. 343(q)). This section provides that most foods are misbranded unless they bear nutrition labeling.

In particular, section 403(q)(5)(F) (originally section 403(q)(5)(E)) of the act provided that separate regulations on the nutrition labeling of dietary supplements of vitamins and minerals could be established that are distinct from those for other foods. In response to this section, FDA proposed a regulation in § 101.36 (21 CFR 101.36) that was specifically on the nutrition labeling of dietary supplements of vitamins and minerals, and a separate general regulation that was on the nutrition labeling in § 101.9 (21 CFR 101.9) of conventional foods and of all other dietary supplements (those of herbs and other nutritional substances) (56 FR 60366, November 27, 1991).

On October 6, 1992, the President signed into law the DS act. The DS act established a moratorium until December 15, 1993, on the implementation of the 1990 amendments with respect to dietary supplements not in the form of conventional food. Also, it required that a new proposed regulation on the nutrition labeling of dietary supplements be issued by June 15, 1993, and a final rule by December 31, 1993.

In response to the DS act, FDA published a new proposed rule in the **Federal Register** of June 18, 1993 (58 FR 33715), and a final rule on January 4, 1994 (59 FR 354), on the nutrition labeling of dietary supplements. As mandated in section 403(q)(5)(F) of the act, the final rule established a regulation (§ 101.36) on the specific requirements for nutrition labeling of dietary supplements of vitamins and minerals.

On October 25, 1994, the DSHEA (Pub. L. 103–417) was signed into law. The DSHEA amended the act by adding section 201(ff) (21 U.S.C. 321(ff)), which defines a ''dietary supplement,'' in part, as a product, other than tobacco, intended to supplement the diet that contains at least one or more of the following ingredients: A vitamin; a mineral; an herb or other botanical; an amino acid; a dietary substance for use to supplement the diet by increasing the total dietary intake; or a concentrate, metabolite, constituent, extract, or combination of any of the previously mentioned ingredients. This section also states that the term ''dietary supplement'' means a product that is labeled as a dietary supplement.

Furthermore, the DSHEA, among other things, amended section 403(q)(5)(F) of the act by adding specific requirements that relate to the labeling of, and ingredient declaration on, dietary supplement products. Previously, this section had applied only to dietary supplements of vitamins and minerals and had not offered any description of how the labeling of these products should differ from the labeling of foods in general. As amended by the DSHEA, section 403(q)(5)(F) of the act provides that dietary ingredients that do not have daily values (i.e., Reference Daily Intakes (RDI's) or Daily Reference Values (DRV's)) must be listed within the nutrition information, that the listing of dietary ingredients must include the quantity of each dietary ingredient (or of a proprietary blend of such dietary ingredients), and that the listing of dietary ingredients may include the source of a dietary ingredient. It also provides that the nutrition information must immediately precede the ingredient information required under the act.

FDA received over 50 letters in response to the December 1995 proposal. Each of these letters contained one or more comments. Responses were received from industry, trade associations, consumers, consumer advocacy organizations, health care professionals, professional societies, and city governments. Many comments supported the proposal generally or supported aspects of the proposal. Other comments objected to specific provisions of the proposal and requested revisions. Some comments addressed issues outside the scope of the proposal and will not be discussed here. A summary of the relevant comments, the agency's responses to the comments, and a discussion of the agency's conclusions follows.

II. The Term ''Dietary Supplement'' in the Statement of Identity

1. A number of comments objected to the proposed requirement in §101.3(g) (21 CFR 101.3(g)) that the term ''dietary supplement'' appear as part of the statement of identity of dietary supplements. Some of these comments requested the flexibility of allowing this term either in the statement of identity or elsewhere on the label, such as on the principal display panel or in the directions for use. A couple of comments stated that, if the nutrition label was given the title ''Dietary Supplement Facts,'' a consumer could utilize the nutrition label to identify the

product as a dietary supplement, making it unnecessary to include the term as part of the statement of identity. Other comments requested that FDA allow for reasonable flexibility in the use of synonyms or modifiers for the term ''dietary supplement,'' such as ''Nutritional Supplement,'' ''Herbal Supplement,'' ''Multivitamin/Multimineral Supplement,'' or ''Amino Acid Blend.''

The comments presented a number of reasons for their disagreement with the proposal. Several comments stated that the inclusion of the term ''dietary supplement'' as part of the statement of identity on the principal display panel overreaches the legislative intent of the DSHEA. These comments stated that the DSHEA does not specify where the term ''dietary supplement'' should be placed, and that, therefore, flexibility of placement of the term is warranted. One comment stated that it objected to FDA transforming an ''identify'' requirement in the DSHEA into an ''identity'' requirement in the use of the term ''dietary supplement.'' The comment asserted that the term ''identify'' in the DSHEA is different from the requirement in 15 U.S.C. 1453(a)(1) (i.e., ''the identity of the commodity''), upon which the identity labeling provisions in § 101.3 are based. Several comments stated that the term ''dietary supplement'' by itself is inappropriate as a common descriptor for dietary supplements because they include a wide range of products, which meet vastly different consumer needs. These comments stated that the term ''dietary'' does not add additional value to the statement of identity, and that consumers might interpret the term ''dietary'' as part of the statement of identity to suggest that the supplement is a weight loss or meal replacement product. These comments stated that the statutory requirement that the term ''identify'' the product could be satisfied with the use of the term ''supplement.'' One comment submitted a market research study on consumer perception of the term ''dietary supplement,'' which indicated that over 50 percent of the subjects were confused by the term when used with the claim ''high potency.'' One comment stated that the United States Pharmacopeia (USP) has established a number of monographs of official names for specific nutritional supplements but they do not include the term ''dietary supplement.'' Several comments pointed out that use of the term ''dietary supplement'' is not part of their products' trademarked terminology.

Several comments suggested that the agency provide alternate requirements for dietary supplements in conventional food form to distinguish them from conventional foods (e.g., cereals, snack bars, drinks), requiring that the term ''dietary supplement'' appear on the principal display panel, although not necessarily as part of the statement of identity. These comments stated that dietary supplements in capsule or tablet form are obviously dietary supplements, are easily distinguished by consumers from conventional foods, and should not have the same identity requirement. A few comments argued that there are space limitations on the principal display panel of some dietary supplements, and that the term ''dietary supplement'' uses up available label space.

The agency has carefully reviewed these comments but concludes that the best reading of the act, as well as the agency's longstanding regulations that implement the act, require that the term ''dietary supplement,'' or some form of this term, appear as part of the statement of identity. Section 201(ff)(2)(C) of the act, in defining the term ''dietary supplement,'' mandates that such a product must be labeled as a dietary supplement. Section 403(s)(2)(B) of the act states that a food shall be deemed to be misbranded if it is a dietary supplement, and the label or labeling of the dietary supplement fails to identify the product by using the term ''dietary supplement, which term may be modified with the name of such an ingredient.'' Section 403(i)(1) of the act requires that a food label must bear the common or usual name of the food, that is, a statement that identifies the food. Dietary supplements are labeled subject to the provisions of section 403(i)(1) of the act (see the last sentence of section 201(ff) of the act). Thus, when the act is read in its entirety, it is clear that sections 201(ff)(2)(C), 403(s)(2)(B), and 403(i)(1) of the act require that the statement of identity of a product that is marketed as a dietary supplement identify the product as such.

FDA's longstanding regulations lead directly to this result. Section 102.5 (21 CFR 102.5) sets out how the common or usual name of a nonstandardized food is to be derived. Under this provision, the common or usual name must accurately identify or describe, in as simple and direct terms as possible, the basic nature of the food. The basic nature of a dietary supplement is that it is a dietary supplement. This is the point made in both sections 201(ff)(2)(C) and 403(s)(2)(B) of the act. Thus, under § 102.5(a), the common or usual name of these products must, at least in part, identify them as a dietary supplement. Section 101.3(b) of FDA's regulation states that the statement of identity of a food shall be in terms of its common or usual name. Thus, § 101.3(g) derives directly from the act and FDA's longstanding regulations that implement the act. Therefore, FDA is adopting § 101.3(g).

However, the agency is persuaded by the comments that flexibility in the use of the term ''dietary'' as part of the name ''dietary supplement''is warranted. The agency notes that section 403(s)(2)(B) of the act states that the product shall be identified ''by using the term 'dietary supplement,' which term may be modified with the name of such an ingredient.'' The agency interprets this provision to mean that the term ''dietary supplement'' may be modified to include the name of a dietary ingredient or ingredients (e.g., ''Vitamin C Supplement''). Furthermore, to provide additional flexibility, an identifying term that describes the types of dietary ingredients contained in the product in appropriately descriptive terms (e.g., ''Multivitamin Supplement,'' ''Herbal Supplement'') may be used. Generic terms that are not descriptive (e.g., ''Food Supplement,'' ''Energy Bar'') would not be appropriate because they do not identify or describe the dietary ingredients (e.g., protein, folic acid, arrowroot) or combination of ingredients that the product supplies.

Accordingly, FDA is revising § 101.3(g) to provide that the term ''dietary supplement'' may be modified by replacing the term ''dietary'' with the name of a dietary ingredient or ingredients or an appropriately descriptive term indicating the type of dietary ingredients that are in the product. The agency notes that, with this increased flexibility, several concerns expressed by the comments (e.g., possible difficulties with space limitations, potential consumer confusion, possible effects on established trademarked names) should be alleviated.

2. One comment asked that the agency change the type size requirements referred to in proposed § 101.3(g), which stated that ''* * * the label shall bear the term 'dietary supplement' as part of the statement of identity in conformance with the provisions of paragraph (d) of this section.'' The comment stated that the type size requirements of § 101.3(d) (i.e., that the statement of identity ''shall be in a size reasonably related to the most prominent printed matter on such panel'') cross-referenced in proposed § 101.3(g) might be counterproductive or impracticable for products in small packages with many dietary ingredients. The comment requested that the agency require the same minimum type size as

that for the declaration of the net quantity of contents (§ 101.105(i)(21 CFR 101.105(i))) because this would permit products to bear the statement of identity in a type size that would be a minimum of one-sixteenth of an inch.

FDA points out that § 101.3(d) does not include minimum type size requirements, but, as noted in the comment, it requires that the size of the statement of identity be related to the size of the most prominent printed matter on the label. Therefore, if the package size is small, and there are many dietary ingredients to be listed, it is reasonable to expect that even the most prominent printed matter will be relatively small, permitting the statement of identity to be proportionally smaller, in some cases as small as one-sixteenth of an inch. Therefore, the agency is taking no action based on this comment. However, because the reference in proposed § 101.3(g) to paragraph (d) of that section is redundant, inasmuch as all foods must meet all regulatory requirements unless specific exceptions are noted, FDA has deleted the reference to paragraph (d).

III. Nutrition Labeling of Dietary Supplements

A. Serving Size

3. Several comments stated that the term ''serving size'' is inappropriate on dietary supplements. One comment stated that the term ''serving size'' should not appear in the nutrition label of dietary supplements, except for products in the physical form of conventional foods or for products with significant amounts of calories and macronutrients, which should be covered by § 101.9. This comment recommended that the directions for use should provide the basis for the quantitative statements contained in the nutrition label. Another comment stated that the term ''serving size'' should not be used in the nutrition label of herbal products and suggested the terms ''recommended use'' or ''suggested use.'' This comment suggested the terms ''dose'' or ''dosage'' in the case of products marketed to health professionals.

The agency is not persuaded by the comments objecting to the term ''serving size.'' As discussed in the final rule of January 4, 1994 (59 FR 354 at 358), information on serving size is as essential on the nutrition label of dietary supplements as it is on that of conventional foods. The agency points out that the directions for use provide the basis for the serving size in the nutrition label of dietary supplements in that serving sizes are derived by the manufacturer in accordance with § 101.12 (21 CFR 101.12). Section 101.12(b), Table 2, states that the reference amount customarily consumed for dietary supplements is ''the maximum amount recommended, as appropriate, on the label for consumption per eating occasion * * *.''

Section 403(q)(1)(A)(i) of the act states that a food is misbranded unless its nutrition information specifies the serving size, and nothing in the DSHEA directs the agency to eliminate the use of this term in the nutrition label of dietary supplements. To the contrary, section 403(q)(5)(F)(ii) of the act, which was added by the DSHEA, states that the listing of dietary ingredients shall include the quantity of each such ingredient per serving. This fact establishes that Congress contemplated that serving size would be a part of the nutrition labeling of dietary supplements.

With respect to using other terms in place of the term ''serving size,'' the agency reiterates that the term ''serving size'' is consistent with the act, and that it would be confusing to consumers if the nutrition labels of dietary supplements used varied terms, such as ''recommended use'' or ''dose,'' in place of the term ''serving size.'' Use of the same term in the same place on all labels will help to avoid confusion. Therefore, the agency has not made any changes in response to these comments.

B. Information on Dietary Ingredients Having RDI's or DRV's

4. Several comments argued that some (sodium, vitamin A, vitamin C, calcium, and iron) or all of the 14 nutrients required under § 101.9(c) should be required to be listed on the labels of dietary supplements only when they are added to the supplement, or when a claim is made about them. These comments argued that dietary supplements of herbs or botanicals, for example, are not generally consumed for their nutritional value, and that, thus, having to determine the levels of the required nutrients would be unduly burdensome and of little use to consumers who rely on the nutrition information to structure their diets to maintain healthy dietary practices. One comment from an independent analytical laboratory stated that mandatory requirements for the listing of nutrients should not pertain to herbal products. This comment stated that official methods of analysis do not apply to herbal products and suggested that these products should be excluded from labeling regulations requiring analysis until such time as official methodology is published. Other comments specifically supported the proposed rule in requiring that macronutrients be declared whenever they are present.

FDA is not persuaded by the comments to modify § 101.36(b)(2). Section 403(q)(1) of the act specifies the nutrients that are to be listed in the nutrition labeling of foods, and section 403(q)(2) of the act gives the Secretary of Health and Human Services (the Secretary) discretion to add to, or subtract from, this list for the purpose of assisting consumers in maintaining healthy dietary practices. Section 403(q)(5)(F) of the act states that the labels of dietary supplements shall comply with the requirements of subparagraphs (q)(1) and (q)(2) in a manner that is appropriate.

In its final rule on nutrition labeling, the agency concluded that information on the calorie, calories from fat, total fat, saturated fat, cholesterol, sodium, total carbohydrate, dietary fiber, sugars, protein, vitamin A, vitamin C, calcium, and iron content of foods was necessary to assist consumers in maintaining healthy dietary practices (58 FR 2079, January 6,1993). Accordingly, these nutrients are required under § 101.9(c) to be listed in nutrition labeling.

In its December 1995 proposal, the agency tentatively concluded that these nutrients were equally as important to maintaining healthy dietary practices when present in dietary supplements and, therefore, should be mandatory on the labels of dietary supplement products as well. However, to ease label crowding and to be consistent with the DSHEA, FDA proposed that the 14 nutrients need only be listed on dietary supplement labels when present in quantitative amounts by weight that exceed the amount that can be declared as zero in accordance with § 101.9(c). FDA tentatively concluded that this action would provide consumers with the information necessary to determine how dietary supplement products fit into dietary regimens that adhere to dietary recommendations.

Dietary supplements are foods under section 201(ff) of the act, unless they are intended to be used as drugs. Moreover, under section 201(ff) of the act and some of the other changes made by the DSHEA, dietary supplements may well be in conventional food form and contain many of the 14 nutrients required to be listed in the nutrition label under § 101.9. Thus, as foods, it is appropriate to require that their labeling bear the same nutrients as the nutrition labeling on conventional foods, unless evidence is presented that justifies the contrary conclusion.

The comments presented no evidence that would be a basis for the agency to reach a conclusion different than it did for conventional foods, i.e., that the listing of these nutrients will assist consumers in maintaining healthy dietary practices. The agency is not convinced that this requirement should be eliminated because of the argument that herbs and botanicals are not generally consumed for their nutritional value. The fact that a product is not generally consumed for its nutritional value is immaterial under the act and its implementing regulations. For example, certain spices, such as paprika, which are consumed for their flavor-enhancing properties, not for nutritional value, are not exempt from nutrition labeling under § 101.9 if any nutrient is present at more than insignificant levels (§ 101.9(j)(4)). The agency concludes that it is appropriate for the nutrients required in § 101.9 to be mandatory on the labels of dietary supplements. Thus, the agency is not modifying

Moreover, one of the principles underlying the agency's food labeling initiative has been that, if nutrition labeling is to assist consumers in making dietary choices, it should provide consistent information for consumers to use (55 FR 29487 at 29490, July 19, 1990). For example, fat is mandatory on the labels of conventional foods because of scientific consensus that high dietary intakes of total fat are associated with an increased risk of coronary heart disease, some types of cancer, gallbladder disease, and obesity (55 FR 29487 at 29495). Thus, the listing of fat on the nutrition label, when it is present, will assist consumers in meeting dietary recommendations to limit fat intake to no more than 30 percent of calories, irrespective of whether the nutrition labels are for conventional foods or dietary supplements.

With respect to methodology issues, FDA is not persuaded that herbal products should be exempt from labeling until analytical methodology is validated for all herbal products. FDA is aware of the difficulties in adapting analytical methods to different matrices and specifically requested comment on this point in the proposal. The agency received comments from industry groups actively working on the development of official methodology, but these comments did not indicate that problems with methodology necessitate exempting herbs from nutrition labeling. Rather, FDA is aware that the adaptation of existing methods to different matrices (e.g., herbs) is ongoing. In addition, FDA has stated that analysis is not needed for nutrients where reliable data bases or scientific knowledge establish that a nutrient is not present in a serving of the product (58 FR 2079 at 2109). Therefore, it may not be necessary to analyze for several nutrients in herbal products. For example, there is no need to analyze for cholesterol because food composition studies have shown it to be found only in animal products.

Thus, FDA concludes based upon these comments and on its own experience that exempting herbs is unwarranted. Moreover, an exemption would be inconsistent with section 403(q)(5)(F) of the act. Therefore, the agency is not taking any action based on these comments.

5. Several comments requested more flexibility with the language used in place of ''Amount Per Serving.'' The comments requested use of phases such as ''Amount per 2 Tablets'' or ''Two Tablets Contain.''

The agency has no objection to the flexibility requested by these comments. The agency proposed in § 101.36(b)(2)(i)(A) that when the serving size of the product is one unit, a heading consistent with the declaration of the serving size, such as ''Amount Per Tablet'' or ''Each Tablet Contains,'' may be used in place of the heading ''Amount Per Serving.'' In response to these comments, the agency agrees that there is no reason to limit the language that can be used in this way. Therefore, the agency is deleting the words ''when the serving size of the product is one unit'' from § 101.36(b)(2)(i)(A) and adding the example ''Amount Per 2 Tablets.''

6. The agency received a couple of comments that recommended changes in nomenclature for thiamin and riboflavin. These comments requested that the name ''B_1'' be used instead of ''thiamin,'' and that ''B_2'' be used for ''riboflavin.'' One comment stated that consumers do not know that these are B vitamins and have been confused by the listing of thiamin and riboflavin on ''B-complex'' products. The comment stated that the mandatory use of ''thiamin'' and ''riboflavin'' is inconsistent with the educational purposes of the 1990 amendments and the DSHEA and recommended that the use of these names be optional following the numerical names. The comment recommended that this approach be followed on the labels of conventional foods as well.

The agency has previously considered this issue. As discussed in the proposal, the use of numerical terminology for these vitamins is obsolete (29487 at 29502). ''The Handbook of Vitamins'' concurs with this conclusion (Ref. 1, pp. 239 and 285). Also, the National Academy of Sciences' National Research Council (NAS/NRC) publication on ''Recommended Dietary Allowances'' (Ref. 2, pp. 125 and 132) uses the terminology ''thiamin'' and ''riboflavin,'' as does the nutrition labeling of conventional foods. Consistent terminology is needed for consumers to be able to calculate their total intake of these vitamins from all food products.

To provide flexibility in the labeling of dietary supplements, the agency proposed in the December 1995 proposal that the terms ''vitamin B_1'' and ''vitamin B_2'' may be listed as synonyms for thiamin and riboflavin. The agency is adopting this provision, so manufacturers who wish to inform consumers that these nutrients are B vitamins will be free to do so. Thus, they will be able to address any consumer confusion as to why these nutrients are included in B-complex products.

The agency concludes that the regulation it is adopting provides the requisite flexibility and yet ensures that the nutrition label conforms to up-to-date scientific views. Thus, FDA is not accepting the recommendation of these comments.

7. One comment requested that ''folic acid'' be listed instead of ''folate,'' stating that the use of ''folic acid'' is consistent with the final rule entitled ''Food Additives Permitted for Direct Addition to Food for Human Consumption; Folic Acid (Folacin),'' published in the **Federal Register** (61 FR 8797, March 5, 1996).

The agency agrees that the term ''folic acid'' can be listed in place of ''folate.'' The December 1995 proposal stated in § 101.36(b)(2)(i)(B)*(2)* that ''folic acid'' and ''folacin'' may be added in parentheses immediately following the listing of ''folate'' (60 FR 67194 at 67198). However, the health claims final rule on folate and neural tube defects, amended the nutrition labeling regulations that FDA had adopted for dietary supplements and conventional foods[1] to allow the terms ''folic acid'' or ''folacin'' to be used synonymously (61 FR 8752 at 8759, March 5, 1996)). In that final rule, the agency acknowledged that the terms ''folic acid'' and ''folate'' are interchangeable in common usage, although technically ''folic acid'' refers

[1] The regulations in place at that time were §§ 101.9(c)(8)(v) for conventional foods and § 101.36(b)(3)(v) for dietary supplements. Thus, FDA amended these regulations. FDA had yet to implement § 101.36(b)(3)(v), however (see 60 FR 7711, February 9, 1995), and, as part of the changes included in the December 1995 proposal, it renumbered this provision as § 101.36(b)(i)(B)*(2)*.

to the synthetic form of this vitamin, and ''folate'' is a general term that refers to both the synthetic and naturally-occurring forms.

Thus, the agency agrees with the comment that it is appropriate for ''folic acid'' to be listed by itself in place of ''folate.'' For clarity, the agency is modifying the language in §§ 101.36(b)(2)(i)(B)*(2)* and 101.9(c)(8)(v) to state ''alternatively, folic acid or folacin may be listed without parentheses in place of folate.''

8. Several comments recommended that the agency require that information on the quantitative amount by weight of each dietary ingredient be placed immediately after the name of the dietary ingredient, rather than in a separate column. The comments requested this change because of space constraints on the label and the cost of reformatting. One of these comments stated that consumers are already familiar with a format in which amounts immediately follow names on both dietary supplement and traditional food labels, and that there is no evidence that they have difficulties understanding this information. Other comments stated that the use of a single column should be optional. At least one comment specifically supported the proposed two columns because of readability.

The agency is persuaded that information on names and the corresponding amounts of dietary ingredients should be allowed to appear in one column to save space. In the January 4, 1994, final rule on labeling of dietary supplements, the agency required that the name of the nutrient and the quantitative amount by weight appear in a single column despite several comments that argued for a separate column for amounts. When the DSHEA amended the act to allow the source of a dietary ingredient to be listed in the nutrition label following the name, the agency's tentative view was that the additional information added sufficient complexity to make it appropriate to have the information on amount in a separate column. Some consumers buy dietary supplements on the basis of quantitative amounts, and FDA tentatively concluded that a separate column would help consumers to locate this information more readily . However, based on the facts the comments pointed out, that one column would make the dietary supplement nutrition label consistent with that on conventional foods, and that there are space and cost advantages to such a format, the agency has no objection to the optional listing of the quantitative information by weight immediately following the listing of names. The agency is modifying § 101.36(b)(2)(ii) accordingly.

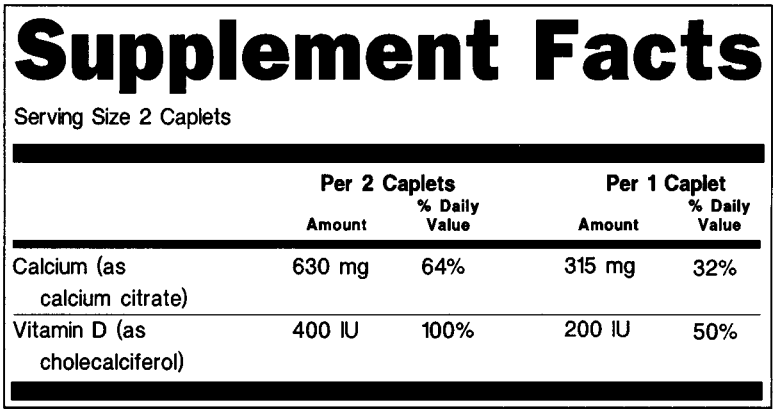
9. A few comments stated that quantitative information should not be declared on the basis of ''per serving.'' Some of these comments requested that information be declared ''per day.'' These comments argued that what is consumed per day is more important than per serving. A couple of other comments preferred dual listing. One suggested ''per unit and per day,'' and the other suggested ''per serving and per day.'' Other comments specifically favored a ''per serving'' basis and opposed dual listing.

The agency does not agree that quantitative information should be declared on a ''per unit'' or a ''per day'' basis instead of ''per serving.'' In its proposal on June 18, 1993 (58 FR 33715 at 33716), FDA tentatively concluded that listing information on the basis of ''per serving'' was preferable to ''per day'' because consumers might not actually consume the amount indicated ''per day.'' With respect to ''per unit,'' FDA expressed concern that this basis alone could confuse consumers when more that 1 unit is to be consumed at one time (e.g. two capsules with each meal) because they might assume that the information is on a ''per serving'' basis because the labels of conventional foods are presented in this manner. For these reasons, the agency required a ''per serving'' basis in the final rule of January 4, 1994 (59 FR 354 at 359), and carried this forward in the December 1995 proposal (60 FR 67194 at 67198). More importantly, the act states in section 403(q)(5)(F)(ii) that the listing of dietary ingredients shall include the quantity of each such ingredient ''per serving.'' Therefore, FDA is not changing § 101.36(b)(2)(ii), which requires that quantitative information be listed on the basis of ''per serving.''

However, with respect to dual listing, the agency is persuaded that there may be some products on which the unit amount may be of interest to consumers, and, therefore, FDA is modifying the regulation to allow the option of listing information on a ''per unit'' basis in addition to a ''per serving'' basis. The agency notes that § 101.9(b)(10)(ii) permits the percent of Daily Value (DV) on the labels of conventional foods to be listed in this manner when the product is in discrete units, and a serving is more than 1 unit. Thus, the agency is adding § 101.36(b)(2)(iv) to provide for quantitative information to be presented voluntarily on the basis of ''per unit'' in addition to the required declaration ''per serving'' as noted in § 101.36(b)(2)(ii). When information is presented on a ''per unit'' basis, it must be declared in additional columns to the right of the ''per serving'' information and must be clearly identified by appropriate headings, as illustrated in Figure 1.

BILLING CODE 4190–01–F

Figure 1



Supplement Facts

Serving Size 2 Caplets

	Per 2 Caplets		Per 1 Caplet	
	Amount	% Daily Value	Amount	% Daily Value
Calcium (as calcium citrate)	630 mg	64%	315 mg	32%
Vitamin D (as cholecalciferol)	400 IU	100%	200 IU	50%

Other ingredients: Polyethylene glycol, carnauba wax, magnesium stearate, and beeswax.

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10. One comment requested different rounding rules for sugars. The comment wanted to be able to declare amounts under 2 grams (g) in tenths of a g or to be able to declare 0, 0.5, 1.0, 1.5 and 2.0 g. This comment stated that sugars are present in much smaller amounts in dietary supplements than in conventional foods, and that the proposed rounding rules are inappropriate.

The agency is not persuaded by the comment. Section 101.9(c)(6)(ii) provides that sugars are expressed to the nearest g, except that if a serving contains less than 1 g, the statement ''less than 1 gram'' may be used, and if the serving contains less than 0.5 g, the content may be expressed as zero. While sugars may be present in much smaller amounts in dietary supplements than in conventional foods, FDA points out that the comment did not justify why amounts of sugars that are under 2 g should be listed any differently on the labels of dietary supplements than on the labels of conventional foods. Moreover, given that amounts under 0.5 g are considered nutritionally insignificant, the agency is not convinced that being able to declare sugars in tenths of a g or half-gram increments up to 2 g is useful in helping consumers to maintain a healthy diet. Accordingly, the agency is not changing § 101.36 in response to this comment.

11. One comment requested clarification of the use of the word ''actual'' in proposed § 101.36(b)(2)(ii)(B), which states ''The amounts of vitamins and minerals, excluding sodium and potassium, shall be the actual amount of the vitamin or mineral included in one serving of the product * * *.'' This comment stated that overages of dietary ingredients that are subject to degradation are added to dietary supplement products to ensure that the products provide the labeled quantities throughout their shelf life. The comment asked FDA to acknowledge in the preamble of the final rule that the labeled amounts of vitamins and minerals are not necessarily the actual amounts added at the time of manufacture, and that the corresponding percent DV is based on the labeled amount.

The agency agrees that the proposed language is not clear with respect to what amount is to be declared. The agency does not intend that the declared amount include any overages that a manufacturer includes in anticipation of degradation. By use of the word ''actual,'' the agency was trying to draw a distinction between sodium and potassium, which are required to be declared in the increments prescribed in § 101.9(c), and other vitamins and minerals, for which increments are not prescribed in § 101.9(c). (Section 101.9(c) does not require declaration of the quantitative amounts by weight for these other vitamins and minerals, only that they be declared as a percent of the DV for the nutrient. Thus, the increments for declaration of the quantitative amount of these nutrients are not specified in § 101.9(c).)

Given the reaction to §§ 101.36(b)(2)(ii)(B) and 101.36(b)(2)(iii)(B) that is reflected in the comments, FDA concludes that use of the word ''actual'' in these provisions is confusing. Therefore, the agency is revising these paragraphs to delete this word.

12. Several comments agreed that the regulation should allow the use of ''<1%'' in place of ''less than 1%'' to save space. Some of these comments supported the use of ''<1%'' on the labels of conventional foods as well as on the labels of dietary supplements. One of these comments stated that this symbol for ''less than'' is taught in elementary math and science classes nationwide and is universally recognized. One comment from a trade association that represents manufacturers of conventional foods stated that the food industry has not been permitted the use of this symbol as there was no information demonstrating that consumers understand its meaning. This comment was opposed to the use of the symbol on the labels of dietary supplements until conventional foods are also able to use it.

FDA is persuaded by the comments to allow for the use of the symbol ''<'' for ''less than'' on the labels of dietary supplements and conventional foods to provide more flexibility when space is limited on the label. While there is no consumer survey data to show the level of consumer understanding of the symbol, the agency acknowledges that elementary and secondary schools are teaching its use, so that a growing number of consumers can be expected to understand its meaning. In addition, the agency is aware that the symbol ''<'' is being used on the labels of some conventional foods, and FDA has not received any consumer complaints about its use. Given these unique circumstances, FDA concludes that it is reasonable to allow use of the symbol, thereby reducing the possibility of overcrowding of information on some nutrition labels. Accordingly, § 101.36(b)(2)(iii)(C) is finalized as proposed.

The agency stated in the December 1995 proposal (60 FR 67194 at 67200)

that if it allowed the symbol on the nutrition labels of dietary supplements, it intended ''to provide for such use'' on the nutrition labels of conventional foods as well. FDA finds that it reasonably follows from this statement, and from the conclusions that it has reached with respect to dietary supplements, for it to take this action. Accordingly, the agency is amending § 101.9(c)(8)(iii) and (d)(7)(i) to allow the use of the symbol ''<'' in place of the words ''less than.''

13. Several comments supported the proposed use of the footnote ''Daily Value not established''(§ 101.36(b)(2)(iii)(F)). However, three comments were against the use of this footnote in some cases. These comments stated that the footnote implied that a DV was not ''yet'' established. Consequently, they stated that it should only be permitted for components having some legitimate claim to nutritional value. One comment said that dietary ingredients such as choline should have an asterisk and a footnote, while dietary ingredients such as bee pollen should have no asterisk and no footnote. This comment said that a product composed solely of dietary ingredients such as bee pollen should have no ''% Daily Value'' column, no asterisks, and no footnote.

The agency does not agree with the comments that argued that the footnote apply only to dietary ingredients that ''have nutritional value.'' The comments did not suggest a definition for dietary ingredients that have a ''claim to nutritional value,'' or how to distinguish such dietary ingredients from the other dietary ingredients for which no DV has been established. Thus, the agency does not know how it would implement the suggested change. The act makes it clear in section 403(q)(5)(F)(i) that dietary ingredients not having a recommendation for daily consumption established by the Secretary are to be identified as ''having no such recommendation.'' Accordingly, FDA is adopting § 101.36(b)(2)(iii)(F) unchanged from the proposal.

C. Other Dietary Ingredients

14. Several comments recommended that ''other dietary ingredients'' (those not having recommendations, i.e., no RDI's or DRV's) should be listed outside the ''box'' format for nutrition information, and that products composed solely of these dietary ingredients, such as herbal supplements, should not be required to use the ''box'' format. One of these comments suggested not requiring a ''box'' format unless a claim is made. These comments stated that herbal supplements are not consumed for their nutritional value, and that it is not appropriate to use a format that mimics that of the Nutrition Facts panel. They said that the use of such a format would confuse consumers and would not convey any meaningful information. They argued that such a format goes beyond the intention of the DSHEA.

One comment stated that simple ingredient listing should be an option in lieu of nutrition labeling. Another comment, which requested more flexibility, said that the agency should allow the ''labeler to present the information to the consumer in the best way they see fit.'' One other comment stated that flexibility in format was needed because of space constraints and recommended that the special labeling provisions in § 101.9(j)(13) should apply to dietary supplements.

The agency is not persuaded by these comments that the format that it proposed goes beyond the intention of the DSHEA. To the contrary, the agency concludes that the format is consistent with the DSHEA.

As a result of the DSHEA, the act requires that nutrition information immediately precede the ingredient information (section 403(q)(5)(F)(iv)), requires that the nutrition information list dietary ingredients not having recommendations (section 403(q)(5)(F)(i)), and defines herbs and other botanicals as dietary ingredients when present in dietary supplements (section 201(ff)(1)). Taken together, the only logical reading of these provisions is that herbal dietary ingredients are to be listed in the nutrition information. Accordingly, the agency is not making any change in § 101.36 in response to these comments. The agency notes that § 101.36(i)(2) provides that dietary supplements are subject to the special labeling provisions specified for small and intermediate-sized packages in § 101.9(j)(13).

15. Several comments requested that the ''other dietary ingredients,'' those not having RDI's or DRV's, including those in a proprietary blend, should be allowed to be declared in paragraph form beneath the bar required in § 101.36(e)(6)(ii) (i.e., in a linear format with the quantity of each dietary ingredient immediately following the name of the ingredient itself) to save space. An example of such a label was included in one comment. One comment from a dietary supplement manufacturer stated that the majority of its products would qualify for an exemption or a linear layout under the special provisions for small or intermediate-sized packages in § 101.9(j)(13) if they were labeled as conventional foods.

FDA points out, as stated in response to the previous comment, that § 101.36(i)(2) provides that dietary supplements are subject to the special labeling provisions specified in § 101.9(j)(13) for foods in small or intermediate-sized packages, which includes the option of a linear layout when there is insufficient space for the vertical or tabular display. Also, § 101.36(c)(2) provides that the ''other dietary ingredients'' contained in a proprietary blend may be listed in linear fashion indented under the term ''Proprietary Blend.'' In addition to the flexibility that these sections provide, FDA has no objection if a linear display is used for the listing of all ''other dietary ingredients'' on the labels of dietary supplement products, regardless of package size. However, as discussed in comment 18 below, when constituents (i.e., subcomponents) of ''other dietary ingredients'' are listed, they must be indented under the listing of the dietary ingredient. Thus, it is not possible to use a linear display for ''other dietary ingredients'' when constituents are listed for any of them.

Therefore, the agency is revising § 101.36(b)(3)(i) and (b)(3)(ii) to provide explicitly that other dietary ingredients may be declared in a linear display as long as none of the dietary ingredients list constituents. Figure 2 illustrates the declaration of other dietary ingredients in a linear display.

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Figure 2

Supplement Facts

Serving Size 2 Capsules

Amount Per 2 Capsules		% Daily Value
Vitamin C	30 mg	50%
Calcium (from dicalcium phosphate)	200 mg	20%
Phosphorous (from dicalcium phosphate)	125 mg	12%

Choline (from choline bitartrate), 30 mg*; Inositol, 15 mg*; Alfalfa Powder, 25 mg*

* Daily Value not established.

Other ingredients: Gelatin, cellulose, magnesium stearate, water.

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16. One comment recommended that the listing of other dietary ingredients be alphabetical. The comment stated that this order would be user-friendly and assist consumers in making comparisons between various products. Several other comments specifically stated that they agreed with the proposed rule, which would allow the manufacturer to determine the order of these dietary ingredients. One of these comments stated that there is no obvious benefit to alphabetical order or to descending order of predominance by weight because the quantity of each dietary ingredient is included. Another comment stated that order based on predominance by weight could confuse consumers by incorrectly implying that the dietary ingredients that are present in greater predominance are of greater value.

As discussed in the proposal (60 FR 67194 at 67210), the agency considered proposing to require alphabetical order but did not because it is not scientifically meaningful. The agency requested comments on this issue. Because the majority of the comments supported the flexibility provided in the proposal, the agency is not persuaded that it is necessary to require that other dietary ingredients be listed in alphabetical order. Manufacturers may, of course, do so if they choose.

17. Several comments strongly opposed the statement in proposed § 101.36(b)(3)(ii) that ''or any dietary ingredients that are liquid extracts, the weight shall not include the weight of solvents.'' The comments stated that the proposal is not practicable because in many cases there are no methods to determine the identity and quantity of entities dissolved in solvents. One comment from a trade association of manufacturers of natural food products stated that FDA should allow a truthful and nonmisleading description of the content of an extract, such as the ratio of the weight of the starting material to the volume of the solvent used. This comment said that the association is working with other industry groups to develop a uniform method of reporting this information that is not false or misleading. Another comment pointed out that the ratio method could be misleading in the absence of compendial standards because different supplies of the same herb can yield various strengths and potencies. For this reason, the comment discouraged the use of indicators of activity until compendial standards are established.

Another comment stated that FDA should defer action on this issue until there is scientific agreement on appropriate methodology and, in the interim, require that extracts be listed with the weight of the entire extract. A comment from a trade association for herbal product manufacturers agreed that extracts should be listed with the weight of the entire extract, e.g. ''Dandelion root extract (0.5 fl oz).'' This comment said that the identity of the dietary ingredients of botanical liquid extracts are the herbal extracts themselves.

The agency is persuaded by the comments that the proposed manner of declaring extracts is not appropriate. The agency acknowledged in the proposal that this matter is a difficult one and specifically requested comment on how these provisions should be implemented. The comments pointed out that the dietary supplement industry and others are developing methods that will result in better information on the composition of such extracts. However, FDA does not agree that it should defer action until validated methods are available or, in the meantime, require only that manufacturers list the weight of the entire extract. The agency is persuaded by the comment that recommended that extracts should be described by a ratio of the weight of the starting material to the volume of the solvent or a description of these values, which would indicate the concentration of the extract. The agency notes that the label must state whether the starting material is fresh or dry. Because fresh botanicals contain water, it is important that the label have this information so that consumers can determine whether the weight listed includes the weight of any water.

FDA has subdivided proposed § 101.36(b)(3)(ii) to address the listing of liquid extracts in § 101.36(b)(3)(ii)(B) and of dried extracts in (b)(3)(ii)(C). The agency is requiring in § 101.36(b)(3)(ii)(B) that the label of liquid extracts clearly state whether the

starting material is fresh or dry, what solvent is used, and the concentration of the botanical in the solvent, e.g., ''fresh dandelion root extract, x mg (y:z) in 70% ethanol'' where ''x'' is the number of mg of the entire extract, ''y'' is the number of mg of the starting material and ''z'' is the number of milliliters of solvent. Where the solvent has been partially removed (not to dryness), the final concentration should be stated (e.g., if the original extract had a ratio of 1:5, and 50 percent of the solvent were removed, the concentration listed would be 1:2.5).

Section 101.36(b)(3)(ii)(C) of this final rule states that where the solvent is removed to dryness, the weight of the dried extract must be listed. Also, the dried extract must be described in a manner that includes the identity of the solvent because the solvent used determines the composition of an extract. For example, hexane as a solvent would concentrate nonpolar constituents, and water would concentrate polar constituents. These two dried extracts could have very different compositions. Thus, the type of extract (e.g., ''dried hexane extract of _____'' or ''_____, dried hexane extract'') is a material fact under sections 201(n) and 403(a) of the act and must be specified on the label, even when the solvent is removed during processing.

The agency points out that solvents removed during processing that do not have any technical or functional effect in a food are exempt from being listed in ingredient labeling in accordance with § 101.100(a)(3)(ii)*(a)* (21 CFR 101.100(a)(3)(ii)*(a)*. However, solvent information is needed in the nutrition label of dietary supplements to appropriately describe extracts because dietary ingredients do not have individual regulations, like the regulations for food additives, that specify how they are to be made, and, when needed for identity or safety reasons, what solvent can be used in the processing. For example, § 172.580(b) (21 CFR 172.580(b)) states that safrole-free extract of sassafras is to be obtained by extracting the bark specified with dilute alcohol. There is no parallel provision for, nor is § 172.580(b) applicable to, the use of this substance in a dietary supplement. Therefore, in the absence of individual regulations on dietary ingredients, the agency is requiring in § 101.36(b)(3)(ii) that a dried extract be described by an appropriately descriptive term that identifies the solvent used.

18. Several comments requested the flexibility of listing both a dietary ingredient and one or more of its constituents (i.e., subcomponents) to provide consumers with more information. One of the comments favoring this approach stated that, while two different supplements may both contain the same amount of a botanical, one product may yield twice as much of a particular constituent as the other brand. Most of these comments suggested that constituents of a dietary ingredient should be indented under the listing of the dietary ingredient because consumers are familiar with this format, as it is comparable to the format used for certain DRV nutrients and their subcomponents in the nutrition labeling of conventional foods. Alternatively, a couple of comments suggested that constituent information immediately follow the listing of the dietary ingredient within parentheses. Most of the comments gave examples where both the constituents and the dietary ingredients do not have RDI's or DRV's, but one comment suggested that vitamin A and vitamin C should be indented under fish oil. One comment stated that if FDA does not allow information about constituents inside the ''Supplement Facts'' box, it should clarify that such information is allowed elsewhere on the label.

The agency is persuaded by the comments to allow more flexibility with respect to the listing of constituents of dietary ingredients that do not have RDI's or DRV's, as long as the resultant labels are not inconsistent with the act and are not confusing to consumers. The agency is requiring that constituents, when they are listed, be indented under the listing of the dietary ingredient in either a column or, to save space, in a horizontal linear display. Quantitative amounts of the constituents must be listed and also must be included in the total quantitative amount listed for the dietary ingredient. The agency is requiring that the dietary ingredient and its weight be presented on one line, and that any information on constituents be indented under the declaration of the dietary ingredient to help clarify to consumers that the constituents are contained in the dietary ingredient. Accordingly, the agency is adding new § 101.36(b)(3)(iii) to provide that the constituents of dietary ingredients not having RDI's or DRV's may be listed. Proposed § 101.36(b)(3)(iii) is redesignated as § 101.36(b)(3)(iv).

When constituents of other dietary ingredients are dietary ingredients described in § 101.36(b)(2), they are to be listed in accordance with § 101.36(b)(2). Section 403(q)(5)(F)(i) of the act provides that dietary ingredients having recognized dietary recommendations are to be listed first to be followed by the dietary ingredients not having recommendations. Accordingly, with respect to the fish oil example, § 101.36(b)(2) requires that vitamin A and vitamin C be listed in the top half of the nutrition label, and that source information may be included following the listing of each in accordance with section 403(q)(5)(F)(iii) of the act , e.g., ''vitamin A (from fish oil).'' Listing vitamin A and vitamin C as constituents under the listing of fish oil is inconsistent with section 403(q)(5)(F) of the act.

D. Proprietary Blends

19. One comment stated that there is no need to require a dietary supplement that is a proprietary blend to be identified specifically as a ''proprietary blend.'' This comment gave an example that used the word ''blend'' in place of ''proprietary blend'' and noted that there are synonyms of ''blend'' that would also accurately describe these products. However the comment did not list specific synonyms. The comment stated that there is no reason to limit label flexibility in this regard. Other comments supported the use of the term ''proprietary blend.'' One comment stated that, while a company has the obligation to identify such blends, most users of these blends have devised fanciful or trademarked names for them, and the term ''proprietary blend'' should not have to be repeated in the top half of the nutrition label when source information is included in parentheses, and the blend is a source of one or more of the 14 mandatory nutrients.

FDA is persuaded by the comment that it is not necessary to include the term ''proprietary blend'' when the blend is identified by another term or fanciful or trademarked name. Inasmuch as the act does not require use of the term ''proprietary blend,'' and the formatting requirements (i.e., declaration of total weight of blend followed by listing of dietary ingredients in the blend) will make the presence of a proprietary blend apparent, the agency is modifying § 101.36(c), (c)(2), and (c)(3) to state that the blend may be identified by the term ''Proprietary Blend'' or another appropriately descriptive term or fanciful name.

Regarding the comment that stated that the name of a proprietary blend should not have to be repeated each time it is a source of a nutrient, the agency points out that this would not happen. Firms are to list the specific ingredient in a proprietary blend that supplies a nutrient, rather than list the name of the proprietary blend.

20. Another comment requested that the words ''Proprietary Blend'' be allowed in bold type. The comment stated that in some instances, a bold type heading may be easier to see and to understand than an indented list of ingredients below the heading. The comment did not include a sample label illustrating its recommendation.

The agency is not persuaded that bolding the term ''Proprietary Blend'' is preferable to indenting the dietary ingredients in the blend under the term to show that these ingredients are included in the blend. Indentation is used in other situations to convey the concept of inclusion (e.g., in the listing of subcomponents of nutrients in nutrition labels on conventional foods in § 101.9(c) and on dietary supplements in § 101.36(b)(2)(i)(B)). As an example, § 101.9(c)(2)(i) provides that ''Saturated Fat'' be indented under the listing of ''Total Fat.''

At the same time, § 101.9(d)(1)(iv) provides that nutrients that are not indented, such as ''Total Fat'' and ''Total Carbohydrate,'' are to be bolded. Consequently, while the agency has decided to retain the requirement in § 101.36(c)(2) that dietary ingredients contained in a proprietary blend be indented under the term ''Proprietary Blend'' or descriptive term or fanciful name used in its place, FDA does not object to the voluntary bolding of this term. Accordingly, the agency is changing § 101.36(c) to permit bolding.

21. One comment objected to the requirement that a proprietary blend list its dietary ingredients in descending order of predominance by weight. This comment requested that the agency permit the listing of a ''lesser ingredient'' first when the weight of the ingredient is specified. The comment did not give a reason for this request.

FDA is rejecting this request. To allow a dietary ingredient in a proprietary blend to be listed first when its weight is voluntarily declared would create an implication that there is less of the other dietary ingredients in the blend than the ingredient that is listed first. The only way to avoid creating this impression would be to list the weight of each of the other ingredients. Yet, by definition, the amounts of the ingredients in the blend are proprietary. Thus, the agency concludes that, when a proprietary blend is involved, the only way to avoid misleading consumers is to require that the ingredients of the blend be listed in descending order of predominance. If a manufacturer wishes to voluntarily list the weights of ingredients, it is free to do so, but FDA is not requiring such a disclosure for other dietary ingredients in a proprietary blend. Therefore, FDA is not changing § 101.36(c)(2) in response to this comment.

E. Sources

22. Several comments requested that dietary ingredient sources be permitted to be declared in the nutrition label without parentheses or without the word ''as'' or ''from.'' One of these comments stated that these points should be left up to the judgment of the manufacturer. This comment stated that the meaning of ''calcium from calcium carbonate'' is clear without the use of parentheses, and that flexibility is needed to save space. One comment expressed support for the proposal and stated that the format proposed will help consumers to understand the relationship between the dietary ingredient and its source.

The agency is not persuaded that space constraints justify making the use of parentheses, or of the words ''as'' or ''from,'' optional. In fact, some dietary supplements in small or intermediate-sized containers currently use the words ''as'' or ''from'' to help consumers understand that such compounds are the source of the dietary ingredients.

The agency continues to be concerned that allowing flexibility in the manner in which dietary ingredient sources are listed in the nutrition label could lead to consumer confusion. FDA has received many inquiries over the years that questioned whether amounts specified on labels refer to the weight of a particular nutrient or to the salt of that nutrient used to make the supplement. Having parentheses around the source compound makes it clear that the quantitative amount and % DV pertain to the dietary ingredient listed and not to the source. Thus, FDA concludes that the format that it proposed is the most clear and should not be optional. Accordingly, FDA is not changing § 101.36(d) in response to these comments.

23. The agency received a comment on the proposed requirement (see proposed §§ 101.4(g) and 101.36(d)) that the ingredient list on dietary supplements be preceded by the word ''Ingredients'' or, when some ingredients (i.e., sources) are identified within the nutrition label, by the words ''Other ingredients.'' The comment, which was from a trade association for conventional foods, noted that the term ''Ingredients'' is in common usage in the labeling of conventional foods to denote the ingredient declaration but is not required. The comment stated that this requirement would set an adverse precedent for the labeling of conventional foods and requested that the use of these identifying terms be optional.

The agency acknowledges that the ingredient declaration on the labels of conventional foods are not required to be preceded by the word ''Ingredient.'' However, the labels of conventional foods do not allow ingredient information in the nutrition label, so the potential for consumer confusion is not an issue. Given the fact that the DSHEA requires dietary ingredients not having RDI's or DRV's to be listed in the nutrition label of dietary supplements along with their amounts and also permits the sources of these dietary ingredients to be included in the nutrition label, the agency concludes that it is important that the nutrition information and the ingredient information on labels of dietary supplements be clearly identified. Inasmuch as no comments from the dietary supplement industry objected on this point, and as the situation presented by dietary supplements is distinguishable from that presented by conventional foods, FDA does not view this regulatory action as setting a precedent for conventional foods. Thus, the agency is not making any changes in § 101.36(d) or § 101.4(g) on the designation of ingredients in response to this comment.

24. One comment urged the agency to abandon the requirement in proposed §§ 101.36(d) and 101.4(h) that the common or usual name of ingredients that are botanicals be followed by the Latin binomial name of the plant. This comment stated that Latin binomials are generally meaningless to consumers and take up valuable label space. Another comment stated that Latin binomials should only be used on dietary supplements sold to health professionals because they have the training to understand them. Several other comments pointed out that the book *Herbs of Commerce* (Ref. 11) establishes individual common names for over 600 of the most prominent botanical ingredients in trade and gives the corresponding Latin name for each common name. These comments recommended that the agency require the use of these standardized common names in labeling and not require the listing of Latin names when they are available in this reference. Other comments did not object to listing Latin binomials but did object to including the designation of the author who published the name. Another comment requested that abbreviations of Latin binomials be allowed to save space.

The agency is persuaded by the comments that the common names for botanicals standardized in the book

Herbs of Commerce (Ref. 11) should be used in labeling. Because this reference lists the Latin binomial for each standardized common name, the agency is persuaded that a Latin binomial need not be included on labels when this information is available in *Herbs of Commerce* (Ref. 11). Thus, the agency is changing §§ 101.36(d)(1) and 101.4(h) accordingly. Latin binomials will be required except when the common or usual name of the botanical is available in this reference, and the designation of the author will be needed when a positive identification can not be made in its absence (§ 101.4(h)(2)). The agency reiterates that when a Latin binomial is required, the complete binomial is required for each botanical present, even when multiple species of the same genus are present.

With respect to the use of abbreviations of Latin binomials, the agency proposed that any name in Latin form shall be in accordance with internationally accepted rules on nomenclature, such as those found in the *International Code of Botanical Nomenclature*, which does not include rules for the use of abbreviations (Ref. 12). The comment that requested that abbreviations be permitted did not address why they should be permitted when they are not included in the *International Code of Botanical Nomenclature* (Ref. 12). In the absence of clearly defined rules, the agency is concerned that allowing abbreviations would cause a great deal of confusion. For example, there are 66 plant names that could be represented by the abbreviation ''*A. alba*.'' For this reason, the agency is not changing the regulation to allow for Latin binomials to be abbreviated.

25. One comment requested that FDA not require the declaration of the part of the plant for botanical ingredients that are used as a source material for other dietary ingredients. This comment stated that section 403(s)(2)(C) of the act requires that the labeling identify the part of the plant from which an herb or other botanical dietary ingredient is derived. Thus, the comment contends that this information should not be required when an herb or other botanical is the source of a dietary ingredient.

The agency agrees with this comment. As stated, the act, as a result of the DSHEA, requires identification of the part of a plant when a supplement contains a dietary ingredient that is an herb or other botanical. However, a constituent (i.e., a chemical component) of a botanical may be a dietary ingredient under section 201(ff)(1)(F) of the act. When a constituent is listed, the agency agrees that information on the part of the plant is not required by the act.

26. Several comments objected to the requirement that the part of the plant be listed in parentheses after the listing of the Latin binomial. These comments requested that, as an alternative to allow flexibility and to save space, the listing of the part of the plant be permitted without parentheses following the common name of the plant. One of these comments stated that listing the part of the plant in this manner was more comprehensible.

The agency points out that these final regulations do not require that Latin binomial names be included when they are available in *Herbs of Commerce* (Ref. 11) (see comment 24 in section III.E. of this document). In these cases, the part of a plant would immediately follow the listing of the common name. When a Latin binomial name is required, the agency has no objection to having it be listed after the part of the plant. Furthermore, FDA is persuaded that, to save space, the listing of the part of the plant should be permitted to follow the common name of the plant without parentheses. Therefore, the agency is reversing the order of proposed § 101.4(h)(1) and (h)(2) to reflect the order in which the information is to be provided and is revising the paragraph renumbered as § 101.4(h)(2) in response to these comments. The agency notes that § 101.36(d)(1) does not need to be changed in response to these comments as it cross references § 101.4 and does not provide specific information on how to list the part of a plant.

27. One comment requested the option of listing each of the separate parts of a plant instead of the words entire ''plant,'' when all parts of a plant are used. The comment stated that it is quite rare to actually use all parts of a plant. This comment also requested that the word ''herb'' be permitted to refer to the above ground parts of a plant. The comment said that Webster's *New Universal Dictionary* (2d ed., 1983) gives ''herbage'' as a definition of ''herb,'' and that ''herbage'' is defined as ''the green foliage and juicy stem of herbs.''

The agency does not object to the listing of each of the separate parts of a plant instead of the words ''entire plant.'' While this point was not addressed in the codified section of the proposal, the agency did make the statement in the preamble that when an entire plant is used, the label should specify ''entire plant'' to meet the requirements of the act. The agency made this statement assuming that manufacturers would not want to list all the parts of a plant. However, the agency would not object if a manufacturer listed all the individual parts of a plant because such a listing is consistent with the DSHEA.

Regarding the request that the word ''herb'' be permitted to describe the above ground parts of a plant, the agency is not convinced that this usage is appropriate. FDA notes that the primary definition of the word ''herb'' in many dictionaries refers to a type of a plant, i.e., a nonwoody plant whose aerial portion is relatively short lived (only a single growing season in the temperate zone), rather than a part of a plant. Accordingly, the agency is not persuaded by the comment that consumers would understand the term ''herb'' to mean that part of the plant grown above ground and is denying this request. However, the agency has no objection to the use of the term ''aerial part'' to describe the above ground parts of a part.

F. Format

28. Several comments requested that the nutrition label be entitled ''Nutrition Facts'' for all dietary supplements. These comments stated that ''Nutrition Facts'' should be used for a variety of reasons, including that: (1) These products are marketed for their nutritional value, (2) the information presented is about nutrition, (3) the DSHEA uses the term ''nutrition information'' (see section 403(q)(5)(F)(i) of the act), (4) the heading should be consistent with the heading used for conventional foods, (5) some conventional foods do not have nutritional value; thus, ''Nutrition Facts'' on dietary supplements is acceptable, and (6) consumers would be confused by the heading ''Supplement Facts'' and think that the products are of lesser value than conventional foods. One of these comments said that the heading ''Supplement Facts'' is a misnomer because it implies that the information is supplemental and not complete. Another comment stated that the heading ''Supplement Facts'' would be a violation of § 101.9(k)(6), which provides that a food is misbranded if its label differentiates in any way between vitamins that are naturally present and those that are added.

Other comments recommended that the use of the heading ''Nutrition Facts'' or ''Supplement Facts'' should depend on the composition of a particular dietary supplement. Some of these comments stated that a product containing even one vitamin or mineral having a DV-nutrient should be able to use the heading ''Nutrition Facts'' because the product would have nutritional value. Another comment

wanted products containing only DV-nutrients to use the heading ''Nutrition Facts'' and had no opinion on other products. Other comments said that products that were mostly DV-nutrients should use the heading ''Nutrition Facts,'' and products that were mostly herbals should use the heading ''Supplement Facts.'' One comment wanted the option of using both headings in one nutrition label, listing DV-nutrients under the heading of ''Nutrition Facts'' and other dietary ingredients under a secondary heading of ''Supplement Facts.'' Some of these comments recommended that the use of ''Nutrition Facts'' or ''Supplement Facts'' for combination products should depend upon how a product is marketed (i.e, the focus of the claims). A couple of these comments wanted the option of using ''Dietary Supplement Facts'' or ''Herbal Facts'' in place of ''Supplement Facts.'' Additionally, at least one of these comments said that all dietary supplements in conventional food form should use the heading ''Nutrition Facts.''

Several other comments supported the proposed heading of ''Supplement Facts'' for all dietary supplements. One of these comments said that this heading is consistent with the DSHEA, and another said that it will help consumers recognize the differences between dietary supplements and conventional foods.

FDA is not persuaded that the heading should be ''Nutrition Facts'' because the DSHEA uses the term ''nutrition information,'' because the information presented, at least in part, is about nutrition, or because these products are marketed for their nutritional value. The nutritional value of a particular product does not determine whether it is a dietary supplement or a conventional food. Many dietary supplements contain many DV-nutrients; many contain none. Additionally, the agency is not persuaded by the argument that consumers will be confused by the heading ''Supplement Facts'' and think that products labeled in this manner are of lesser value. ''Supplement'' is the single word that must be used in the statement of identity for all dietary supplements (see comment 1 in section II. of this document), so use of the term in the title of the nutrition label can assist consumers in identifying dietary supplement products. The agency is not convinced that the name ''Supplement Facts'' will result in any consumer judgment of the value of the product. Dietary supplements have been known as ''supplements'' for years, and FDA is not aware of any confusion caused by this term. Also, the supplemental nature of these products is supported by the new definition in section 201(ff)(2)(B) of the act, which states that a dietary supplement can not be ''represented for use as the sole item of a meal or the diet.''

The agency does not agree that use of the title ''Supplement Facts'' is a violation of § 101.9(k)(6). The distinguishing characteristic between products bearing nutrition labeling entitled ''Supplement Facts'' and those bearing nutrition labeling entitled ''Nutrition Facts''is whether the products are dietary supplements or conventional foods, not whether the vitamins are natural or synthetic. Both conventional foods and dietary supplements can include natural and synthetic vitamins.

Furthermore, the agency does not accept the suggestion that some dietary supplement products should have the heading ''Nutrition Facts,'' while others have various headings (''Supplements Facts,'' ''Herbal Facts,'' and ''Dietary Supplements Facts'') or even two headings (''Nutrition Facts'' for the top half and ''Supplement Facts'' for the bottom half). The act does not support treating supplements of vitamins and minerals any differently than other types of supplements. Therefore, the agency is not doing so. In addition, if the agency consented to these recommendations, it would be possible for some chemically identical products to use up to four different headings. The agency concludes that so many different headings would only serve to confuse consumers.

FDA agrees with the comments that said that the heading of the nutrition label for all dietary supplements should be entitled ''Supplement Facts.'' While dietary supplements are a category of foods, the act distinguishes dietary supplements from conventional foods in many important ways, e.g., different requirements with respect to safety, to the types of claims that can be made, and to the kind of information that must be provided in the nutrition label. As stated in the preamble of the proposal and in one of the comments, the heading ''Supplement Facts'' will help consumers to clearly distinguish between dietary supplements and conventional foods. Nothing in the comments has persuaded FDA that the heading ''Supplement Facts'' would not help consumers to readily identify these products as dietary supplements. Therefore, the agency is not changing § 101.36(e)(1) in response to the comments.

However, the agency does advise that the decision whether a product is sold as a dietary supplement is made by the manufacturer. Under the act, as amended by the DSHEA, the term ''dietary supplement'' is defined as a product (other than tobacco) intended to supplement the diet that bears or contains a vitamin, a mineral, an herb or other botanical, an amino acid, a dietary substance for use by man to supplement the diet by increasing the total dietary intake, or a concentrate, metabolite, constituent, extract, or combination of any of the above ingredients (section 201(ff)(1) of the act). Section 201(ff)(2) of the act further states that dietary supplements are intended for ingestion in a form described in section 411(c)(1)(B)(i) of the act (21 U.S.C. 350 (c)(1)(B)(i)) or in compliance with section 411(c)(1)(B)(ii) of the act, are not represented as conventional food or as a sole item of a meal or the diet, and are labeled as a dietary supplement.

Thus, dietary supplements may be similar to conventional foods in composition and form. Whether a product is a dietary supplement or a conventional food, however, will depend on how it is represented. To be a dietary supplement, a product must bear the term ''dietary supplement'' as part of its common or usual name. (As stated in comment 1 in section II. of this document, this term may be modified to include the name of the dietary ingredient or type of dietary ingredient, such as ''Vitamin C Supplement'' or ''Multivitamin Supplement.'')

Products that are not represented as dietary supplements will be subject to regulation as conventional foods. For example, the manufacturer of a product that is in the form of a tablet or capsule that has nutritive value or a powdered herbal product with no nutritive value may choose to market the product as a conventional food that bears nutrition labeling in accordance with § 101.9. In that situation, the nutrition labeling on the package of tablets with nutritive value would use the title ''Nutrition Facts,'' while the herbal product with no nutritive value would be exempt from nutrition labeling under § 101.9(j)(4). Should the manufacturer choose to do this, however, the label or labeling could not represent the food as a ''dietary supplement,'' and the product could not rely on any of the special provisions for dietary supplements that were added by the DSHEA. Thus, for example, the ingredients of the product would not be eligible for the exception for dietary ingredients from the definition of a ''food additive,'' and the product could not bear statements under the authority of section 403(r)(6) of the act.

29. Several comments objected to the use of hairlines in the nutrition label for space and readability reasons. One of these comments said that the use of hairlines should be optional, and another said that hairlines should not be required if there are more than eight dietary ingredients to be declared. Another comment requested that dots be allowed instead of hairlines when the use of hairlines would cause the type size to fall under 4.5 points. This comment sent sample labels with hairlines, without hairlines, and with dots. The dots connected the name of a dietary ingredient to the quantitative amount and the amount to the percent DV (see sample label in Figure 3).

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Figure 3

Supplement Facts
Serving Size 1 Caplet

Amount Per Caplet		% Daily Value
Vitamin A (20% as beta-carotene)	5000 IU	100%
Vitamin C	90 mg	150%
Vitamin D	400 IU	100%
Vitamin E	30 IU	100%
Vitamin K	28 mcg	35%
Thiamin	3 mg	200%
Riboflavin	3.4 mg	200%
Niacin	20 mg	100%
Vitamin B_6	3 mg	150%
Folate	400 mcg	100%
Vitamin B_{12}	9 mcg	150%
Biotin	30 mcg	10%
Pantothenic Acid	10 mg	100%
Calcium	40 mg	4%
Iron	18 mg	100%
Phosphorous	31 mg	3%
Iodine	150 mcg	100%
Magnesium	100 mg	25%
Zinc	15 mg	100%
Selenium	21 mcg	30%
Copper	2 mg	100%
Manganese	3.5	175%
Chromium	26 mcg	22%
Molybdenum	32 mcg	43%
Chloride	10 mg	<1%
Potassium	10 mg	<1%
Boron	150 mcg	*
Nickel	5 mcg	*
Silicon	2 mg	*
Tin	10 mcg	*
Vanadium	10 mcg	*

* Daily Value not established

BILLING CODE 4190–01–C

The comments did not provide information to show that the legibility of the nutrition label is maintained if hairlines are allowed to be used optionally. Section 2(b)(1)(A) of the 1990 amendments directed the Secretary (and by delegation FDA) to require that the information required in nutrition labeling be conveyed in a manner that enables the public to readily observe and comprehend such information. To implement this provision of the 1990 amendments, FDA issued a rule that required hairlines in the nutrition label. Hairlines make the nutrition label easier to read by aiding consumers' eye movement from the name of the nutrient to the percent DV. Consumer surveys have shown that the graphic requirements in the nutrition labeling in § 101.9 were successful in that the majority of shoppers who are aware of the new label think it is clear and understandable (Ref. 3). Therefore, FDA is not willing to remove the requirement for hairlines without evidence that the legibility and readability of the nutrition label will be maintained on dietary supplement products, particularly when the product contains a large number of dietary ingredients.

However, the agency finds that the sample label submitted that uses dots to connect the nutrient name to the weight and percent DV is a satisfactory substitute to assist eye movement when the only other option would be to reduce type size below 4.5 points, the minimum type size consistent with the Nonprescription Drug Manufacturers Association (NDMA) Label Readability Guidelines used for over-the-counter drugs (Ref. 4). This suggested flexibility appears to offer a reasonable balance between the competing needs for label space and readability on small and intermediate-sized packages. Accordingly, the agency is adding § 101.36(i)(2)(v) to provide that dots connecting columns of nutrient names and quantitative amounts are allowed in place of hairlines between rows of type on small and intermediate-sized packages when it is not possible to meet the minimum type size requirements of 4.5 points if hairlines are used.

30. Several comments objected to the bar that separates the dietary ingredients having RDI's or DRV's from other dietary ingredients because it may imply to consumers that other dietary ingredients are of lesser importance and it takes up space. One comment said that the bar should be optional because the asterisk and footnote ''Daily Value not established'' are sufficient to distinguish other dietary ingredients. One trade association said that some of their members disliked this bar because it creates an artificial and illogical separation in some cases, e.g., for a product containing only vitamins and minerals, but with some minerals for which an RDI has not been established. This comment said that other members liked the bar because it highlights the second portion of the list of dietary ingredients. Other comments supported the proposed use of the bar.

The agency is not persuaded by the comments that the bar should be eliminated because it may imply that the dietary ingredients below it are of lesser importance. While the agency acknowledges that the use of a bar is not expressly required by the act, section 403(q)(5)(F)(i) of the act states that ''nutrition information shall first list those dietary ingredients * * * for which a recommendation for daily consumption has been established by the Secretary * * * and shall list any other dietary ingredient present and identified as having no such recommendation.'' As discussed in the December 1995 proposal (60 FR 67194 at 67206), the bar helps consumers to readily distinguish these two types of dietary ingredients, just as a bar differentiates between macronutrients and vitamins or minerals in the nutrition labeling of conventional foods. The agency does not agree that the asterisk and the footnote are sufficient for consumers to readily distinguish between these two groups because there are some cases where the asterisk and the footnote would be required for dietary ingredients listed above the bar (e.g., sugars). For these reasons, the agency is not willing to eliminate the bar to conserve space. The agency points out that it has made a number of changes to save space, such as allowing the names of dietary ingredients and the corresponding amounts to appear in one column. Thus, the agency is not making any change in § 101.36(e)(6)(ii) in response to these comments.

G. Compliance

31. Several comments objected to the statement in proposed § 101.36(f)(1) that compliance will be determined in accordance with § 101.9(g)(1) through (g)(8). In particular, the comments objected to the application of § 101.9(g)(4)(i), which provides that the content of added nutrients should be at least 100 percent of the value declared in the nutrition label, except for variability because of analytical methods. One comment supported the proposal and said that products should contain the levels that are declared.

Many of the comments in opposition requested that § 101.36(f)(1) be revised to state that supplements claiming to comply with compendial standards shall be judged ''based on compliance procedures specified or incorporated by reference in the compendial specifications.'' Specifically, these comments requested that the compliance level be a fixed minimum of 90 percent that does not allow for variability because of methods, in accordance with standards in the USP.

A comment from USP stated that its lower limit is not a moving target depending on analytical precision or on whose laboratory is performing the test.

Another comment explained that some nutrients are subject to degradation. This comment said that overages of these nutrients are added to dietary supplement products to ensure that the products provide the labeled amounts throughout their shelf life. To avoid excessive overages, the USP has required that at any time that a product is analyzed during its shelf life, the product must be shown to supply at least 90 percent of the labeled amount of any ingredient. These comments argued that Congress called for compendial products to meet compendial specifications (see section 403(s)(2)(D) of the act), and that FDA should not alter those requirements.

The agency is not persuaded that a fixed minimum of 90 percent of the labeled amount should be acceptable for the nutrition panel of dietary supplements. FDA agrees that section 403(s)(2)(D) of the act provides that a dietary supplement is misbranded if it is covered by the specifications of an official compendium, is represented as conforming to those specifications, but fails to do so. Thus, dietary supplement products that are represented to meet the specifications of an official compendium, such as the USP, and fail to do so are misbranded under this section. However, the agency points out that products not misbranded under this section may be misbranded under other sections of the act.

The issue of the acceptable amount of an added vitamin or mineral in a dietary supplement has been raised in earlier final rules (58 FR 2079 at 2171, January 6, 1993; and 59 FR 354 at 369, January 4, 1994). As discussed in those final rules, the agency informed USP in 1991 that anything less that 100 percent of the value declared on the label was not acceptable with the exception of a deviation that is attributable to the analytical method (Ref. 5). FDA finds nothing in the comments that would justify accepting less than 100 percent of the value declared as compliance for added nutrients in dietary supplements. The argument that 90 percent is appropriate because some nutrients degrade is not sufficient justification for the agency to change its position. Because the degradation is foreseeable, FDA expects that manufacturers will take it into account when fabricating dietary supplements. Manufacturers have complete control over the level of dietary ingredients added to their products. Thus, the manufacturers are appropriately charged with ensuring that the amounts present are at least 100 percent of the amounts declared throughout the shelf life of their products, except for any variability that is attributable to methods. The agency concludes that a dietary supplement not meeting this requirement is misbranded under section 403(a)(1) of the act. Therefore, the agency is not modifying § 101.36(f)(1) in response to these comments.

Furthermore, FDA advises that it is aware that Compliance Policy Guide 530.400 (CPG 7121.02), entitled ''Vitamin Products for Human Use—Low Potency,'' is inconsistent with § 101.36(f)(1). CPG 530.400 sets forth the criteria for multivitamin products and states that legal action is recommended when a deficiency is found in excess of 20 percent in one or more nutrients. Because this position is contrary to § 101.36(f)(1), FDA is revoking CPG 530.400.

Additionally, based on its review of the proposed regulations in preparation of this final rule, FDA has come to recognize that the requirement in § 101.9(g)(2) that a sample for analysis shall consist of a composite of 12 subsamples (consumer units) taken 1 from each of 12 different shipping cases is impractical for many dietary supplement products. The agency has found that it is not always possible to locate 12 different shipping cases of dietary supplement products. Inventories of dietary supplement products are often smaller than those of conventional foods, particularly at distribution and retail sites. Accordingly, when 12 shipping cases are not available, it is not possible for FDA to collect a compliance sample that complies with § 101.9(g)(2).

To provide for greater flexibility, the agency is modifying § 101.36(f)(1) to eliminate the requirement that consumer units come from 12 different shipping cases. The agency is requiring only that the consumer units come from the same inspection lot (that is, the product available for inspection at a specific location) and be randomly selected to be representative of that lot.

Furthermore, the agency is providing flexibility with respect to the number of consumer units that are to be collected. FDA is requiring in § 101.36(f)(1) that the ''sample for analysis shall consist of a composite of 12 subsamples (consumer packages) or 10 percent of the number of packages in the same inspection lot, whichever is smaller''. In other words, the entire contents of 12 packages would be needed when there are over 120 packages available. Fewer packages would be needed when the total number of consumer units available is less than 120. In this case, the agency concludes that a 10 percent sample is sufficiently representative for compliance purposes. While not statistically based, the 10 percent sample has been well accepted in enforcement proceedings (Ref. 6, pp. 818 through 821). This approach allows the agency to take compliance actions as necessary, without being impeded by the low availability of the product in question. At the same time, FDA is introducing the term ''packages'' to clarify that this section pertains to packages labeled for retail sale rather than individual units of the product, e.g., tablets or capsules, as the term ''unit'' is defined in other parts of this document.

This provision is a logical outgrowth of the proposal because by cross-referencing § 101.9(g)(1) through (g)(8) in the proposal, FDA raised the question of whether these provisions appropriately apply to dietary supplements. Based on the factors discussed above, FDA concludes that the requirements regarding the number of consumer units in § 101.9(g)(2) should not apply to dietary supplements and is modifying § 101.36(f)(1) accordingly.

H. Special Provisions and Misbranding

32. One comment stated that small-sized packages (i.e., those having a total surface area available to bear labeling of less than 12 square inches) should be allowed to use a minimum type size of 4.0 point when there are more than eight dietary ingredients to be listed in the nutrition label. The comment stated that the proposed minimum of 4.5 point is impractical for certain dietary supplements products, and that a type size of 4.0 point is still legible. The comment included sample labels using a type size of 4.0 point. Another comment requested that small-sized packages be allowed to use a minimum type size of 3 point. This comment did not include sample labels.

FDA is not persuaded by these comments. As discussed in the final rule of January 4, 1994, FDA set the minimum type size at 4.5 point in response to the majority of the comments, which stated that this minimum is consistent with the NDMA's Label Readability Guidelines used for over-the-counter drugs (Ref. 4). FDA has received information from NDMA that shows that it did not set this minimum arbitrarily or subjectively, but that it arrived at this minimum type size based on studies of visual acuity and demographics (Ref. 7). While one of the comments that objected included sample labels using a type size of 4.0

point, it did not present any visual acuity studies in support of its contention that a type size of 4.0 point is legible. FDA has been persuaded by NDMA's data and points out that the vast majority of comments did not object to a minimum type size of 4.5 point. Moreover, firms in need of special allowances may seek alternative means of compliance or an exemption under § 101.36(f)(2). Therefore, FDA is not modifying § 101.36(i)(2)(i) in response to this comment.

33. Several comments requested that § 101.2(c) be amended to include § 101.36. This amendment would allow type size smaller than 1/16th inch in certain instances. One of these comments said that this request is reasonable because the labels of dietary supplements commonly include information not found on the labels of conventional foods, e.g., the iron warning statement.

The agency is not persuaded by these comments. As discussed in the December 1995 proposal, the request to amend several paragraphs in § 101.2(c) to include § 101.36 was included in a citizen petition (Docket No. 94P–0110/CP1) submitted to FDA by the Council for Responsible Nutrition in 1994. The agency denied this request because § 101.36 addresses the type size requirements for information in the nutrition label of dietary supplements (60 FR 67194 at 67208). The agency noted that § 101.9 covers the corresponding requirements for conventional foods. The purpose of § 101.2(c)(1) through (c)(3) was to encourage voluntary declaration of nutrition information and complete ingredient listing on all foods before declaration became mandatory under the 1990 amendments. FDA gave notice of its intention to revoke the exemptions in § 101.2(c)(1), (c)(2), and (c)(3) in its December 1995 proposal (60 FR 67194 at 67208), and proposed to do so in the **Federal Register** of June 12, 1996 (61 FR 29708), because they are obsolete. Therefore, FDA is not accepting these comments.

34. At least one comment recommended that a minimum type size of 4.5 point be allowed for dietary supplement packages that have a total surface area available to bear labeling of less than 40 square inches and have more than 8 dietary ingredients to be listed in the nutrition label. The comment said that it is impracticable to comply with the proposed type size requirements for dietary supplement products that contain many dietary ingredients.

FDA is not persuaded by the comment that a minimum type size of 4.5 point should be allowed on dietary supplement packages with 20 to less than 40 square inches of total surface area available to bear labeling that have more than 8 dietary ingredients to be listed. The agency proposed to require a minimum type size of 4.5 point for packages of less than 12 square inches and 6 point for packages of 12 to 40 square inches, except that it proposed that 4.5 point may be used on packages of less than 20 square inches that have more than 8 dietary ingredients to be listed in the nutrition label. This exception for packages of less than 20 square inches was in response to a citizen petition filed by the Council for Responsible Nutrition (Docket No. 94P–0110/CP1).

In its proposal (60 FR 67194 at 67208), FDA explained how it arrived at its tentative determination that a minimum of 4.5 point should be allowed only on packages of less than 20 square inches that have more than 8 dietary ingredients. Agency precedent provided that not more than 30 percent of the total surface area of a package should be required to be devoted to FDA-required information that is not on the principal display panel. The agency calculated that this 30 percent level would likely be exceeded on packages of 12 to 20 square inches of surface area available to bear labeling if more than 8 dietary ingredients were listed using 6 point type size. Accordingly, FDA proposed to allow those packages to bear nutrition labeling that uses the smaller type.

Applying the same calculations as discussed in the preamble of the proposed rule, the agency estimates that listing 24 dietary ingredients in 6 point type size plus 1 point leading between each line of type could use up to 6 square inches of label space. This would be equivalent to 30 percent of the total surface area of a package having 20 square inches of surface area available to bear labeling (i.e., 20 X 0.3). Accordingly, in response to the comment, the agency will allow for the use of a minimum 4.5 type size in such situations. In addition, based on the agency's observation that about 20 percent of dietary ingredients listed in sample labels submitted with comments that include ingredient information require two lines of type, the agency concludes that it is reasonable to allow the minimum type size of 4.5 point for packages with 20 to 40 square inches of label space available to bear labeling having more than 16 dietary ingredients. Section 101.36(i)(2)(ii) is revised accordingly.

This final rule represents a full response to the Council for Responsible Nutrition's citizen petition referred to above (Docket No. 94P–0110/CP1), in accordance with 21 CFR 10.30(e).

35. Several comments supported the proposed deletion of § 101.9(k)(2) and (k)(5). Some of these comments recommended that all of § 101.9(k) be deleted, asserting that it is not scientifically defensible, and that it is not consistent with the protection of free speech provided in the First Amendment and the Supreme Court decision of *Rubin* v. *Coors Brewing Co*., 517 U.S.____, 115 S. Ct. 1585 (1995). While these comments specifically addressed the deletion of § 101.9(k)(3), (k)(4), and (k)(6), none addressed § 101.9(k)(1).

Two comments addressed § 101.9(k)(3) and (k)(4), which prohibit statements that represent, suggest, or imply that the suboptimal nutritional quality of a food because of soil conditions or storage, transportation, or processing methods may be responsible for an inadequacy in the quality of the daily diet. One comment argued that these paragraphs should be deleted because any conditions that adversely affect the nutritional quality of foods will ultimately affect the nutritional quality of diets, even if such effects are not so extensive as to lead to widespread nutritional deficiencies. Two other comments addressed § 101.9(k)(4) specifically, citing evidence to show that various food processing techniques do cause nutrient losses and stating that national food consumption patterns are changing, leading to reduced consumption of fresh foods and increased use of processed convenience foods.

A few comments recommended deletion of § 101.9(k)(6), which prohibits any representation that naturally-occurring vitamins are superior to added or synthetic vitamins or any differentiation between added and naturally occurring vitamins. The comments argued that FDA should not forbid truthful representations on the label of the composition and biochemical forms of natural and synthetic vitamins, citing biochemical distinctions between naturally occurring and synthetic vitamins and stating that this information enables consumers to make more informed purchasing decisions.

FDA has considered the comments pertaining to § 101.9(k)(3) and (k)(4) and is not persuaded that they are no longer supportable. The agency agrees with the comments that stated that the nutritional quality of a diet is affected by the nutritional quality of the foods contained in that diet. However, when diets are inadequate, many factors must

be considered as causal, and it would be misleading to attribute such a result only to soil conditions and storage, transportation, and processing methods. For example, the food choices a person makes are a major determinant of the quality of his/her diet. Recent research has shown that the more a diet adheres to the Food Guide Pyramid (Ref. 8) and to dietary recommendations to eat a variety of foods and to moderate the consumption of fat, saturated fat, cholesterol, and sodium, the greater the likelihood that nutrient requirements will be met (Ref. 9).

The comment that suggested that the consumption of fresh fruits and vegetables is decreasing is not supported by recent research on the U.S. food supply by the U.S. Department of Agriculture Economic Research Service. This research found that the per capita consumption of fresh fruits rose 25 percent from 1970 to 1994, while the per capita consumption of fresh vegetables rose 33 percent from 1970 to 1994 (Ref. 10, pp. 18–19).

Accordingly, FDA concludes that it is still appropriate to prohibit misleading and unsubstantiated generalizations on the label or in labeling about dietary inadequacies because of nutrient losses resulting from poor soil conditions or storage, transportation, or processing methods. Nothing in *Rubin* v. *Coors Brewing Co.*, *supra*, prevents the government from regulating misleading speech. (See 115 S. Ct. at 1589.)

As stated earlier, current § 101.9(k)(3) and (k)(4) (redesignated as § 101.9(k)(2) and (k)(3)) do not preclude a producer, manufacturer, or vendor from indicating a higher nutrient retention in a particular product as compared to other similar products. Nor do they preclude an indication that such retention results from special handling of the product, provided that such indications are factual and is not misleading (58 FR 2079 at 2167).

In regard to § 101.9(k)(6), FDA has stated in the past that this section permitted truthful designation of any nutrient as natural in origin (38 FR 6950 at 6958, March 14, 1973; and 58 FR 2079 at 2167). However, the agency is persuaded by the comments that the phrase ''differentiate in any way between vitamins naturally present from those added'' in § 101.9(k)(6) is easily misinterpreted to mean that labels cannot identify nutrients as naturally-occurring or synthetic. Accordingly, FDA is modifying that paragraph (renumbered as § 101.9(k)(4)) to remove the prohibition on differentiating between naturally-occurring and synthetic vitamins.

It should be noted that FDA addressed the use of the term ''natural'' in rulemaking implementing the 1990 amendments (58 FR 2302 at 2407, January 6, 1993). At that time, the agency said it was not establishing a definition for ''natural,'' but that it would maintain its policy not to restrict truthful and non-misleading use of the term, except for products with added color, synthetic substances, or artificial flavors as provided in § 101.22, for which use of the term ''natural'' on the label would be considered misleading. However, the agency advises that the term ''natural'' should not be used when referring to a vitamin that is only obtained through chemical synthesis (e.g., use of ''natural vitamin E'' for a product containing dl-alpha tocopheryl acetate).

Comments did not specifically address that part of current § 101.9(k)(6) that prohibits any suggestion that a natural vitamin is superior to an added vitamin. Comments pointed out, and FDA is in agreement, that differences between natural and synthetic vitamins are often really differences in the form of the nutrient. For example, comments pointed out that vitamin E occurs in natural oils in the d-alpha form and exists in synthetic products as a racemic mixture, with less biological activity. Comments did not, however, provide information to support any difference between a natural or synthetic version of the same form of a nutrient. Thus, the agency is aware of nothing that establishes that a claim of difference between the natural and synthetic version of the same form of a nutrient is not misleading. Therefore, FDA is maintaining the prohibition against statements that a natural vitamin is superior to an added one in § 101.9(k)(4).

However, the agency advises that there are no restrictions in the regulations on identification of the chemical form of the nutrient. In fact, such identification is helpful on certain nutrients, such as carotene, whose biological activity varies according to its isomeric composition. FDA notes that when the chemical form of the vitamin is identified on the label or in labeling, manufacturers are free to use statements that characterize the structure and function of that stereoisomer. Label statements may thus differentiate between the different forms of a vitamin.

I. Miscellaneous Issues

36. One comment asked whether nutrition labeling is required on samples of dietary supplements that are distributed free of charge, such as at trade shows.

The nutrition labeling requirements of the 1990 amendments apply to foods offered for sale (section 403(q)(1) of the act). Nutrition labeling would not be required on dietary supplements that are not offered for sale because there is nothing in the DSHEA that requires dietary supplements to be treated any differently than conventional foods in this respect. FDA inadvertently did not make this clear in the December 1995 proposal. Accordingly, FDA is revising § 101.36(a) to state ''The label of a dietary supplement that is offered for sale shall bear nutrition labeling in accordance with this regulation unless an exemption is provided for the product in paragraph (h) of this section.''

37. One comment stated that products composed only of mixtures of free amino acids should be able to declare ''protein'' in the nutrition label and list the total weight of the amino acids as the amount of protein in the product. The comment said that the only difference between free amino acids and protein is that the amino acids in protein are connected to each other by peptide bonds. Another comment stated that amino acids that are essential should be distinguished from those that are nonessential. This comment also stated that the dangers of using single amino acids should also be listed with a warning that many of the uses are unproven. With respect to protein supplements, the comment said that such products should indicate their sources of protein, and ''when collagen with a little tryptophan added is called a protein supplement it should be stated that this is not a complete protein and cannot support life or tissue building on its own.'' The comment recommended that protein supplements used for body building should contain a statement that muscle building requires not only protein, but calories and especially carbohydrates.

FDA agrees that protein differs from free amino acids in that protein is composed of amino acids connected to each other by peptide bonds (60 FR 67194 at 67198). In recognition of this difference, FDA proposed that the nutrition label of dietary supplements list whatever is actually present, i.e., protein or individual amino acids. The comment did not justify why it was not misleading to declare protein content in the nutrition label of a dietary supplement that contains only free amino acids. Therefore, FDA concludes that this requirement is appropriate and consistent with section 201(ff)(1) of the act, which lists amino acids in

subparagraph (D) as a separate entity from protein, which would be covered in subparagraph (E) as a dietary substance.

Furthermore, FDA is not persuaded to require that amino acids be identified as essential or nonessential in the nutrition label of dietary supplements because the act does not require this information in the nutrition label, and the comment did not provide any reason for this approach. In fact, the comment in question did not state clearly where this information should be presented. FDA points out that such information may be stated outside of the nutrition label on the labels of dietary supplements and conventional foods as well.

In response to the comment that requested that the source of protein supplements should be identified, the agency points out that, under the act, manufacturers of dietary supplements, including protein supplements, may choose either to list the source of any dietary ingredient in the nutrition label or in the ingredient statement that appears below the nutrition label. While the concerns of the comment would apparently be better addressed by the former approach, FDA is not aware of any reason to require it. The other points in this comment about warning or other statements are beyond the scope of this rulemaking.

38. One comment recommended that herbal products be required to declare any possible drug interactions. The comment stated that herbs were the first medicines and should be treated as such.

FDA disagrees with this comment. The herbal products that are the subject of this rulemaking are foods and not drugs. To the extent that herbal products are intended for use as medicines, they are drugs under the act and subject to regulation under Chapter V of the act, not Chapter IV (the food provisions). As for possible drug interactions, FDA will consider the need for warnings under sections 201(a), 403(a), and 701(a) of the act (21 U.S.C. 371(a)), but warnings about drug interactions are not typically the subject of food labeling requirements.

IV. Other Provisions

FDA has made a few editorial changes in certain provisions of § 101.36. Specifically, § 101.36(h)(2) (designated as § 101.36(f)(2) in the final rule on small business exemptions in the **Federal Register** of August 7, 1996 (61 FR 40963), has been revised to make it clear that either a manufacturer, packer, or distributor may file a claim for an exemption. This change is consistent with the language in § 101.9(j)(18). Also, to avoid confusion, the first sentence in § 101.36(h)(1) through (h)(3) reads ''foods'' instead of ''dietary supplements.''

FDA did not receive any comments that dealt specifically with the other provisions of the proposal. In the absence of any basis for doing otherwise, FDA is adopting those provisions as proposed.

V. Effective Date

39. Several comments recommended that the compliance date of this final rule be coordinated with other final rules on dietary supplements. Most of these comments requested that a uniform effective date be set at 18 months after the publication of the last final rule concerning dietary supplements based on any pending proposals, although 3 comments requested 12 months, and 1 comment requested 24 months. One comment stated that multiple effective dates will balloon the cost of all label changes to the industry and to consumers, who ultimately will bear the cost of multiple revisions. Other comments stated that an 18-month extension is needed because of the great number of labels to be redesigned. One comment said that they may manufacture an identical multivitamin product for more than 100 different retail customers that sell the product under their own private label name, e.g., store brand names. Thus, this manufacturer has to make new labels for each customer, not for each product. Another comment stated that a manufacturer of ''private label'' products may have over 10,000 labels to redesign.

FDA is persuaded by the majority of the comments that it is appropriate to have the effective date of this final rule be 18 months after its publication, consistent with the time period allowed for the labels of conventional foods to comply with the final rules implementing the 1990 amendments. As discussed in section VI. of this document, an 18-month compliance period will minimize the cost of the changeover compared to a 12-month compliance period. The agency does not agree with the comment that requested a 24-month compliance period because the majority of the comments stated that an 18-month compliance period is sufficient.

Moreover, the agency agrees that it is reasonable and practical to have the same date apply to the other final rules on dietary supplement labeling that are published elsewhere in this issue of the **Federal Register**, as multiple effective dates will increase costs and are unjustified. Therefore, the agency concludes that the effective date of this final rule is 18 months from the date of its publication and that this date shall apply to the other final rules on dietary supplements that are published in this issue of the **Federal Register**.

The same will also apply to the enforcement of prescribed iron statements on products that currently bear voluntary iron warning statements, as discussed in the final rule on iron statements (62 FR 2218, January 15, 1997). In that final rule, the agency stated that it intended to use enforcement discretion for these products that bear a voluntary warning until the date for label changes made in response to the DSHEA (62 FR 2218 at 2246).

The agency notes that this effective date is not in accordance with the uniform compliance date of January 1, 2000, established by regulation on December 27, 1996 (61 FR 68145). As stated in that document, ''If any food labeling regulation involves special circumstances that justify a compliance date other than January 1, 2000, the agency will determine for that regulation an appropriate compliance date, which will be specified when the final regulation is published'' (61 FR 68145 at 68146). The DSHEA states that dietary supplement products shall be labeled in accordance with its amendments after December 31, 1996. Because final rules were not published in sufficient time for the industry to be in compliance with them by January 1, 1997, FDA stated on April 15, 1996, that it would exercise its enforcement discretion such that it would not enforce the provisions of the DSHEA until January 1, 1998 (61 FR 16423). At this time, FDA is extending this period of nonenforcement until March 23, 1999. Any further extension (i.e., to January 1, 2000) would be unresponsive to the directives of the statute, as well as unnecessary based on comments received.

In addition, in response to the directive in the DSHEA that dietary supplements ''be labeled'' after December 31, 1996, and consistent with the approach taken by Congress in the 1990 amendments, the agency advises that the effective date of this regulation, the other dietary supplement regulations published in this issue of the **Federal Register**, and the final rule on iron statements, will apply to the attachment of labels to dietary supplement products rather than to the introduction of products into interstate commerce as specified in the agency's final rule on uniform compliance dates for food labeling regulations (61 FR

68145). In other words, products bearing labels that are affixed prior to March 23, 1999 do not have to be in compliance with these final rules, and products labeled after March 23, 1999 do.

Although the effective date is 18 months hence, FDA encourages manufacturers to have new labels that are in compliance with these final rules printed as soon as current inventories are exhausted to assure a smooth and timely changeover. The agency does not anticipate extending its use of enforcement discretion any further.

VI. Analysis of Impacts

FDA has examined the economic implications of the final rule as required by Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select the regulatory approach which maximizes net benefits (including potential economic, environmental, public health and safety effects; distributive impacts; and equity). Executive Order 12866 classifies a rule as significant if it meets any one of a number of specified conditions, including having an annual effect on the economy of $100 million or adversely affecting in a material way a sector of the economy, competition, or jobs, or if it raises novel legal or policy issues. If a rule has a significant impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze options that would minimize the economic impact of that rule on small entities. FDA finds that this final rule is not an economically significant rule as defined by Executive Order 12866 and finds under the Regulatory Flexibility Act, that the final rule will have a significant impact on a substantial number of small entities.

There are several different types of products that may be considered to be dietary supplements. These products include but are not limited to vitamin or mineral supplements, herbal products, and products that contain other similar nutritional substances. An estimate of the number of such products is approximately 29,000. The number of stockkeeping units, a more accurate count of the number of labels, is approximately 75,000. Estimates of the number of dietary supplements are approximate because no one source collects information on all types of dietary supplements. In fact, until the DSHEA, there was no agreed upon definition of a dietary supplement. Some sources include only dietary supplements of vitamin or minerals, others include herbals or botanicals, and still others include other types of products that may or may not be dietary supplements, such as sports nutrition products and ''functional foods,'' a term for which there is no recognized definition.

In its proposed analysis, FDA estimated the number of dietary supplement firms to be between 150 and 650 firms. According to Duns Market Identifiers, there are approximately 250 manufacturers of vitamin and mineral products. According to *Nutrition Business Journal* (August 1996), the dietary supplement industry includes 850 supplement manufacturing companies. The *Journal* reports 1995 industry revenues at $4.5 billion. Although FDA concludes that there are clearly at least 250 firms, the *Journal's* estimate of 850 is most likely an overestimate of the dietary supplement industry because it includes homeopathic products, which are drugs by statutory definition, and ''functional foods'' and sports nutrition products, which may be either conventional foods or dietary supplements depending on how they are marketed and used. Although the *Journal* does not break down the number of firms by the type of dietary supplement produced, it does specify that 250 firms produce herbal or botanical products. FDA received one comment on its proposed analysis that suggested that estimates of the number of firms should include the product manufacturer, label printer, product packager, label/brand owner, and brand wholesaler. FDA notes that, with the exception of administrative costs, costs of labeling regulations are calculated on a per product or per label basis, not on a per firm basis. Administrative costs, which are typically calculated on a per firm basis, include the cost of reading and interpreting the regulation and formulating a compliance policy which must be done once for each regulation, not for each product.

For purposes of determining the costs of this regulation, FDA will use 850 as an upper bound estimate of the number of firms. As a lower bound estimate, FDA will use 500 (250 vitamin/mineral firms + 250 herbal/botanical firms).

A. Costs

Categories of costs for relabeling include administrative, analytical, printing, and inventory disposal.

The administrative costs associated with a labeling regulation result from the incremental administrative labor expended in order to comply with a regulation. FDA received one comment objecting to the estimated administrative costs. The comment stated that administrative costs fail to include both scientific and legal review, but the comment did not provide any information to help FDA modify its previous estimate. Therefore, FDA will continue to estimate administrative costs at $425 per firm for a 1-year compliance period and approximately $320 for an 18-month compliance period. Longer compliance periods decrease administrative effort because firm executives often delegate downward decisions that are less immediate. Total administrative costs are estimated to be between $160,000 ($320 x 500 firms) and $272,000 ($320 x 850 firms) with an 18-month compliance period.

FDA received one comment stating that its estimate of analytical costs substantially underestimated the true costs. The comment estimated analytical costs at $340 per product. FDA notes, however, that although the comment stated that FDA's estimates were too low, the comment's per product estimate is lower than FDA's estimate of $615 per product. Therefore, FDA will continue to estimate costs at $615 per product for each of 29,000 products. All products will be tested once during the 18-month compliance period in order to determine initial compliance. In the proposed rule, FDA assumed that products would undergo retesting once every 5 years. FDA received no objections to that assumption. Therefore, FDA estimates total discounted analytical costs of $75 million (discounted to infinity at 7 percent), of which $17.8 million ($615 x 29,000 products) will occur during the 18-month compliance period.

FDA received several comments that its estimates of printing/redesign costs were too low. One comment suggested that costs would be $1,370 for each printed label and $3,870 for each direct-printed package label. Estimates from other comments ranged from $50 to $3,500 per label. Based on an average of the estimates provided by the comments, FDA estimates that the average per label redesign cost for a 1-year compliance period is $1,700. However, because FDA is allowing a compliance period of 18 months, firms will be able to combine planned label changes with mandated changes, thus lowering redesign costs. Redesign costs associated with an 18-month compliance are typically 3/4 of those for a 1-year compliance period. Therefore, FDA estimates redesign costs to be $1,300 for each of 75,000 labels, or a total $97.5 million.

FDA received one comment indicating that inventory disposal costs would range between $8 and $15

million depending on the length of the compliance period. In the analysis to the proposed rule, FDA estimated inventory disposal costs at $6.5 million assuming the rules would become effective 12 months after publication of the final regulations. FDA will not alter its previous estimates based on the comment because dietary supplement firms have known about these label changes since at least January 1994, and the majority of firms have been taking the necessary steps to reduce their label inventories. However, because FDA is providing firms with 18 months to comply, firms will have an additional 6 months to dispose of label inventory. As with redesign costs, inventory disposal costs associated with an 18-month compliance period are approximately 3/4 of the costs associated with a 1-year compliance period. Therefore, disposal costs for this rule are estimated at $4.8 million.

FDA has estimated the impact of the final regulations and has determined that administrative costs would be between $160,000 and $272,000, discounted analytical costs would be $75 million (discounted to infinity at 7 percent), redesign costs would be $97.5 million, and inventory disposal costs would be $4.8 million. Therefore, total discounted costs are estimated to be $177.8 million (discounted to infinity at 7 percent). Costs during the 18-month compliance period are estimated to be $120 million. If we assume that the rate at which firms comply is evenly distributed throughout the compliance period, then costs during the most expensive 12-month period, the first year, would be $80.3 million. Costs in the second year would be $39.7 million. Recurring costs would be $17.8 million every 5 years. According to basic economic principles, firms are profit maximizers. Therefore, it is logical to assume that firms will select the least costly alternative. The supply of label redesign and analytical laboratory services is limited in the short run. When demand for those services increases as a result of regulatory requirements, the cost of those services also increases. If compliance were skewed toward one end of the compliance period, then the demands places on those services would cause prices to increase more than if the demand were more evenly distributed. Firms are aware of this phenomenon and will, therefore, attempt to spread out the demands on the redesign and laboratory services. Also, because the capacity for these services is fixed in the short run, the suppliers of redesign and laboratory services will force firms to space out their demand. Because it is unlikely that the rate at which firms comply is heavily skewed toward one end of the compliance period, it is unlikely that costs will exceed $100 million during any single year. Therefore, FDA concludes that this rule is not economically significant as defined by Executive Order 12866.

B. Benefits

Although almost all dietary supplements of vitamins and minerals currently contain substantial nutrition information, many other dietary supplements do not. This regulation will benefit consumers by assuring that adequate and complete nutrition information is provided accurately and consistently to aid consumers in their choices.

C. Regulatory Flexibility

According to the Regulatory Flexibility Act, the definition of a small entity is a business independently owned and operated and not dominant in its field. The Small Business Administration (SBA) has set size standards for most business categories through use of four-digit Standard Industrial Classification codes. For dietary supplements of vitamins and minerals, a business is considered small if it has fewer than 750 employees. According to Duns Market Identifiers, there are approximately 250 producers of vitamin and mineral supplements, of which 200 have fewer than 750 employees. The remaining dietary supplement products come closest to the industry groups Food Preparations N.E.C. (SIC 2099) and Medicinal Chemicals and Botanical Products (SIC 2834). The SBA size standards are 500 or fewer employees for food preparations and 750 or fewer employees for medicinal and botanical products. Under either employee-based size standard, virtually all firms could be classified as small, including some firms that are among the leaders in sales revenues. Therefore, FDA is basing size classifications on sales revenue rather than employees.

According to *Nutrition Business Journal*, of the 850 dietary supplement manufacturing firms, 11 have total revenues over $100 million, accounting for 53 percent of total sales; 30 firms have sales revenues between $20 and $100 million, accounting for 28 percent of industry sales; and 809 firms have sales under $20 million, accounting for 19 percent of industry sales. The 809 firms in the under $20 million category have an average sales revenue of $800,000 and will be considered small by FDA. The SBA sales revenue standard for businesses that cannot be classified into a specific industry is $5 million. FDA concludes therefore that as many as 809 firms in the dietary supplement industry, or 95 percent of firms, could be considered small (sales under $20 million). As stated previously in this analysis, this may be an overestimate because it counts firms that produce homeopathic products, which are drugs, and sports nutrition products and ''functional foods,'' which may be foods or dietary supplements. If there are as few as 500 dietary supplement firms, there may be 475 small dietary supplement firms.

The agency has published an exemption from mandatory nutrition labeling for small businesses in § 101.9(j)(1) and has proposed an exemption for low-volume food products of small businesses in § 101.9(j)(18) (59 FR 11872, March 14, 1994). These regulations are cross-referenced in this final rule on labeling of dietary supplements, in § 101.36(h)(1) and (h)(2), respectively. As of January 1, 1997, § 101.9(j)(1) will only apply to retailers. As of May 1997, § 101.9(j)(18) will apply to manufacturers, packers, distributors, or retailers of low volume products, defined as fewer than 100,000 units, produced by firms with fewer than 100 employees. FDA does not have information to show how many dietary supplement products would be exempted under this provision. Comments to the proposed analysis suggested that very few products will qualify for exemptions for low volume products. According to the limited information available to the FDA, approximately 72 percent of vitamin/mineral producers and 86 percent of herbal/botanical producers have fewer than 100 employees. Even if every firm with fewer than 100 employees produced low volume products, between 9 and 13 percent of the firms with annual sales less than $20 million would still not meet the definition. Therefore, although it is likely that many firms will be able to take advantage of the small business exemption, FDA concludes that this rule will impact on a substantial number of small entities.

Dietary supplement firms each produce between 3 and over 50 distinct products. A firm that produces three products will incur costs of $14,000 during the compliance period. A firm that produces 50 products will incur costs of $236,000 during the compliance period. If the average small firm incurs costs of $125,000 ((14,000 + 236,000)/2), using an average annual sales of $800,000, the increase in costs due to this regulation will be 16 percent of

sales for the average small firm. Therefore, FDA concludes this rule will result in a significant economic impact on a substantial number of small entities.

The Regulatory Flexibility Act requires agencies to examine regulatory alternatives that would minimize the impact on small entities. Because the DSHEA mandates nutrition labeling for all dietary supplement products, except low-volume products as described above, there are very few alternatives available to the agency. However, as discussed elsewhere in this document, FDA received many comments requesting that firms be given 18 months to comply with these regulations. FDA has examined the impact of different compliance periods and has determined that extending the compliance to 18 months reduces the burden on small entities. With a 12-month compliance period, first year costs for an average small entity would be $158,500, or 20 percent of sales. Extending the compliance period to 18 months reduces first year costs to the average small firm by $33,500. If FDA did not extend the compliance period, the total discounted costs of this regulation would be $209.5 million, of which $152 million would occur in the first year. The longer compliance period reduces total discounted costs of the regulation by $31.2 million.

D. Summary

Total discounted costs of this regulation are estimated to be between $177.8 million (discounted to infinity at 7 percent). These costs include administrative, analytical, printing, and inventory disposal costs. The benefits are improved and more consistent information with which consumers can refine their choices for health or other reasons. FDA is unable to quantify this benefit.

FDA has analyzed the costs and benefits of this proposed rule and has determined that, because neither costs nor benefits are likely to exceed $100 million in any single year, it does not constitute an economically significant rule as defined by Executive Order 12866.

FDA has also analyzed the impacts on small firms according to the Regulatory Flexibility Act and has determined that these rules will have a significant impact on a substantial number of small entities. FDA has reviewed alternatives to reduce the burden on small entities and has concluded that providing for a compliance period of 18 months will alleviate that burden.

E. Public Outreach

FDA has conducted extensive outreach to a wide audience, including small businesses, on the labeling of dietary supplements. This outreach included independent FDA activities as well as cooperative efforts between FDA and professional trade organizations.

FDA has informed small businesses of the requirements in the DSHEA regarding dietary supplements and of FDA's implementation of these requirements in a number of ways. Since passage of the DSHEA, FDA representatives have responded on a daily basis to numerous inquiries on supplements, including inquiries from small businesses. In addition, FDA has had meetings on the regulation of dietary supplements with representatives of at least four trade organizations that include small businesses in their membership. Furthermore, FDA has participated in a number of trade organization conferences on dietary supplements and has cooperated with the Drug Information Association, which has sponsored conferences on botanicals.

FDA has issued a number of publications on dietary supplements that have been available to small businesses, including an article in the *FDA Consumer* of November 1993 and an ''FDA Backgrounder'' of August 1995, which described the DSHEA. FDA has distributed about 500 reprints of its December 1995 proposals on the labeling of dietary supplements to various interested parties, including small businesses. FDA has also placed information on these proposed rules in the FDA News section of the agency's home page on the World Wide Web. In response to these proposals, FDA has received numerous comments from small businesses. FDA concludes that its efforts to inform small businesses of activity in this area have been successful.

VII. Environmental Impact

The agency has previously considered the environmental effects of this rule as announced in the proposed rule (60 FR 67194, December 28, 1995). No new information or comments have been received that would affect the agency's previous determination that there is no significant impact on the human environment and that an environmental impact statement is not required.

VIII. Paperwork Reduction Act

This rule contains information collection requirements that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (Pub. L. 104–13). The title, description, and respondent description of the information collection are shown below with an estimate of the annual reporting and recordkeeping burden. Included in the estimate is the time for reviewing procedures, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Title: Requirements for Nutrition and Ingredient Labeling of Dietary Supplements.

Description: In a final rule, FDA is amending § 101.36 to require that most dietary supplements provide on their labels, and in their labeling, information on the quantity of specific nutrients present in them, along with the daily value for each, and the quantity of other dietary ingredients. This requirement implements the requirements of the 1990 amendments and the DSHEA. The agency is also providing a mechanism by which firms may request an alternative approach to providing the necessary nutrition information.

Section 101.36(b)(2) specifies the nutrients for which the amount must be present on the labels of dietary supplements and § 101.36(b)(3) provides for the listing of the quantity of other dietary ingredients, respectively. Other paragraphs of § 101.36 provide information to assist manufacturers and distributors of dietary supplements in determining how the amount of nutrients that their products contain should be disclosed on the labels of the products. Section 101.36(f)(2) provides a mechanism whereby firms may request in writing from FDA alternative means of compliance or additional exemptions when it is not technologically feasible, or some other circumstance makes it impracticable, for the firm to comply with the requirements of § 101.36.

FDA had submitted these information collection requirements to OMB for review under section 3504(h) of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*) at the time the December 1995 proposal was published. In response, OMB disapproved the information collection but gave an OMB control number, 0910–0314, and requested that FDA respond to the following concerns at the time of resubmission for OMB approval of the information collection package at the final rule stage:

OMB does not approve this package. OMB is concerned about the accuracy of the cost and hour burden estimates, as well as the utility of the nutrition info. required to be disclosed on the labels of dietary supplements and whether the labels are sufficiently clear to the third party recipients

of this information. When the package is resubmitted to OMB for approval at the final stage, the agency will address OMB's concerns and the public comments received on these issues in the preamble of the final rule and in the paperwork submission package.

FDA estimates the total annual disclosure and reporting hour burden for the information collection requirements contained in this final rule to be 136,040 hours, as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Hours	Hours per Response	Total Annual Hours	Total Operating & Maintenance Costs
101.36 (b)(2) and (b)(3) (disclosure)	850	40	34,000	4	136,000	40,000,000
101.36(f)(2) (reporting)	20	1	20	2	40	0
Totals			34,020		136,040	40,000,000

FDA estimates that each supplier of dietary supplements will revise the labels for each product that is not otherwise exempt to comply with the requirements for nutrition labeling within the first 18 months after publication of the final rule. The agency estimates that, on average, each supplier will have 40 products whose labels will require revision. The agency expects that the number of respondents and corresponding annual burden hours will decrease over succeeding years because it does not believe that firms will modify the composition of each of their products and revise the labeling for each of their products each year. Similarly requests for alternative approaches for providing nutrition information are most likely to be submitted within the first 18 months. The agency estimated the number of such requests based on its experience with the similar requirement that is provided in § 101.9(g)(9) for conventional foods. Thus, there will be a significant decrease in the number of respondents and product labels requiring revision in succeeding years with a corresponding decrease in annual burden hour cost. The hour burden estimates contained above are for the information collection requirements established by regulation alone and do not include those that stem solely from the act or the DSHEA.

FDA has estimated that the total annualized operating and maintenance costs will approximate $40,000,000 over the next 3 to 4 years. This is based on annualized estimated relabeling costs of $32.5 million, analytical costs of $6 million, and labor and overhead costs of $1.5 million over the next 3 to 4 years. The agency believes that these costs will decrease significantly over succeeding years. FDA will reexamine these estimates at the end of 3 to 4 years. The agency has determined that the requirements in § 101.36 do not require capital costs on the part of respondents.

The first concern expressed by OMB was about the accuracy of the cost and hour burden estimates for the information collection requirements. FDA received one comment in response to the proposal that estimates of the number of firms should include the product manufacturer, label printer, product packager, label/brand owner, and the brand wholesaler. FDA received no comments that suggested alternative costs or hour burdens from the agency's estimates. As discussed in more detail in section V. of this document and as indicated in the preceding table ''Estimated Annual Reporting Burden,'' the agency has modified the number of respondents that will be affected by the information collection requirements from 600 to 850 but has retained the estimates of hour burden per response that was contained in the December 1995 proposal.

OMB also expressed its concern about the utility of the nutrition information required to be disclosed on the labels of dietary supplements and whether the labels are sufficiently clear to the third-party recipients of this information. Several comments to the December 1995 proposal recommended that nutrients should be listed on dietary supplements only when they are added. Other comments expressed concerns about the format requirements for the nutrition facts panel. As discussed in more detail above, FDA is not persuaded by the comments that it should change the requirements for the listing of nutrients on dietary supplements. As also noted above, the agency points out that, except for certain specified exceptions, section 403(q) of the act requires nutrition labeling on most foods. With respect to dietary supplements, section 403(q)(5)(F) of the act, as amended by the DSHEA, specifies that the labels of dietary supplements shall comply with the requirements for nutrition labeling contained in subparagraphs (q)(1) and (q)(2) in a manner which is appropriate. Furthermore, the agency believes that nutrition information on dietary supplements is essential for those that are interested to be able to calculate their daily intakes of nutrients.

As to OMB's concern that the information will be sufficiently clear to the third-party recipients, FDA notes that consumer surveys have indicated that the graphic requirements in the nutrition labeling rules for food (i.e., § 101.9) were successful in that the majority of shoppers who are aware of the new label think it is clear and understandable. FDA has no reason to believe that the requirements for nutrition labeling of dietary supplements will be any less clear.

FDA has resubmitted the information collection requirements contained in this rule to OMB for its review under the Paperwork Reduction Act of 1995. Interested persons are requested to send comments regarding information collection by October 23, 1997 to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., rm. 10235, Washington, DC 20503, ATTN: Desk Officer for FDA. No person may be required to respond to, or may be subjected a penalty for failure to comply with, these information collection requirements until they have been approved by OMB and FDA has displayed the assigned OMB control number. The OMB control number, when assigned, will be announced by separate notice in the **Federal Register**.

IX. References

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

1. Machlin, L. J., editor, *Handbook of Vitamins*, 2d ed., pp. 239 and 285, Dekker, NY, 1991.

2. Subcommittee on the 10th Edition of the RDA's, Food and Nutrition Board, Commission of Life Sciences, National Research Council, ''Recommended Dietary Allowances, 10th Ed.,'' pp. 125 and 132, Washington, DC, National Academy Press, 1989.

3. Food Marketing Institute Prevention Magazine Report, ''Shopping for Health 1995,'' Food Marketing Institute, Washington, DC, and *Prevention Magazine*, Emmaus, PA, 1995.

4. Nonprescription Drug Manufacturers Association's Special Task Force on Label Readability, ''Label Readability Guidelines,'' Washington, DC, 1991.

5. Tanner, J. T., letter to V. Srinivasan, U.S. Pharmacopeial Convention, Inc., May 7, 1991.

6. Deming, W. E., ''On the Presentation of the Results of Sample Surveys as Legal Evidence,'' *The Journal of the American Statistical Association*, 49:818–821, December 1954.

7. Memorandum between Bill Bradley, Nonprescription Drug Manufacturers Association, and Susan Thompson, CFSAN, FDA, October 15, 1993.

8. U.S. Department of Agriculture, Human Nutrition Information Service, ''The Food Guide Pyramid,'' Home and Garden Bulletin Number 252, August 1992.

9. U.S. Department of Agriculture, Center for Nutrition Policy and Promotion, ''The Healthy Eating Index,'' October 1995.

10. U.S. Department of Agriculture, Economic Research Service, ''Food Consumption, Prices, and Expenditures, 1996,'' Statistical Bulletin Number 928, pp. 18–19.

11. Foster, S., editor, *Herbs of Commerce*, Amercian Herbal Products Association, Bethesda, MD, 1992.

12. Greuter, W., editor (chairperson), *International Code of Botanical Nomenclature (Tokyo Code)*, adopted by the 15th International Botanical Congress, Koeltz Scientific Books, D–61453 Konigstein, Germany, 1994.

List of Subjects in 21 CFR Part 101

Food labeling, Incorporation by reference, Nutrition, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 101 is amended as follows:

PART 101—FOOD LABELING

1. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: Secs. 4, 5, 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs. 201, 301, 402, 403, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 371).

2. Section 101.2 is amended by revising paragraphs (b), (d)(1), and (f) to read as follows:

§ 101.2 Information panel of package form food.

* * * * *

(b) All information required to appear on the label of any package of food under §§ 101.4, 101.5, 101.8, 101.9, 101.13, 101.17, 101.36, subpart D of part 101, and part 105 of this chapter shall appear either on the principal display panel or on the information panel, unless otherwise specified by regulations in this chapter.

* * * * *

(d)(1) Except as provided by §§ 101.9(j)(13) and (j)(17) and 101.36(i)(2) and (i)(5), all information required to appear on the principal display panel or on the information panel under this section shall appear on the same panel unless there is insufficient space. In determining the sufficiency of the available space, except as provided by §§ 101.9(j)(17) and 101.36(i)(5), any vignettes, designs, and other nonmandatory label information shall not be considered. If there is insufficient space for all of this information to appear on a single panel, it may be divided between these two panels, except that the information required under any given section or part shall all appear on the same panel. A food whose label is required to bear the ingredient statement on the principal display panel may bear all other information specified in paragraph (b) of this section on the information panel.

* * * * *

(f) If the label of any package of food is too small to accommodate all of the information required by §§ 101.4, 101.5, 101.8, 101.9, 101.13, 101.17, 101.36, subpart D of part 101, and part 105 of this chapter, the Commissioner may establish by regulation an acceptable alternative method of disseminating such information to the public, e.g., a type size smaller than one-sixteenth inch in height, or labeling attached to or inserted in the package or available at the point of purchase. A petition requesting such a regulation, as an amendment to this paragraph, shall be submitted under part 10 of this chapter.

3. Section 101.3 is amended by adding new paragraph (g) to read as follows:

§ 101.3 Identity labeling of food in packaged form.

* * * * *

(g) Dietary supplements shall be identified by the term ''dietary supplement'' as a part of the statement of identity, except that the word ''dietary'' may be deleted and replaced by the name of the dietary ingredients in the product (e.g., calcium supplement) or an appropriately descriptive term indicating the type of dietary ingredients that are in the product (e.g., herbal supplement with vitamins).

4. Section 101.4 is amended by revising paragraph (a)(1) and adding new paragraphs (g) and (h) to read as follows:

§ 101.4 Food; designation of ingredients.

(a)(1) Ingredients required to be declared on the label or labeling of a food, including foods that comply with standards of identity, except those ingredients exempted by § 101.100, shall be listed by common or usual name in descending order of predominance by weight on either the principal display panel or the information panel in accordance with the provisions of § 101.2, except that ingredients in dietary supplements that are listed in the nutrition label in accordance with § 101.36 need not be repeated in the ingredient list. Paragraph (g) of this section describes the ingredient list on dietary supplement products.

* * * * *

(g) When present, the ingredient list on dietary supplement products shall be located immediately below the nutrition label, or, if there is insufficient space below the nutrition label, immediately contiguous and to the right of the nutrition label and shall be preceded by the word ''Ingredients,'' unless some ingredients (i.e., sources) are identified within the nutrition label in accordance with § 101.36(d), in which case the ingredients listed outside the nutrition label shall be in a list preceded by the words ''Other ingredients.'' Ingredients in dietary supplements that are not dietary ingredients or that do not contain dietary ingredients, such as excipients, fillers, artificial colors, artificial sweeteners, flavors, or binders, shall be included in the ingredient list.

(h) The common or usual name of ingredients of dietary supplements that are botanicals (including fungi and algae) shall be consistent with the names standardized in *Herbs of Commerce*, 1992 edition, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the American Herbal Products Association, 4733 Bethesda Ave., suite 345, Bethesda, MD 20814, or may be examined at the Center for Food Safety and Applied Nutrition's Library, 200 C St. SW., rm. 3321, Washington, DC, or at the Office of the Federal Register, 800 Capital St. NW., suite 700, Washington, DC. The listing of these names on the label shall be followed by statements of:

(1) The part of the plant (e.g., root, leaves) from which the dietary ingredient is derived (e.g., ''Garlic bulb'' or ''Garlic (bulb)''), except that this designation is not required for algae. The name of the part of the plant shall

pressed in English (e.g., ''flower'' rather than ''flos'');

(2) The Latin binomial name of the plant, in parentheses, except that this name is not required when it is available in the reference entitled: *Herbs of Commerce* for the common or usual name listed on the label, and, when required, the Latin binomial name may be listed before the part of the plant. Any name in Latin form shall be in accordance with internationally accepted rules on nomenclature, such as those found in the *International Code of Botanical Nomenclature* and shall include the designation of the author or authors who published the Latin name, when a positive identification cannot be made in its absence. The *International Code of Botanical Nomenclature* (Tokyo Code), 1994 edition, a publication of the International Association for Plant Taxonomy, is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of the *International Code of Botanical Nomenclature* may be obtained from Koeltz Scientific Books, D–61453 Konigstein, Germany, and University Bookstore, Southern Illinois University, Carbondale, IL 62901–4422, 618–536–3321, FAX 618–453–5207, or may be examined at the Center for Food Safety and Applied Nutrition's Library, 200 C St. SW., rm. 3321, Washington DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington DC.

(3) On labels of single-ingredient dietary supplements that do not include an ingredient list, the identification of the Latin binomial name, when needed, and the part of the plant may be prominently placed on the principal display panel or information panel, or included in the nutrition label.

5. Section 101.9 is amended by removing paragraphs (k)(2) and (k)(5), by redesignating paragraphs (k)(3), (k)(4), and (k)(6) as paragraphs (k)(2), (k)(3), and (k)(4), respectively, and by revising paragraphs (c)(8)(iii), (c)(8)(v), (d)(7)(i), (j)(6), and newly redesignated (k)(4) to read as follows:

§ 101.9 Nutrition labeling of food.

* * * * *

(c) * * *

(8) * * *

(iii) The percentages for vitamins and minerals shall be expressed to the nearest 2-percent increment up to and including the 10-percent level, the nearest 5-percent increment above 10 percent and up to and including the 50-percent level, and the nearest 10-percent increment above the 50-percent level. Amounts of vitamins and minerals present at less than 2 percent of the RDI are not required to be declared in nutrition labeling but may be declared by a zero or by the use of an asterisk (or other symbol) that refers to another asterisk (or symbol) that is placed at the bottom of the table and that is followed by the statement ''Contains less than 2 percent of the Daily Value of this (these) nutrient (nutrients)'' or ''Contains < 2 percent of the Daily Value of this (these) nutrient (nutrients).'' Alternatively, except as provided for in paragraph (f) of this section, if vitamin A, vitamin C, calcium, or iron is present in amounts less than 2 percent of the RDI, label declaration of the nutrient(s) is not required if the statement ''Not a significant source of _____ (listing the vitamins or minerals omitted)'' is placed at the bottom of the table of nutrient values. Either statement shall be in the same type size as nutrients that are indented.

* * * * *

(v) The following synonyms may be added in parentheses immediately following the name of the nutrient or dietary component:
Calories—Energy,
Vitamin C—Ascorbic acid,
Thiamin—Vitamin B_1,
Riboflavin—Vitamin B_2,
Folate—Folic acid or Folacin.
Alternatively, folic acid or folacin may be listed without parentheses in place of folate.

* * * * *

(d) * * *

(7) * * *

(i) The name of each nutrient, as specified in paragraph (c) of this section, shall be given in a column and followed immediately by the quantitative amount by weight for that nutrient appended with a ''g'' for grams or a ''mg'' for milligrams as shown in paragraph (d)(12) of this section. The symbol ''<'' may be used in place of ''less than.''

* * * * *

(j) * * *

(6) Dietary supplements, except that such foods shall be labeled in compliance with § 101.36.

* * * * *

(k) * * *

(4) That a natural vitamin in a food is superior to an added or synthetic vitamin.

6. Section 101.12 is amended in paragraph (b), Table 2, under the subheading ''Miscellaneous category'' by revising the entry ''Dietary supplements not in conventional food form'' to read as follows:

§ 101.12 Reference amounts customarily consumed per eating occasion.

* * * * *

(b) * * *

TABLE 2.—REFERENCE AMOUNTS CUSTOMARILY CONSUMED PER EATING OCCASION: GENERAL FOOD SUPPLY[1,2,3,4]

Product category	Reference amount	Label statement[5]
* *	* *	* * *
Miscellaneous category:		
Dietary supplements	The maximum amount recommended, as appropriate, on the label for consumption per eating occasion, or, in the absence of recommendations, 1 unit, e.g., tablet, capsule, packet, teaspoonsful, etc.	_____tablet(s), _____capsule(s), _____packet(s), _____tsp(s), (_____g), etc.
* *	* *	* * *

[1] These values represent the amount (edible portion) of food customarily consumed per eating occasion and were primarily derived from the 1977–78 and the 1987–1988 Nationwide Food Consumption Surveys conducted by the U.S. Department of Agriculture.

[2] Unless otherwise noted in the Reference Amount column, the reference amounts are for the ready-to-serve or almost ready-to-serve form of the product (i.e, heat and serve, brown and serve). If not listed separately, the reference amount for the unprepared form (e.g., dry mixes; concentrates; dough; batter; fresh and frozen pasta) is the amount required to make the reference amount of the prepared form. Prepared means prepared for consumption (e.g., cooked).

[3] Manufacturers are required to convert the reference amount to the label serving size in a household measure most appropriate to their specific product using the procedures in 21 CFR 101.9(b).

[4] Copies of the list of products for each product category are available from the Office of Food Labeling (HFS–150), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204.

[5] The label statements are meant to provide guidance to manufacturers on the presentation of serving size information on the label, but they are not required. The term ''piece'' is used as a generic description of a discrete unit. Manufacturers should use the description of a unit that is most appropriate for the specific product (e.g., sandwich for sandwiches, cookie for cookies, and bar for ice cream bars). The guidance provided is for the label statement of products in ready-to-serve or almost ready-to-serve form. The guidance does not apply to the products which require further preparation for consumption (e.g., dry mixes, concentrates) unless specifically stated in the product category, reference amount, or label statement column that it is for these forms of the product. For products that require further preparation, manufacturers must determine the label statement following the rules in § 101.9(b) using the reference amount determined according to § 101.12(c).

* * * * *

7. Section 101.36 is revised to read as follows:

§ 101.36 Nutrition labeling of dietary supplements.

(a) The label of a dietary supplement that is offered for sale shall bear nutrition labeling in accordance with this regulation unless an exemption is provided for the product in paragraph (h) of this section.

(b) The declaration of nutrition information on the label and in labeling shall contain the following information, using the subheadings and the format specified in paragraph (e) of this section.

(1) *Serving size*—(i) The subheading ''Serving Size'' shall be placed under the heading ''Supplement Facts'' and aligned on the left side of the nutrition label. The serving size shall be determined in accordance with §§ 101.9(b) and 101.12(b), Table 2. Serving size for dietary supplements shall be expressed using a term that is appropriate for the form of the supplement, such as ''tablets,'' ''capsules,'' ''packets,'' or ''teaspoonfuls.''

(ii) The subheading ''Servings Per Container'' shall be placed under the subheading ''Serving Size'' and aligned on the left side of the nutrition label, except that this information need not be provided when it is stated in the net quantity of contents declaration.

(2) *Information on dietary ingredients that have a Reference Daily Intake (RDI) or a Daily Reference Value (DRV) as established in § 101.9(c) and their subcomponents (hereinafter referred to as ''(b)(2)-dietary ingredients'')*—(i) The (b)(2)-dietary ingredients to be declared, that is, total calories, calories from fat, total fat, saturated fat, cholesterol, sodium, total carbohydrate, dietary fiber, sugars, protein, vitamin A, vitamin C, calcium and iron, shall be declared when they are present in a dietary supplement in quantitative amounts by weight that exceed the amount that can be declared as zero in nutrition labeling of foods in accordance with § 101.9(c). Calories from saturated fat and polyunsaturated fat, monounsaturated fat, soluble fiber, insoluble fiber, sugar alcohol, and other carbohydrate may be declared, but they shall be declared when a claim is made about them. Any other vitamins or minerals listed in § 101.9(c)(8)(iv) or (c)(9) may be declared, but they shall be declared when they are added to the product for purposes of supplementation, or when a claim is made about them. Any (b)(2)-dietary ingredients that are not present, or that are present in amounts that can be declared as zero in § 101.9(c), shall not be declared (e.g., amounts corresponding to less than 2 percent of the RDI for vitamins and minerals). Protein shall not be declared on labels of products that, other than ingredients added solely for technological reasons, contain only individual amino acids.

(A) The names and the quantitative amounts by weight of each (b)(2)-dietary ingredient shall be presented under the heading ''Amount Per Serving.'' When the quantitative amounts by weight are presented in a separate column, the heading may be centered over a column of quantitative amounts, described by paragraph (b)(2)(ii) of this section, if space permits. A heading consistent with the declaration of the serving size, such as ''Each Tablet Contains,'' or ''Amount Per 2 Tablets'' may be used in place of the heading ''Amount Per Serving.'' Other appropriate terms, such as capsule, packet, or teaspoonful, also may be used in place of the term ''Serving.''

(B) The names of dietary ingredients that are declared under paragraph (b)(2)(i) of this section shall be presented in a column aligned on the left side of the nutrition label in the order and manner of indentation specified in § 101.9(c), except that calcium and iron shall follow pantothenic acid, and sodium and potassium shall follow chloride. This results in the following order for vitamins and minerals: Vitamin A, vitamin C, vitamin D, vitamin E, vitamin K, thiamin, riboflavin, niacin, vitamin B_6, folate, vitamin B_{12}, biotin, pantothenic acid, calcium, iron, phosphorus, iodine, magnesium, zinc, selenium, copper, manganese, chromium, molybdenum, chloride, sodium, and potassium. The (b)(2)-dietary ingredients shall be listed according to the nomenclature specified in § 101.9 or in paragraph (b)(2)(i)(B)*(2)* of this section.

(1) When ''Calories'' are declared, they shall be listed first in the column of names, beneath a light bar separating the heading ''Amount Per Serving'' from the list of names. When ''Calories from fat'' or ''Calories from saturated fat'' are declared, they shall be indented beneath ''Calories.''

(2) The following synonyms may be added in parentheses immediately following the name of these (b)(2)-dietary ingredients: Vitamin C (ascorbic acid), thiamin (vitamin B_1), riboflavin (vitamin B_2), folate (folacin or folic acid), and calories (energy). Alternatively, the term ''folic acid'' or ''folacin'' may be listed without parentheses in place of ''folate.'' Energy content per serving may be expressed in kilojoules units, added in parentheses immediately following the statement of caloric content.

(3) Beta-carotene may be declared as the percent of vitamin A that is present as beta-carotene, except that the declaration is required when a claim is made about beta-carotene. When declared, the percent shall be declared to the nearest whole percent, immediately adjacent to or beneath the name vitamin A (e.g., ''Vitamin A (90% as beta-carotene)''). The amount of beta-carotene in terms of international units (IU) may be included in parentheses following the percent statement (e.g., ''Vitamin A (90% (4500 IU) as beta-carotene)'').

(ii) The number of calories, if declared, and the quantitative amount by weight per serving of each dietary ingredient required to be listed under paragraph (b)(2)(i) of this section shall be presented either in a separate column aligned to the right of the column of names or immediately following the listing of names within the same column. The quantitative amounts by weight shall represent the weight of the dietary ingredient rather than the weight of the source of the dietary ingredient (e.g., the weight of calcium rather than that of calcium carbonate).

(A) These amounts shall be expressed in the increments specified in § 101.9(c)(1) through (c)(7), which includes increments for sodium and potassium.

(B) The amounts of vitamins and minerals, excluding sodium and potassium, shall be the amount of the vitamin or mineral included in one serving of the product, using the units of measurement and the levels of significance given in § 101.9(c)(8)(iv), except that zeros following decimal points may be dropped, and additional levels of significance may be used when the number of decimal places indicated is not sufficient to express lower amounts (e.g., the RDI for zinc is given in whole milligrams (mg), but the quantitative amount may be declared in tenths of a mg).

(iii) The percent of the Daily Value of all dietary ingredients declared under paragraph (b)(2)(i) of this section shall be listed, except that the percent for protein may be omitted as provided in § 101.9(c)(7); no percent shall be given for subcomponents for which DRV's have not been established (e.g., sugars); and, for labels of dietary supplements of vitamins and minerals that are represented or purported to be for use by infants, children less than 4 years of age, or pregnant or lactating women, no percent shall be given for total fat, saturated fat, cholesterol, total carbohydrate, dietary fiber, vitamin K, selenium, manganese, chromium, molybdenum, chloride, sodium, or potassium.

(A) When information on the percent of Daily Values is listed, this information shall be presented in one column aligned under the heading of ''% Daily Value'' and to the right of the column of amounts. The headings ''% Daily Value (DV),'' ''% DV,'' ''Percent Daily Value,'' or ''Percent DV'' may be substituted for ''% Daily Value.'' The heading ''% Daily Value'' shall be placed on the same line as the heading ''Amount Per Serving.'' When the acronym ''DV'' is unexplained in the heading and a footnote is required under (b)(2)(iii)(D), (b)(2)(iii)(F), or (b)(3)(iv) of this section, the footnote shall explain the acronym (e.g. ''Daily Value (DV) not established'').

(B) The percent of Daily Value shall be calculated by dividing the quantitative amount by weight of each (b)(2)-dietary ingredient by the RDI as established in § 101.9(c)(8)(iv) or the DRV as established in § 101.9(c)(9) for the specified dietary ingredient and multiplying by 100, except that the percent of Daily Value for protein, when present, shall be calculated as specified in § 101.9(c)(7)(ii). The quantitative amount by weight of each dietary ingredient in this calculation shall be the unrounded amount, except that for total fat, saturated fat, cholesterol, sodium, potassium, total carbohydrate, and dietary fiber, the quantitative amount by weight declared on the label (i.e, rounded amount) may be used. The numerical value shall be followed by the symbol for percent (i.e., %).

(C) The percentages based on RDI's and on DRV's shall be expressed to the nearest whole percent, except that for dietary ingredients for which DRV's have been established, ''Less than 1%'' or ''<1%'' shall be used to declare the ''% Daily Value'' when the quantitative amount of the dietary ingredient by weight is great enough to require that the dietary ingredient be listed, but the amount is so small that the ''% Daily Value'' when rounded to the nearest percent is zero (e.g., a product that contains 1 gram of total carbohydrate would list the percent Daily Value as ''Less than 1%'' or ''<1%'').

(D) If the percent of Daily Value is declared for total fat, saturated fat, total carbohydrate, dietary fiber, or protein, a symbol shall follow the value listed for those nutrients that refers to the same symbol that is placed at the bottom of the nutrition label, below the bar required under paragraph (e)(6) of this section and inside the box, that is followed by the statement ''Percent Daily Values are based on a 2,000 calorie diet.''

(E) The percent of Daily Value shall be based on RDI and DRV values for adults and children 4 or more years of age, unless the product is represented or purported to be for use by infants, children less than 4 years of age, pregnant women, or lactating women, in which case the column heading shall clearly state the intended group. If the product is for persons within more than one group, the percent of Daily Value for each group shall be presented in separate columns as shown in paragraph (e)(10)(ii) of this section.

(F) For declared subcomponents that have no DRV's and, on the labels of dietary supplements of vitamins and minerals that are represented or purported to be for use by infants, children less that 4 years of age, or pregnant or lactating women, for total fat, saturated fat, cholesterol, total carbohydrate, dietary fiber, vitamin K, selenium, manganese, chromium, molybdenum, chloride, sodium, or potassium, a symbol (e.g., an asterisk) shall be placed in the ''Percent Daily Value'' column that shall refer to the same symbol that is placed at the bottom of the nutrition label, below the last heavy bar and inside the box, and followed by the statement ''Daily Value not established.''

(G) When calories, calories from fat, or calories from saturated fat are declared, the space under the ''% Daily Value'' column shall be left blank for these items. When there are no other (b)(2)-dietary ingredients listed for which a value must be declared in the ''% Daily Value'' column, the column may be omitted as shown in paragraph (e)(10)(vii) of this section. When the ''% Daily Value'' column is not required, but the dietary ingredients listed are subject to paragraph (b)(2)(iii)(F) of this section, the symbol required in that paragraph shall immediately follow the quantitative amount by weight for each dietary ingredient listed under ''Amount Per Serving.''

(iv) The quantitative amount by weight and the percent of Daily Value may be presented on a ''per unit'' basis in addition to on a ''per serving'' basis, as required in paragraph (b)(2)(ii) of this section. This information shall be presented in additional columns and clearly identified by appropriate headings.

(3) *Information on dietary ingredients for which RDI's and DRV's have not been established*—(i) Dietary ingredients for which FDA has not established RDI's or DRV's and that are not subject to regulation under paragraph (b)(2) of this section (hereinafter referred to as ''other dietary ingredients'') shall be declared by their common or usual name when they are present in a dietary supplement, in a column that is under the column of names described in paragraph (b)(2)(i)(B) of this section or, as long as the constituents of an other dietary ingredient are not listed, in a linear display, under the heavy bar described in paragraph (e)(6) of this section, except that if no (b)(2)-dietary ingredients are declared, other dietary ingredients shall be declared directly beneath the heading ''Amount Per Serving'' described in paragraph (b)(2)(i)(A) of this section.

(ii) The quantitative amount by weight per serving of other dietary ingredients shall be presented in the same manner as the corresponding information required in paragraph (b)(2)(ii) of this section or, when a linear display is used, shall be presented immediately following the name of the other dietary ingredient. The quantitative amount by weight shall be the weight of the other dietary ingredient listed and not the weight of any component, or the source, of that dietary ingredient.

(A) These amounts shall be expressed using metric measures in appropriate units (i.e., 1,000 or more units shall be declared in the next higher set of units, e.g., 1,100 mg shall be declared as 1.1 g).

(B) For any dietary ingredient that is a liquid extract from which the solvent

has not been removed, the quantity listed shall be the weight of the total extract with information on the concentration of the dietary ingredient, the solvent used, and the condition of the starting material (i.e., whether it is fresh or dried), e.g., ''fresh dandelion root extract, x mg (y:z) in 70% ethanol,'' where x is the number of mg of the entire extract, y is the weight of the starting material and z is the volume (milliliters) of solvent. Where the solvent has been partially removed (not to dryness), the final concentration shall be stated (e.g., if the original extract was 1:5 and 50 percent of the solvent was removed, then the final concentration shall be stated as 1:2.5).

(C) For a dietary ingredient that is an extract from which the solvent has been removed, the weight of the ingredient shall be the weight of the dried extract. The dried extract shall be described by an appropriately descriptive term that identifies the solvent used, e.g., ''dried hexane extract of _____'' or ''_____, dried hexane extract.''

(iii) The constituents of a dietary ingredient described in paragraph (b)(3)(i) of this section may be listed indented under the dietary ingredient and followed by their quantitative amounts by weight, except that dietary ingredients described in paragraph (b)(2) of this section shall be listed in accordance with that section. When the constituents of a dietary ingredient described in paragraph (b)(3)(i) of this section are listed, all other dietary ingredients shall be declared in a column; however, the constituents themselves may be declared in a column or in a linear display.

(iv) Other dietary ingredients shall bear a symbol (e.g., an asterisk) in the column under the heading of ''% Daily Value'' that refers to the same symbol placed at the bottom of the nutrition label and followed by the statement ''Daily Value not established,'' except that when the heading ''% Daily Value'' is not used, the symbol shall follow the quantitative amount by weight for each dietary ingredient listed.

(c) A proprietary blend of dietary ingredients shall be included in the list of dietary ingredients described in paragraph (b)(3)(i) of this section and identified by the term ''Proprietary Blend'' or other appropriately descriptive term or fanciful name and may be highlighted by bold type. Except as specified in this paragraph, all other requirements for the listing of dietary ingredients in dietary supplements are applicable.

(1) Dietary ingredients contained in the proprietary blend that are listed under paragraph (b)(2) of this section shall be declared in accordance with paragraph (b)(2) of this section.

(2) Dietary ingredients contained in the proprietary blend that are listed under paragraph (b)(3) of this section (i.e., ''other dietary ingredients'') shall be declared in descending order of predominance by weight, in a column or linear fashion, and indented under the term ''Proprietary Blend'' or other appropriately descriptive term or fanciful name.

(3) The quantitative amount by weight specified for the proprietary blend shall be the total weight of all other dietary ingredients contained in the proprietary blend and shall be placed on the same line to the right of the term ''Proprietary Blend'' or other appropriately descriptive term or fanciful name underneath the column of amounts described in paragraph (b)(2)(ii) of this section. A symbol (e.g., asterisk), which refers to the same symbol placed at the bottom of the nutrition label that is followed by the statement ''Daily Value not established,'' shall be placed under the heading ''% Daily Value,'' if present, or immediately following the quantitative amount by weight for the proprietary blend.

(4) The sample label shown in paragraph (e)(10)(v) of this section illustrates one method of nutrition labeling a proprietary blend of dietary ingredients.

(d) The source ingredient that supplies a dietary ingredient may be identified within the nutrition label in parentheses immediately following or indented beneath the name of a dietary ingredient and preceded by the words ''as'' or ''from'', e.g., ''Calcium (as calcium carbonate),'' except that manner of presentation is unnecessary when the name of the dietary ingredient (e.g., Oriental ginseng) or its synonym (e.g., ascorbic acid) is itself the source ingredient. When a source ingredient is identified in parentheses within the nutrition label, or when the name of the dietary ingredient or its synonym is the source ingredient, it shall not be required to be listed again in the ingredient statement that appears outside of the nutrition label. When a source ingredient is not identified within the nutrition label, it shall be listed in an ingredient statement in accordance with § 101.4(g), which shall appear outside and immediately below the nutrition label or, if there is insufficient space below the nutrition label, immediately contiguous and to the right of the nutrition label.

(1) Source ingredients shall be identified in accordance with § 101.4 (i.e., shall be listed by common or usual name, and the listing of botanicals shall specify the part of the plant from which the ingredient is derived) regardless of whether they are listed in an ingredient statement or in the nutrition label.

(2) When source ingredients are listed within the nutrition label, and two or more are used to provide a single dietary ingredient, all of the sources shall be listed within the parentheses in descending order by weight.

(3) Representations that the source ingredient conforms to an official compendium may be included either in the nutrition label or in the ingredient list (e.g., ''Calcium (as calcium carbonate USP)'').

(e) Nutrition information specified in this section shall be presented as follows:

(1) The title, ''Supplement Facts,'' shall be set in a type size larger than all other print size in the nutrition label and, unless impractical, shall be set full width of the nutrition label. The title and all headings shall be bolded to distinguish them from other information.

(2) The nutrition information shall be enclosed in a box by using hairlines.

(3) All information within the nutrition label shall utilize:

(i) A single easy-to-read type style,

(ii) All black or one color type, printed on a white or other neutral contrasting background whenever practical,

(iii) Upper- and lowercase letters, except that all uppercase lettering may be utilized for packages that have a total surface area available to bear labeling of less than 12 square inches,

(iv) At least one point leading (i.e., space between lines of text), and

(v) Letters that do not touch.

(4) Except as provided for small and intermediate-sized packages under paragraph (i)(2) of this section, information other than the title, headings, and footnotes shall be in uniform type size no smaller than 8 point. Type size no smaller than 6 point may be used for column headings (e.g., ''Amount Per Serving'' and ''% Daily Value'') and for footnotes (e.g., ''Percent Daily Values are based on a 2,000 calorie diet'').

(5) A hairline rule that is centered between the lines of text shall separate each dietary ingredient required in paragraph (b)(2) and (b)(3) of this section from the dietary ingredient above and beneath it, as shown in paragraph (e)(10) of this section.

(6) A heavy bar shall be placed:

(i) Beneath the subheading ''Servings Per Container'' except that if ''Servings Per Container'' is not required and, as a result, not declared, the bar shall be

placed beneath the subheading ''Serving Size,''

(ii) Beneath the last dietary ingredient to be listed under paragraph (b)(2)(i) of this section, if any, and

(iii) Beneath the last other dietary ingredient to be listed under paragraph (b)(3) of this section, if any.

(7) A light bar shall be placed beneath the headings ''Amount Per Serving'' and ''% Daily Value.''

(8) If the product contains two or more separately packaged dietary supplements that differ from each other (e.g., the product has a packet of supplements to be taken in the morning and a different packet to be taken in the afternoon), the quantitative amounts and percent of Daily Value may be presented as specified in this paragraph in individual nutrition labels or in one aggregate nutrition label as illustrated in paragraph (e)(10)(iii) of this section.

(9) In the interest of uniformity of presentation, FDA urges that the information be presented using the graphic specifications set forth in Appendix B to part 101, as applicable.

(10) The following sample labels are presented for the purpose of illustration:

BILLING CODE 4190–01–F

(i) Multiple vitamins:

Supplement Facts

Serving Size 1 Tablet

	Amount Per Serving	% Daily Value
Vitamin A (as retinyl acetate and 50% as beta-carotene)	5000 IU	100%
Vitamin C (as ascorbic acid)	60 mg	100%
Vitamin D (as cholecalciferol)	400 IU	100%
Vitamin E (as dl-alpha tocopheryl acetate)	30 IU	100%
Thiamin (as thiamin mononitrate)	1.5 mg	100%
Riboflavin	1.7 mg	100%
Niacin (as niacinamide)	20 mg	100%
Vitamin B_6 (as pyridoxine hydrochloride)	2.0 mg	100%
Folate (as folic acid)	400 mcg	100%
Vitamin B_{12} (as cyanocobalamin)	6 mcg	100%
Biotin	30 mcg	10%
Pantothenic Acid (as calcium pantothenate)	10 mg	100%

Other ingredients: Gelatin, lactose, magnesium stearate, microcrystalline cellulose, FD&C Yellow No. 6, propylene glycol, propylparaben, and sodium benzoate.

(ii) Multiple vitamins for children and adults:

Supplement Facts

Serving Size 1 Tablet

Amount Per Serving		% Daily Value for Children Under 4 Years of Age	% Daily Value for Adults and Children 4 or more Years of Age
Calories	5		
Total Carbohydrate	1 g	†	< 1%*
Sugars	1 g	†	†
Vitamin A (50% as beta-carotene)	2500 IU	100%	50%
Vitamin C	40 mg	100%	67%
Vitamin D	400 IU	100%	100%
Vitamin E	15 IU	150%	50%
Thiamin	1.1 mg	157%	73%
Riboflavin	1.2 mg	150%	71%
Niacin	14 mg	156%	70%
Vitamin B_6	1.1 mg	157%	55%
Folate	300 mcg	150%	75%
Vitamin B_{12}	5 mcg	167%	83%

* Percent Daily Values are based on a 2,000 calorie diet.
† Daily Value not established.

Other ingredients: Sucrose, sodium ascorbate, stearic acid, gelatin, maltodextrins, artificial flavors, dl-alpha tocopheryl acetate, niacinamide, magnesium stearate, Yellow 6, artificial colors, stearic acid, palmitic acid, pyridoxine hydrochloride, thiamin mononitrate, vitamin A acetate, beta-carotene, folic acid, cholecalciferol, and cyanocobalamin.

(iii) Multiple vitamins in packets:

Supplement Facts

Serving Size 1 Packet
Servings Per Container 10

	AM Packet		PM Packet	
Amount Per Serving		**% Daily Value**		**% Daily Value**
Vitamin A	2500 IU	50%	2500 IU	50%
Vitamin C	60 mg	100%	60 mg	100%
Vitamin D	400 IU	100%		
Vitamin E	30 IU	100%		
Thiamin	1.5 mg	100%	1.5 mg	100%
Riboflavin	1.7 mg	100%	1.7 mg	100%
Niacin	20 mg	100%	20 mg	100%
Vitamin B_6	2.0 mg	100%	2.0 mg	100%
Folic Acid	200 mcg	50%	200 mcg	50%
Vitamin B_{12}	3 mcg	50%	3 mcg	50%
Biotin			30 mcg	10%
Pantothenic Acid	5 mg	50%	5 mg	50%

Ingredients: Sodium ascorbate, ascorbic acid, calcium pantothenate, niacinamide, dl-alpha tocopheryl acetate, microcrystalline cellulose, artificial flavors, dextrin, starch, mono- and diglycerides, vitamin A acetate, magnesium stearate, gelatin, FD&C Blue #1, FD&C Red #3, artificial colors, thiamin mononitrate, pyridoxine hydrochloride, citric acid, lactose, sorbic acid, tricalcium phosphate, sodium benzoate, sodium caseinate, methylparaben, potassium sorbate, BHA, BHT, ergocalciferol and cyanocobalamin.

(iv) Dietary supplement containing dietary ingredient with and without RDI's and DRV's:

Supplement Facts

Serving Size 1 Capsule

Amount Per Capsule	% Daily Value
Calories 20	
Calories from Fat 20	
Total Fat 2 g	3%*
Saturated Fat 0.5 g	3%*
Polyunsaturated Fat 1 g	†
Monounsaturated Fat 0.5 g	†
Vitamin A 4250 IU	85%
Vitamin D 425 IU	106%
Omega-3 fatty acids 0.5 g	†

* Percent Daily Values are based on a 2,000 calorie diet.
† Daily Value not established.

Ingredients: Cod liver oil, gelatin, water, and glycerin.

(v) A proprietary blend of dietary ingredients:

Supplement Facts

Serving Size 1 tsp (3 g) (makes 8 fl oz prepared)
Servings Per Container 24

	Amount Per Teaspoon	% Daily Value
Calories	10	
Total Carbohydrate	2 g	< 1%*
Sugars	2 g	†
Proprietary blend	0.7 g	
German Chamomile (flower)		†
Hyssop (leaves)		†

* Percent Daily Values are based on a 2,000 calorie diet.
† Daily Value not established.

Other ingredients: Fructose, lactose, starch, and stearic acid.

(vi) Dietary supplement of an herb

Supplement Facts

Serving Size 1 Capsule

Amount Per Capsule	
Oriental Ginseng, powdered (root)	250 mcg*

* Daily Value not established.

Other ingredients: Gelatin, water, and glycerin.

(vii) Dietary supplement of amino acids:

Supplement Facts

Serving Size 1 Tablet

Amount Per Tablet	
Calories	15
Isoleucine (as L-isoleucine hydrochloride)	450 mg*
Leucine (as L-leucine hydrochloride)	620 mg*
Lysine (as L-lysine hydrochloride)	500 mg*
Methionine (as L-methionine hydrochloride)	350 mg*
Cystine (as L-cystine hydrochloride)	200 mg*
Phenylalanine (as L-phenylalanine hydrochloride)	220 mg*
Tyrosine (as L-tyrosine hydrochloride)	900 mg*
Threonine (as L-threonine hydrochloride)	300 mg*
Valine (as L-valine hydrochloride)	650 mg*

* Daily Value not established.

Other ingredients: Cellulose, lactose, and magnesium stearate.

BILLING CODE 4190–01–C

(11) If space is not adequate to list the required information as shown in the sample labels in paragraph (e)(10) of this section, the list may be split and continued to the right as long as the headings are repeated. The list to the right shall be set off by a line that distinguishes it and sets it apart from the dietary ingredients and percent of Daily Value information given to the left. The following sample label illustrates this display:

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Supplement Facts

Serving Size 1 Packet

Amount Per Packet		% Daily Value
Vitamin A (from cod liver oil)	5,000 IU	100%
Vitamin C (as ascorbic acid)	250 mg	417%
Vitamin D (as ergocalciferol)	400 IU	100%
Vitamin E (as d-alpha tocopherol)	150 IU	500%
Thiamin (as thiamin mononitrate)	75 mg	5000%
Riboflavin	75 mg	4412%
Niacin (as niacinamide)	75 mg	375%
Vitamin B_6 (as pyridoxine hydrochloride)	75 mg	3750%
Folic Acid	400 mcg	100%
Vitamin B_{12} (as cyanocobalamin)	100 mcg	1667%
Biotin	100 mcg	33%
Pantothenic Acid (as calcium pentothenate)	75 mg	750%
Calcium (from oystershell)	100 mg	10%
Iron (as ferrous fumarate)	10 mg	56%
Iodine (from kelp)	150 mcg	100%
Magnesium (as magnesium oxide)	60 mg	15%

Amount Per Packet		% Daily Value
Zinc (as zinc oxide)	15 mg	100%
Selenium (as sodium selenate)	25 mcg	36%
Copper (as cupric oxide)	1 mg	50%
Manganese (as manganese sulfate)	5 mg	250%
Chromium (as chromium chloride)	50 mcg	42%
Molybdenum (as sodium molybdate)	50 mcg	67%
Potassium (as potassium chloride)	10 mg	< 1%
Choline (as choline chloride)	100 mg	*
Betaine (as betaine hydrochloride)	25 mg	*
Glutamic Acid (as L-glutamic acid)	25 mg	*
Inositol (as inositol monophosphate)	75 mg	*
para-Aminobenzoic acid	30 mg	*
Deoxyribonucleic acid	50 mg	*
Boron	500 mcg	*

* Daily Value not established

Other ingredients: Cellulose, stearic acid and silica.

(f)(1) Compliance with this section will be determined in accordance with § 101.9(g)(1) through (g)(8), except that the sample for analysis shall consist of a composite of 12 subsamples (consumer packages) or 10 percent of the number of packages in the same inspection lot, whichever is smaller, randomly selected to be representative of the lot. The criteria on class I and class II nutrients given in § 101.9(g)(3) and (g)(4) also are applicable to other dietary ingredients described in paragraph (b)(3)(i) of this section. Reasonable excesses of these other dietary ingredients over labeled amounts are acceptable within current good manufacturing practice.

(2) When it is not technologically feasible, or some other circumstance makes it impracticable, for firms to comply with the requirements of this section, FDA may permit alternative means of compliance or additional exemptions to deal with the situation in accordance with § 101.9(g)(9). Firms in need of such special allowances shall make their request in writing to the Office of Food Labeling (HFS–150), Food and Drug Administration, 200 C St. SW., Washington, DC 20204.

(g) Except as provided in paragraphs (i)(2) and (i)(5) of this section, the location of nutrition information on a label shall be in compliance with § 101.2.

(h) Dietary supplements are subject to the exemptions specified as follows in:

(1) Section 101.9(j)(1) for foods that are offered for sale by a person who makes direct sales to consumers (i.e., a retailer) who has annual gross sales or business done in sales to consumers that is not more than $500,000 or has annual gross sales made or business done in sales of food to consumers of not more than $50,000, and whose labels, labeling, and advertising do not provide nutrition information or make a nutrient content or health claim;

(2) Section 101.9(j)(18) for foods that are low-volume products (that is, they meet the requirements for units sold in § 101.9(j)(18)(i) or (j)(18)(ii)); that, except as provided in § 101.9(j)(18)(iv), are the subject of a claim for an exemption that provides the information required under § 101.9(j)(18)(iv), that is filed before the beginning of the time period for which the exemption is claimed, and that is filed by a person, whether it is the manufacturer, packer, or distributor, that qualifies to claim the exemption under the requirements for average full-time equivalent employees in § 101.9(j)(18)(i) or (j)(18)(ii), and whose labels, labeling, and advertising do not provide nutrition information or make a nutrient content or health claim;

(3) Section 101.9(j)(9) for foods shipped in bulk form that are not for distribution to consumers in such form and that are for use solely in the manufacture of other dietary supplements or that are to be processed, labeled, or repacked at a site other than where originally processed or packed.

(i) Dietary supplements are subject to the special labeling provisions specified in:

(1) Section 101.9(j)(5)(i) for foods, other than infant formula, represented or purported to be specifically for infants and children less than 2 years of age, in that nutrition labels on such foods shall not include calories from fat, calories from saturated fat, saturated fat, polyunsaturated fat, monounsaturated fat, and cholesterol;

(2) Section 101.9(j)(13) for foods in small or intermediate-sized packages, except that:

(i) All information within the nutrition label on small-sized packages, which have a total surface area available to labeling of less than 12 square inches, shall be in type size no smaller than 4.5 point;

(ii) All information within the nutrition label on intermediate-sized packages, which have from 12 to 40 square inches of surface area available to bear labeling, shall be in type size no smaller than 6 point, except that type size no smaller than 4.5 point may be used on packages that have less than 20 square inches available for labeling and more than 8 dietary ingredients to be listed and on packages that have 20 to 40 square inches available for labeling and more than 16 dietary ingredients to be listed.

(iii) When the nutrition information is presented on any panel under § 101.9(j)(13)(ii)(D), the ingredient list shall continue to be located immediately below the nutrition label, or, if there is insufficient space below the nutrition label, immediately contiguous and to the right of the nutrition label as specified in § 101.4(g).

(iv) When it is not possible for a small or intermediate-sized package that is enclosed in an outer package to comply with these type size requirements, the type size of the nutrition label on the primary (inner) container may be as small as needed to accommodate all of the required label information provided that the primary container is securely enclosed in outer packaging, the nutrition labeling on the outer packaging meets the applicable type size requirements, and such outer packaging is not intended to be separated from the primary container under conditions of retail sale.

(v) Where there is not sufficient space on a small or intermediate-sized package for a nutrition label that meets minimum type size requirements of 4.5 points if hairlines are used in accordance with paragraph (e)(5) of this section, the hairlines may be omitted and replaced by a row of dots connecting the columns containing the name of each dietary ingredient and the quantitative amounts (by weight and as a percent of Daily Value).

(3) Section 101.9(j)(15) for foods in multiunit food containers;

(4) Section 101.9(j)(16) for foods sold in bulk containers; and

(5) Section 101.9(j)(17) for foods in packages that have a total surface area available to bear labeling greater than 40 square inches but whose principal display panel and information panel do not provide sufficient space to accommodate all required label information, except that the ingredient list shall continue to be located immediately below the nutrition label, or, if there is insufficient space below the nutrition label, immediately contiguous and to the right of the nutrition label as specified in § 101.4(g).

(j) Dietary supplements shall be subject to the misbranding provisions of § 101.9(k).

7. Section 101.65 is amended by revising paragraph (b)(4) to read as follows:

§ 101.65 Implied nutrient content claims and related label statements.

* * * * *

(b) * * *

(4) A statement of identity for a food in which an ingredient constitutes essentially 100 percent of a food (e.g., ''corn oil,'' ''oat bran,'' ''dietary supplement of vitamin C 60 mg tablet'').

* * * * *

Dated: September 11, 1997.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 97–24739 Filed 9–22–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 95N–0282]

Food Labeling; Requirements for Nutrient Content Claims, Health Claims, and Statements of Nutritional Support for Dietary Supplements

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its nutrient content claims regulations to change the terminology used to describe dietary supplements; provide for the use of statements that characterize the percentage level of dietary ingredients that do not have Reference Daily Intakes (RDI's) or Daily Reference Values (DRV's); and withdraw the provision that dietary supplements of vitamins and minerals may not give prominence to any ingredient that is not a vitamin or a mineral on its label or in labeling. The agency is also amending its regulations to specify how (i.e., text, placement, and type size) the disclaimer that must be contained in statements made in accordance with the Federal Food, Drug, and Cosmetic Act (the act) is to be presented. Additionally, FDA is removing the definition of ''dietary supplements,'' and revising the terminology used to describe these products in the regulations on health claims for food products. FDA is taking this action to implement, in part, the Dietary Supplement Health and Education Act of 1994 (the DSHEA).

EFFECTIVE DATE: March 23, 1999.

FOR FURTHER INFORMATION CONTACT: Camille E. Brewer, Center for Food Safety and Applied Nutrition (HFS–165), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5483.

SUPPLEMENTARY INFORMATION:

I. Background

On October 25, 1994, the President signed into law the DSHEA (Pub. L. 103–417). The DSHEA, among other things, defined ''dietary supplement'' by adding section 201(ff) to the act (21 U.S.C. 321(ff)); made provision for statements that characterize the percentage level of dietary ingredients that do not have RDI's or DRV's by adding section 403(r)(2)(F) to the act (21 U.S.C. 343(r)(2)(F)); and amended sections 411(b)(2) and (c)(1) of the act (21 U.S.C. 350(b)(2) and (c)(1)) on the labeling of products that contain vitamins and minerals. In addition, the DSHEA added section 403(r)(6) to the act, which states that statements may be made for dietary supplements if:

> [t]he statement claims a benefit related to a classical nutrient deficiency disease and discloses the prevalence of such disease in the United States, describes the role of a nutrient or dietary ingredient intended to affect the structure or function in humans, characterizes the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function, or describes general well-being from consumption of a nutrient or dietary ingredient * * *

(section 403(r)(6)(A) of the act), and if certain other conditions are met. The manufacturer of the dietary supplement must have substantiation that the statement is truthful and not misleading (section 403(r)(6)(B)), and the statement must prominently contain the following:

> This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

Section 403(r)(6)(C) of the act.

In the **Federal Register** of December 28, 1995, FDA published a proposed rule entitled ''Food Labeling; Requirements for Nutrient Content Claims, Health Claims, and Statements of Nutritional Support for Dietary Supplements'' (60 FR 67176)(hereinafter referred to as ''the dietary supplement proposal''), in which the agency proposed to conform its regulations on nutrient content claims and health claims to the DSHEA. The proposed rule addressed how the statements provided for in section 403(r)(6) of the act (referred to as ''statements of nutritional support'' in the dietary supplement proposal) are to be presented on the label or in labeling of a dietary supplement. In addition, the proposal sought to provide for the use of statements that characterize the percentage level of dietary ingredients that do not have RDI's or DRV's on the labels and in the labeling of dietary supplements.

The agency received approximately 30 letters in response to the proposed rule. Each letter contained one or more comments. Several comments supported the proposal generally or supported aspects of the proposal. Other comments addressed issues outside the scope of the proposal (e.g., monitoring of adverse events, definition of fiber) and will not be discussed here. Several comments suggested modifications or revisions of various aspects of the proposal. A summary of these comments, and a discussion of the agency's conclusions, follow.

II. Revised Regulations

A. Coverage

1. A couple of comments maintained that there is no statutory basis for the issuance of FDA's dietary supplement proposal. These comments argued that the Nutrition Labeling and Education Act of 1990 (hereinafter referred to as ''the 1990 amendments'') limits the reach of ''nutrient content claims'' to claims regarding nutrients of the type required under section 403(q)(1) and (q)(2) of the act, that is, according to these comments, the nutrients that are to be declared in nutrition labeling. One comment maintained that the existence of the alternative language in section 403(r)(5)(D) of the act suggests that Congress was aware of the difference between ''nutrients'' and ''other similar nutritional substances,'' and that it intentionally utilized different language for nutrient content claims and health claims. Similarly, another comment stated that there is no justification for FDA to conclude that the phrase ''other similar nutritional substances'' is applicable to nutrient content claims.

The agency has addressed the question of the application of the nutrient content claims provisions to nutrients without RDI's or DRV's (59 FR 378, January 4, 1994; and 60 FR 67176, December 28, 1995). In the dietary supplement proposal (60 FR 67176), the agency stated:

> Section 403(r)(1)(A) of the act states that a food intended for human consumption is misbranded if it bears a claim that expressly or by implication ''characterizes the level of any nutrient which is of the type required by paragraph (q)(1) or (q)(2) to be in the label or labeling of the food * * *.'' The statute uses the same language in section 403(r)(1)(B) to describe the substances that could be the subject of a health claim. A health claim is a claim that ''characterizes the relationship of any nutrient which is of the type required by paragraph (q)(1) or (q)(2) to be in the label or labeling of the food to a disease or a health-related condition * * *.'' Under section 403(r)(1)(B), a health claim may be made in accordance with section 403(r)(5)(D) as well as section 403(r)(3). Thus, because a statute must be read as a whole, the language in both sections 403(r)(1)(A) and (r)(1)(B) of the act that describes the substances that may be the subject of a nutrient content or of a health claim must be read in conjunction with section 403(r)(5)(D), which addresses health claims for vitamins, minerals, herbs, or other similar nutritional substances that are components of dietary supplements. Thus, the ''nutrients of the type required by paragraph (q)(1) or (q)(2)'' that are the subject of sections 403(r)(1)(A) and (r)(1)(B) of the act include vitamins, minerals, herbs, and other similar nutritional substances.

The agency also noted in the dietary supplement proposal (60 FR 67176) that the legislative history of ''other

nutritional substances'' reveals that its coverage is broad and could, in appropriate circumstances, include dietary ingredients without RDI's or DRV's (136 Congressional Record S16609 (October 24, 1990)). In a discussion between Senators Metzenbaum and Symms before the passage of the 1990 amendments, Senator Symms stated:

* * * What follows is a list of a few of the items and foods that I believe would fall under the ''other similar nutritional substances'' category established by this bill:

Primrose oil, black currant seed oil, coldpressed flax seed oil, ''Barleygreen'' and similar nutritional powdered drink mixes, Coenzyme Q 10, enzymes such as bromelain and quercetin, amino acids, pollens, propolis, royal jelly, garlic, orotates, calcium-EAP (colamine phosphate), glandulars, hydrogen peroxide (H_2O_2), nutritional antioxidants such a superoxide dismutase (SOD), and herbal tinctures.

Based on this colloquy, the agency interprets the list of dietary ingredients that fall under the definition of ''dietary supplement'' in section 201(ff) of the act as an explication of ''other similar nutritional substances.'' The comments to this rulemaking ignored the identity of language between 403(r)(1)(A) and 403(r)(1)(B) of the act and that the 403(r)(5)(D) language (i.e., ''other similar nutritional substances'') is subsumed under the ''nutrients of the type'' language that appears in 403(r)(1)(B) as well as in 430(r)(1)(A) of the act.

The comments to this rulemaking did not provide any information to persuade the agency to modify its tentative conclusions. The comments construed the language in section 403(1)(A) and (1)(B) of the act too narrowly. As the discussion from the proposal quoted above makes clear, the structure of the law itself compels FDA's conclusion with respect to the coverage of the language in question. Nor is there anything in the DSHEA that would suggest a different result with regard to the coverage of these provisions. FDA therefore rejects the comments that disagreed with the proposal on the coverage of the nutrient content claim provisions.

2. Several comments from the conventional food industry expressed concern that the statutory requirements for claims on dietary supplements can result in claims that give the misleading impression that dietary supplements provide more health benefits than conventional foods, as well as the erroneous impression that the presence of a dietary ingredient in a supplement is superior to the same ingredient provided in a matrix of conventional food by allowing dietary supplements to make claims that foods cannot. To illustrate these points, one comment stated that powdered, dehydrated cranberries sold in capsule form could bear a claim stating that they are beneficial for urinary tract health, while cranberry juice cocktail may not. The comment argued that such a claim is denied cranberry juice despite the fact that it has been demonstrated in clinical trials to prevent recurrence of urinary tract infections in women.

Other comments stated that the percentage claim provisions are an example of inequality in the regulatory treatment of conventional foods and dietary supplements. One comment stated that under the proposal, comparative percentage claims (e.g. ''as much as,'' ''twice the amount of * * *,'' ''500 percent of * * *'') for dietary ingredients that do not have RDI's or DRV's are forbidden to conventional food marketers, because the 1990 amendments prohibit claims that ''characterize'' the level of these dietary ingredients unless such claims have been defined by the agency in a regulation, but not to dietary supplement marketers. The comment argued that this situation is inequitable and internally inconsistent because it permits dietary supplement marketers to make, by circuitous language, claims that they cannot make directly. As an example, the comment stated that the effect of the agency's proposal is to lay down for dietary supplement marketers the following two rules: (1) You cannot claim that your product has ''more'' of a dietary ingredient than ''x'' product; but (2) you can claim that your product has ''twice as much'' of a dietary ingredient as ''x'' product. The comment argued that virtually every consumer will understand the latter claim to communicate the impermissible message contained in the former claim.

Another comment from a trade association for conventional food manufacturers stated that accurate statements describing the quantity of a dietary ingredient for which there is no RDI or DRV would be more appropriate than percentage claims. The comment stated that should FDA allow quantitative declarations for dietary ingredients without RDI's or DRV's, equity and fairness require that such statements also be allowed on conventional foods. The comment stated that such quantitative statements will be meaningful to consumers, and that conventional foods will be placed at a competitive disadvantage if prohibited from using these statements.

One comment stated that labeling claims for which there is no scientific basis are not in the public interest. The comment maintained that such statements undermine the public's confidence in the government's ability to protect consumers from products that may pose health risks. Further, the comment stated that the proposed regulations will undermine the credibility of FDA's regulations on nutrient content and health claims for foods.

On the other hand, a comment from a trade association for dietary supplement manufacturers stated that dietary supplements should be treated differently than conventional foods because the supplement industry thrives on open competition and does not seek government regulation to limit competition. The comment also stated that the dietary supplement industry wants to be able to make content claims for its products without FDA's approval because consumers are protected under the agency's general misbranding authority.

FDA acknowledges that there are some differences between dietary supplements and conventional foods with respect to the types of claims that can be made on their product labels, and that the content claims that can be made on both types of products without FDA authorization are limited. These differences and limitations, however, are created by the statute itself. FDA has no authority to modify the regulatory regime that is established by the act.

Section 201(g)(1)(B) of the act states that the term ''drug'' means articles intended for use in diagnosis, cure, mitigation, treatment, or prevention of disease. FDA points out that the claim that cranberry juice cocktail prevents the recurrence of urinary tract infections mentioned by one of the comments is a claim that brings the product within the ''drug'' definition whether it appears on a conventional food or on a dietary supplement because it is a claim that the product will prevent disease. However, a claim that cranberry products help to maintain urinary tract health may be permissible on both cranberry products in conventional food form and dietary supplement form if it is truthful, not misleading, and derives from the nutritional value of cranberries. If the effect derives from the nutritive value of cranberries, the claim would describe an effect of a food on the structure or function of the body and thus fall under one exception to the definition for the term ''drug'' found in 201(g)(1)(C) of the act. The claim is not a health claim because no disease is mentioned explicitly or implicitly (see section 403(r)(1)(B) of the act).

Only if the claimed benefit did not derive from the nutritional value of cranberries would it be true that the

claim could appear on a dietary supplement but not a conventional food. This result is dictated by section 403(r)(6) of the DSHEA.

With regard to percentage claims, section 7(c) of the DSHEA amends section 403(r)(2) of the act by adding clause (F) which reads:

Subclause (i) clause (A) does not apply to a statement in the labeling of a dietary supplement that characterizes the percentage level of a dietary ingredient for which the Secretary has not established a reference daily intake, daily recommended value, or other recommendation for daily consumption.

This new provision refers to section 403(r)(2)(A)(i) of the act, which states that nutrient content claims may be made only if the characterization of the level made in the claim uses terms which are defined in regulations of the Secretary. The effect of section 403(r)(2)(F) of the act is to permit, on dietary supplement labels or in dietary supplement labeling, the use of statements that have not been defined by FDA but that, nonetheless, characterize the percentage level of a dietary ingredient for which an RDI or DRV has not been established.

In the dietary supplement proposal (60 FR 67176), the agency interpreted section 403(r)(2)(F) of the act as permitting percentage claims for substances for which an RDI or DRV has not been established on labels or labeling of dietary supplements but not on conventional foods. Significantly, while comments objected to FDA doing so, no comments argued that the agency had misinterpreted this aspect of section 403(r)(2)(F). The limited legislative history does not make clear why Congress chose to differentiate between these two types of food in this way.

However, the structure of the DSHEA suggests that Congress recognized that dietary supplements are not necessarily like other foods. Where other foods are consumed for taste, aroma, or nutritive value, some dietary supplements are consumed for none of these reasons. Congress apparently concluded that the labeling of dietary supplements should be able to accommodate this fact. Thus, Congress provided for the inclusion in the nutrition label of dietary ingredients for which no daily consumption recommendations have been established, as well as for the use of percentage claims about such ingredients. Congress did not make similar provision for such ingredients in conventional foods, presumably because it saw no reason to distract consumers from the traditional reasons why they choose particular conventional foods.

In the percentage claims provisions in § 101.13(q)(3)(ii) (21 CFR 101.13(q)(3)(ii)), the agency sought to interpret section 403(r)(2)(F) of the act in a flexible manner. Giving section 403(r)(2)(F) of the act a significantly broader or different application must be accomplished through the legislative process. For now, however, it remains the case that, except for the provisions for amount or percentage statements under § 101.13(i)(3), statements that characterize the level of a dietary ingredient without an established RDI or DRV will misbrand a conventional food.

It is important to note that the use of defined nutrient content claims, such as ''more'' and ''high,'' remains limited, for both conventional foods and dietary supplements, to those dietary ingredients that have RDI's or DRV's. Consumer research shows that the defined nutrient content claims are widely recognized and used by consumers, and that consumers understand that the defined claims have specific meanings (Ref. 1). The agency is not convinced that consumers will automatically associate comparative percentage statements on dietary supplements with these defined nutrient content claims. Consumer research shows that public confidence in the food label is high (Ref. 2), and FDA has no reason to believe that the comparative percentage claims provisions for dietary supplements will undermine public confidence in the agency's regulations.

Moreover, as the agency has previously stated (60 FR 67175 at 67177), FDA is not without recourse to curtail percentage claims that are misleading on the labels and in the labeling of dietary supplements. Percentage statements on the label or in labeling of dietary supplements that characterize the percentage level of a dietary ingredient for which there is no established RDI or DRV in relation to an equivalent or increased/decreased amount of the dietary ingredient in another food, would be misleading under sections 403(a) and 201(n) of the act if there is not a meaningful amount of the dietary ingredient in either of the foods being compared, or if there is not a meaningful difference in the level of the dietary ingredient between the two foods.

The agency recognizes that it cannot provide a completely satisfying resolution for the differences in the types of percentage claims that can be made on the labels and in labeling of dietary supplements as opposed to conventional foods. FDA is committed, however, to as much parity between dietary supplements and conventional foods as is possible within the statute. The agency rejects the comment that dietary supplements should be treated differently than conventional foods because differences in treatment are in the interest of a free market in dietary supplements. The agency has an obligation to implement the law that Congress has enacted in a fair and equitable manner. FDA is doing exactly that in its regulation of content claims for dietary supplements as well as for conventional foods.

3. One comment from a food manufacturer interpreted the proposal to mean that food companies may no longer make percentage statements about ingredients contained in their products (e.g., ''70% milk,'' ''twice as much milk as the leading brand'') because FDA has not adopted RDI's or DRV's for these ingredients. The manufacturer argued that there is nothing in any statute or regulation that prohibits a food manufacturer from stating that its product contains a particular ingredient, or from comparing the amount of the ingredient to the amount present in another food.

FDA concludes that this comment misconstrues the statute. The agency proposed to implement section 403(r)(2)(F) of the act, which, as stated above, applies only to claims in the labeling of a dietary supplement that characterize the percentage of a dietary ingredient for which FDA has not established an RDI or DRV (e.g., omega-3 fatty acids, amino acids, phytochemicals). This provision has no application to conventional foods.

As for the milk claims that the comment cites, the agency advises that it has no intention of limiting percentage statements on conventional foods that clearly describe ingredients in a manner that relates to their organoleptic properties or that presents them as adding value to the product. Manufacturers of conventional foods may continue to state that products contain particular ingredients and to compare the amounts of such ingredients to the amounts present in other foods (see 21 CFR 101.65(b)(3)). However, the agency will continue to evaluate the context in which claims such as ''70% milk'' and ''twice as much milk as a leading brand'' are made to determine whether they fall under the nutrient content claims regime. Such claims can be, in some cases, implied nutrient content claims about the level of calcium in the product that bears the claim. If such statements are found to be implied nutrient content claims for calcium by the agency, they may be used as long as they meet the criteria for the claim (see 21 CFR 101.54). If they are not implied claims, nothing in the regulations precludes the use of such

statements so long as they are truthful and nonmisleading.

4. One comment argued that the new definition of ''dietary supplement'' is ambiguous and would include products marketed in ''traditional food form.'' The comment requested that the agency clarify whether conventional food products that contain high levels of nutrients, such as breakfast cereals and fruits and vegetables can be marketed as supplements.

The distinction between dietary supplements and conventional foods becomes more apparent when the act is read carefully. The DSHEA added section 201(ff)(2) which provides that a ''dietary supplement'' is a product that is not represented for use as a conventional food. It also struck the provision that excluded products that simulate conventional foods from the coverage of section 411 of the act (see section 3(c)(2) of the DSHEA). Thus, under the act, as amended by the DSHEA, a dietary supplement may be ''in conventional food form.'' In other words, a dietary supplement may be a product with physical attributes (e.g., product size, shape, taste, packaging) that are essentially the same as a conventional food, so long as it is not represented for use as a conventional food.

Thus, whether a product is a dietary supplement or a conventional food will depend on how it is labeled. To be a dietary supplement, a product must bear the term ''dietary supplement'' as part of its common or usual name. This term may be modified to include the name of the dietary ingredient (e.g, ''vitamin C supplement'') or an appropriately descriptive term (e.g., ''multivitamin supplement''). (See comment number 1 in the companion document entitled ''Food Labeling; Statement of Identity, Nutrition Labeling and Ingredient Labeling of Dietary Supplements'' published elsewhere in this issue of the **Federal Register** for further discussion of this issue.) All other food products, that is, those that are not identified as dietary supplements, will be subject to regulation as conventional foods.

While use of the term ''dietary supplement'' in the statement of identity is a necessary condition for a product to be represented as a dietary supplement, it may not be enough to establish that the food is appropriately regulated as one. If the food is represented as a dietary supplement and is only intended to increase the dietary intake of specific substances (e.g., vitamins), then the product would likely be subject to regulation as a dietary supplement (section 201(ff)(1) of the act). It would not be subject to regulation as a dietary supplement, however, if it bears a statement that associates it with a conventional food. For example, a product in bar form that is labeled as a dietary supplement but that also bears label statements that represent it as a snack food or as a substitute for a candy bar would be subject to regulation as a conventional food. Similarly, a breakfast cereal-type product could characterize itself as a dietary supplement if it did not represent itself as a breakfast food or use the term ''cereal'' as a statement of identity. Either of the latter two scenarios would represent the product as a conventional food.

This result is compelled by section 201(ff)(1) of the act, which states that a dietary supplement is intended to supplement the diet. Claims that represent the product as being a snack food or a breakfast cereal would evidence that the product is intended to do more than supplement the diet and thus would subject it to the regime that applies to foods other than dietary supplements.

B. Quantitative Amounts for Percentage Claims

5. A comment from a manufacturer of a dietary supplement stated that percentage claims such as ''40 percent omega-3 fatty acids'' do not give the consumer any meaningful information because the consumer will not know whether the claim means that 40 percent of the product is omega-3 fatty acids, or that the product contains an ingredient that is composed of 40 percent omega-3 fatty acids, or even that the product contains 40 percent of the omega-3 fatty acids as compared to another brand or another food. The comment stated that the only way to make this information useful and nonmisleading is to require that the percentage level be immediately accompanied by a statement of the quantity of the dietary ingredient per serving of the product.

The comment also stated that there are inherent problems in comparing a manufactured or synthetic dietary ingredient with a dietary ingredient in its natural source because natural sources are subject to wide variability in composition. For example, the comment maintained that there would be no way to accurately quantify the actual amount that comprises ''100 percent of the dietary ingredient 'X' in a bulb of garlic.'' The comment stated that this example is meaningless and would mislead consumers. The comment suggested that to provide any meaningful comparative information to consumers, there must be some generally recognized quantitative amount of the dietary ingredient in the reference substance. The comment also suggested that in the absence of a scientifically accepted standard for measuring the dietary ingredient in a natural source, FDA should clarify that when there is a comparison of an added, or a synthetic, dietary ingredient to a natural source (e.g., garlic bulb, fish liver oil), the natural source is the ''reference food,'' which is subject to the requirement for clear identification. The comment suggested that the actual amounts of the dietary ingredient in the labeled and reference foods be declared.

The agency is persuaded that percentage claims will provide more useful information to the consumer, and that the potential for misleading claims will be limited, if quantitative information is provided along with the percentage information. This information will facilitate comparisons of the amounts of dietary ingredients in products that bear percentage claims, which, in turn, will assist consumers in selecting products with the amount of the dietary ingredient that they are seeking and will allow consumers to make comparisons of the content of specific dietary ingredients across products.

Accordingly, FDA is revising § 101.13(q)(3)(ii) by adding § 101.13(q)(3)(ii)(A) to state that, for dietary supplements, whenever a statement is made that characterizes the percentage level of a dietary ingredient for which there is no RDI or DRV, the actual amount of the dietary ingredient in a serving of the product shall also be declared (e.g., ''40 percent omega-3 fatty acids, 10 mg per capsule'').

In addition, FDA is adding § 101.13(q)(3)(ii)(B), which states that, for dietary supplements, where a statement that characterizes the percentage level for a dietary ingredient for which there is no RDI or DRV is used to compare the amount of the ingredient in the food that bears the claim to the amount in a reference food, the amount of the dietary ingredient in the food must be declared and the amount of the dietary ingredient in the reference food to which the product is being compared must also be declared. Moreover, the reference food must be clearly identified (e.g., ''twice the omega-3 fatty acids per capsule (80 mg) as in 100 mg of menhaden oil (40 mg)'').

While FDA acknowledges that there may be variability in the content of certain dietary ingredients in natural source products (e.g., garlic) based on a variety of conditions (e.g., soil, cultivars, climate), FDA is not persuaded that the inherent variability

in the content of a dietary ingredient is a barrier to the declaration of the quantitative amount of the dietary ingredient on the product label. Variability in nutrient content is a factor that the agency takes into consideration in evaluating label statements for all foods, not just dietary supplements. Implicit in the compliance sampling provisions in 21 CFR 101.9(g) is the concept that there will be variation in naturally-occurring nutrients present in subsamples of a product. Variability is taken into consideration in the development of data bases and food composition tables. FDA expects that, as more analyses are performed in support of label values for naturally-occurring dietary ingredients that have and do not have RDI's or DRV's, guidance on sampling strategies, weighing procedures, and statistical treatment to account for variation among samples will improve. Because of potential variation in the dietary ingredient content, firms may label the dietary ingredient values on products conservatively, so that the products declaring such values have a high probability of passing the FDA compliance evaluation. Statistical procedures for doing so are discussed in ''FDA Nutrition Labeling Manual: A Guide for Developing and Using Databases.'' At the same time, consumers have the right to expect, with a reasonable probability, that label values honestly and reasonably represent the content in the products they purchase.

6. A couple of comments noted that in many instances there are no validated methods to analyze for a variety of dietary ingredients, particularly herbal ingredients. The comments pointed out that the accuracy of label claims will be impossible to verify because of the lack of accepted quantitative analytical methods or standards.

FDA recognizes that analytical methods are needed for a variety of dietary ingredients. The agency encourages the dietary supplement industry to participate in developing and in validating analytical methods for dietary ingredients for which there are not generally accepted methods. The lack of methodology to assess the validity of label claims is of concern because it increases the possibility of consumer fraud. However, FDA has every expectation that dietary supplement manufacturers will make claims in a responsible manner. This is the premise on which section 403(r)(6) of the act (see section 403(r)(6)(B)) was apparently based. Therefore, FDA expects that firms will not make claims unless they are in possession of evidence that establishes the validity of their claims.

7. Several comments suggested that all examples discussing the amount of allicin in garlic (e.g., ''100 percent of the allicin in a bulb of garlic'') be dropped because there is no allicin in a bulb of garlic or in dietary supplements of garlic. One comment stated that allicin is produced as a result of an enzymatic reaction of alliin with the enzyme alliinase (which are both components of raw garlic), and that this reaction occurs only when the garlic clove is ruptured by crushing, cutting, or some other manner. The comment stated that allicin is associated with garlic only during the process of decomposition, and that it has a half-life of less than 24 hours at room temperature. The comment stated that it is helpful to have some examples that illustrate the distinction between ''ingredient'' and ''dietary ingredient.''

The agency used the allicin and garlic examples only to illustrate distinctions in label statements about dietary ingredients and ingredients. Based on the comments, the agency concludes that the examples, which were taken from statements by representatives of the dietary supplement industry, were not the best choices to illustrate this distinction. Questions regarding the presence or absence of allicin are beyond the scope of this rulemaking. Accordingly, the agency will remove all examples referring to garlic and allicin from § 101.13(q).

The agency agrees that examples that show the difference between a dietary ingredient and an ingredient are helpful. Calcium, iron, and omega-3 fatty acids are examples of dietary ingredients, while calcium carbonate, ferrous sulfate, and cod liver oil respectively, are examples of ingredients.

8. One comment requested that the agency drop the proposed requirements for referral statements, disclosure statements, and accompanying information for percentage claims on dietary supplements.

The comment did not provide any explanation to support its request, and therefore, the agency has no basis upon which to change its position on these requirements. While section 403(r)(2)(F) of the act states that section 403(r)(2)(A)(i) does not apply to statements on the labels of dietary supplements that characterize the percent level of dietary ingredients, there is nothing in the DSHEA that exempts such statements from the requirement in section 403(r)(2)(B) of the act for referral statements (i.e., ''See *[location]* for nutrition information'') or from other requirements for nutrient content claims. Therefore, FDA has made no change in response to this comment.

C. Disclaimer

9. Several comments requested that FDA clarify that the disclaimer for statements made under section 403(r)(6) of the act is required only when the manufacturer wishes to take advantage of the provisions for exemption from the drug definition. Other comments requested that the agency clarify that section 6 of the DSHEA (which added section 403(r)(6) to the act) does not apply to recognized nutrients with RDI's or DRV's. Other comments requested that the agency clarify the type of claims that may be made, the form and amount of substantiation that FDA will require, and to whom and in what form the 30-day notification must be made.

Section 403(r)(6) of the act sets out the circumstances in which certain types of statements can be made about all of the substances listed in section 201(ff) of the act in the label or labeling of dietary supplements. FDA is no longer referring to these statements as ''statements of nutritional support,'' even though this phrase is used in the title of section 6 of the DSHEA, because many of the substances that can be the subject of this type of claim do not have nutritional value. Thus, the term ''statement of nutritional support'' is not accurate in all instances.

The agency agrees that the disclaimer provided for in section 403(r)(6) of the act is required only when the manufacturer wishes to take advantage of the exception from the drug definition that is provided for in section 201(g)(1) of the act for products that comply with section 403(r)(6). Section 201(g)(1)(C) of the act recognizes that common sense foods, that is, products with nutritional value, affect the structure or function of the body because of their nutritional value. Thus, the types of claims described in section 403(r)(6)(A) of the act can be made to describe the nutritive value of a product without fear of action against the product as a drug (e.g., ''calcium builds strong bones and teeth'') so long as the claims are not false or misleading. The claim would simply describe the nutritive value of the substance in question. However, a dietary supplement manufacturer may still choose to comply with section 403(r)(6) of the act in making a claim about a substance with nutritive value if the manufacturer chooses to take advantage of the protection provided by that section and the last sentence of section of section 201(g)(1) of the act. Products without nutritive value, however, would be subject to regulatory action as drugs

under section 201(g)(1)(C) of the act if they make any of the claims listed in section 403(r)(6)(A) of the act without compliance with all of the provisions of section 403(r)(6).

Questions regarding substantiation and notification requirements for statements provided for under section 403(r)(6) of the act are outside the scope of this rulemaking. The agency advises that it published a proposed rule on notification procedures for such statements in the **Federal Register** on September 27, 1996 (61 FR 50771). The agency's tentative conclusions with respect to notification procedures are discussed in that proposal.

The agency concludes that it is desirable to streamline its regulations by covering all provisions addressing statements provided for under section 403(r)(6) of the act in one section. For consistency with the proposed regulation on notification procedures, the agency is changing the title and the section number from ''§ 101.94 *Statements of nutritional support; disclaimer*'' to ''§ 101.93 *Notification procedures for certain types of statements on dietary supplements*.'' Additionally, the agency is redesignating proposed § 101.94(a), (b), (c), and (d) as § 101.93 (b), (c), (d), and (e) and reserving § 101.93(a) in anticipation of the final rule on notification procedures.

10. One comment requested that the agency eliminate a reference to ''the exemption to section 201(g)(1)(C) of the act'' from proposed § 101.94(a) (redesignated as § 101.93(b)) because there are two exceptions to 201(g)(1)(C) of the act. The comment stated that the first exemption is the exception for ''food'' in section 201(g)(1)(C) of the act. The comment stated that the second exemption is the one that was added by the DSHEA. The comment stated that the DSHEA provides that those dietary ingredients that are not covered by the first exception from the drug definition (i.e., for food) are covered by the mechanism in section 403(r)(6) of the act that permits claims to be made concerning the role of other dietary ingredients in the body while avoiding classification as a ''drug.''

FDA acknowledges that there are now two exceptions to section 201(g)(1)(C) of the act. Accordingly, the agency is clarifying that § 101.93(b) refers to the second exception, that is, for dietary supplements that are labeled in compliance with section 403(r)(6) of the act. FDA is revising § 101.93(b) to reflect the comment's point that there are now two exceptions to section 201(g)(1)(C) of the act.

However, FDA disagrees with the comment in two respects. First, the comment seems to imply that all dietary supplements are covered per se by the exception, which is not the case. Dietary supplements have to comply with section 403(r)(6) of the act to be subject to the exception (unless, of course, as stated above, they are subject to the other exception for ''food'' as that term has been interpreted by the courts, see *Nutrilab Inc.* v. *Schweiker*, 713 F.2d. 335, 338 (7th Cr. 1983)). In addition, paragraph (a) of the conforming amendments found in section 10 of the DSHEA states that a product that bears a statement made in accordance with section 403(r)(6) of the act is not a drug under section 201(g)(1)(C) of the act ''solely because the label or the labeling contains such a statement.'' Thus, the dietary supplement may be found to be a drug based on some evidence of intended use other than the statement made in accordance with section 403(r)(6) of the act.

11. Several comments supported the proposal to place the disclaimer adjacent to the statement provided for under section 403(r)(6) of the act where there is a single statement. Other comments disagreed with this aspect of the proposal. The latter comments stated that it is sufficient to tie the statement to the disclaimer through the use of asterisks. These comments maintained that dietary supplement packages tend to be small, that space is at a premium on dietary supplement labels, and that consumers are sufficiently accustomed to the asterisk to locate the disclaimer elsewhere on the label.

Similarly, other comments supported the proposal that the disclaimer be placed on the same panel or page where there are multiple statements. Other comments objected to this placement and stated that the repetition of the disclaimer on every panel or page on which a statement appears is redundant and unnecessary. To justify the placement of the disclaimer on an alternate panel, one comment stated that safety claims are often found on separate label panels, and that there is no evidence that separating a message on different parts of a label leads to a lack of consumer understanding of the safety information on these products. Other comments stated that the agency's proposed approach is not required by statute, places an undue burden on dietary supplement manufacturers and distributors, and would inhibit, rather than aid, consumer understanding of information on the labeling of these products. These comments also maintained that there is typically insufficient space to repeat the disclaimer on every panel or page.

One comment urged the agency to use a single ''global'' disclaimer for all claims made on a dietary supplement label and claimed that if the agency did so, no asterisks or symbols would be necessary.

A variety of locations were suggested for the placement of the disclaimer. A couple of comments suggested that the disclaimer be placed under, or adjacent to, the nutrition label. Other comments suggested that the disclaimer be placed on the panel to the left of the principal display panel. Another comment suggested that the disclaimer be placed next to the most prominent claim.

FDA has evaluated the comments and concludes that the placement of the disclaimer on a panel other than where the statement is made would not meet the statutory requirement for the placement of the disclaimer. Section 403(r)(6)(C) of the act requires that the statement ''contain'' the disclaimer, prominently displayed in boldface type. A literal reading of section 403(r)(6)(C) of the act suggests that each statement must contain the disclaimer in its entirety.

In the case of multiple statements, the agency sought to minimize the burdens imposed by the act by proposing that when the statements provided for in section 403(r)(6) of the act are tied to the disclaimer by means of an asterisk or other symbol, the statutory requirement that the statement contain the disclaimer would be met because the two discrete pieces would be linked together.

Based on its experience with asterisks within the nutrition label, the agency concludes that consumers are accustomed to using asterisks on labels to associate two discrete pieces of important information when they are in the same field of vision (Ref. 3). For this reason, the agency is persuaded that the use of an asterisk or other symbol that links the statement to the disclaimer meets the statutory requirement for single statements. Ideally, the disclaimer should be placed immediately adjacent to each statement, but the agency is convinced that the use of asterisks or other symbols will adequately serve the same purpose while providing flexibility to the manufacturers. The agency is revising proposed § 101.94(c) (redesignated as § 101.93(d)) to reflect this judgement.

The agency rejects the comments that stated that repetition of the disclaimer on every panel or page where a statement made in accordance with section 403(r)(6) of the act appears is unnecessary. The agency concludes that

to meet the statutory requirement that the disclaimer be ''contained'' within the statement, the disclaimer must be within the same field of vision as the statement itself. Because the agency concludes that the placement of the disclaimer anywhere on the same page or panel of labeling is equivalent to meeting the requirement of being ''contained,'' each of the suggestions for the placement of a single disclaimer on a product label (e.g., under the nutrition label, adjacent to the most prominent claim) would not provide an acceptable alternative.

The agency points out that the requirements for the disclaimer also extend to labeling: There are potentially many vehicles (e.g., placards, pamphlets, catalogs, books) that would have to bear the disclaimer. The agency is concerned that the disclaimer be prominent in these forms of labeling. Even with the flexibility of the use of an asterisk to tie the claim and the disclaimer to a single statement, the disclaimer could be obscured in pages of text of a package insert, pamphlet, or book if it did not appear on the same page or panel (i.e., in the same field of vision) as the statement itself. Because of the variety of possibilities for the presentation of the disclaimer, the agency concludes that for labeling, as for labels, it is important to retain the provision that the disclaimer appear within the same field of vision, that is, on each package panel or page where a statement is made, under section 403(r)(6) of the act.

The use of the statements provided for in section 403(r)(6) of the act is entirely voluntary, and the agency is not persuaded that the use of the disclaimer would be unduly burdensome to manufacturers that choose to use such statements.

The agency rejects the concept of a ''global'' disclaimer because its application would be undefined and thus could create misleading or false impressions. For example, some products may bear a variety of claims, including nutrient content and health claims, which are authorized by the agency. In this case, the use of a ''global'' disclaimer could create the impression that these claims had not been evaluated by FDA, which would be false.

Accordingly, the agency is revising proposed § 101.94(c) (redesignated as § 101.93(d)) to state that a symbol (e.g., an asterisk) can be used to link a single statement to the disclaimer. On product labels and in labeling for single and multiple statements, the disclaimer shall appear on each panel or page where there is a statement.

12. A couple of comments supported the placement of the disclaimer within a box. These comments stated that placement of the statement within a box should help ensure that consumers will read the disclaimer and will give adequate prominence to the statutory statement. Other comments disagreed with the placement of the disclaimer within a box. Several comments stated that the DSHEA makes no reference to a box. A couple of comments stated that warnings are typically set out in boxes in labeling, and the disclaimer is not intended to be a warning. Another comment objected to boldface type.

One comment referred to the definition of prominence in section 403(f) of the act and stated that all this section requires is that the information be placed such that consumers are likely to read it under customary conditions of purchase and use. One comment stated that it should be left to the discretion of the manufacturer to ensure that the disclaimer is prominently featured, through some combination of boldface type, color, a box, or other design features.

The agency is not aware of any research that specifically examines whether consumers associate boxed information with warning information. No evidence was included in the comments to persuade the agency that boxed information is viewed by consumers as a warning. Manufacturers may voluntarily enhance the disclaimer by a variety of other graphic measures. However, section 403(r)(6)(C) of the act requires that the disclaimer be in boldface type. Graphic devices such as boxing are used to draw attention to important information. For example, the nutrition label is placed in a box. Thus, the relevant question is whether the information is important enough to be boxed, not whether it will be seen as a warning.

Congress has made the judgment that the disclaimer is important information by requiring that the statement be in boldface type. Because the statue explicitly requires boldface type, FDA is not persuaded that the standard for prominence in 403(f) of that act is sufficient to meet the standard for prominence for the disclaimer intended by the Congress. FDA is providing that the statement may be physically separated from the statements made under section 403(r)(6) of the act. To ensure that the disclaimer gets the prominence that Congress intended, FDA is requiring that it be put in a box if it is separated from the statement made under section 403(r)(6) of the act. Therefore, the agency is is retaining the requirement in § 101.94(c)(2) (redesignated as § 101.93(d)) that the disclaimer be set off in a box where it is not adjacent to the statement.

13. One comment requested that the type size requirement be revised to meet the requirements in § 101.2 (21 CFR 101.2) which provide one-sixteenth of an inch as a general minimum type size. The comment maintained that inasmuch as FDA has determined that the requirements in § 101.2 are adequate to satisfy section 403(f) of the act, the requirements of § 101.2 are also appropriate in implementing the disclaimer provisions specified in section 403(r)(6) of the act. In addition, the comment urged the agency to clarify that the type size options for special package sizes are available to dietary supplements which often come in small packages.

Based on the plain language of section 403(r)(6)(C) of the act, the agency concludes that it was Congress' intent that the disclaimer be prominent and not obscured on the label or in labeling. For that reason, the agency proposed that the typesize for the disclaimer be no smaller than the larger of one-half the type size of the largest statement provided for in section 403(r)(6) of the act, but in no case no smaller than one-sixteenth of an inch. FDA tentatively concluded that in this manner, prominence could be assured because the disclaimer would be proportional to the section 403(r)(6) of the act statement or, at minimum, one-sixteenth of an inch (60 FR 67176 at 6781).

Because FDA is retaining the provisions that the disclaimer be on the same panel or page as the statement, and that the disclaimer be boxed when it is not adjacent to the statement, the agency concludes that the disclaimer can be readily located and, thus, that the statutory requirement for prominence is largely met. Readability is a clear attribute of prominence, and based on its experience with food labeling, one-sixteenth of an inch is generally readable (Ref. 3). Section 403(r)(6)(C) of the act requires that the disclaimer be in boldface type, which should also facilitate readability. Therefore, FDA has no objection to a minimum typesize of one-sixteenth of an inch for the disclaimer. Accordingly, the agency is revising proposed § 101.94(d) (redesignated as § 101.93(e)) to specify that one-sixteenth inch is the minimum typesize for the disclaimer.

Statements provided for in section 403(r)(6) of the act are entirely voluntary. All required information must first be considered in designing labels. Moreover, the firm must consider that the disclaimer must be prominent as required by the statute. Therefore,

there will be instances in which statements under section 403(r)(6) of the act should not be used on a label or in labeling because it is not feasible to accommodate both the required information and the statutory requirement for prominence for the disclaimer.

Inasmuch as the purpose of § 101.2(c)(1) through (c)(3) was to encourage voluntary declaration of nutrition information and complete ingredient listing on all foods before the provision of this information was made mandatory by the 1990 amendments, FDA gave notice of its intention to revoke the exemptions in § 101.2(c)(1), (c)(2), and (c)(3) in its December 1995 proposal entitled ''Food Labeling: Statement of Identity, Nutrition Labeling, and Ingredient Labeling of Dietary Supplements'' (60 FR 67194 at 67208) and proposed to do so in the **Federal Register** of June 12, 1996 (61 FR 29708). These provisions are now obsolete. Therefore, FDA is not accepting the recommendation of these comments, and the request to include the options for small package size listed under § 101.2(c) is denied.

III. Effective Date

14. Several comments recommended an effective date of 18 months following the publication of the final rule. One comment stated that the dietary supplement industry is unique because of the number of dietary supplement products sold that are ''private label,'' that is manufactured for or distributed by the company named on the label (the brand owner). The comment noted that many products in the ''private label'' category are store brands. The comment stated that these facts mean that many manufacturers must prepare a wide variety of labels for the same product. The comment used the example of one company producing private label merchandise that may have over 10,000 labels that will need to be conformed to the new regulations, and that for such store brand private label products, the time it would take to deplete the inventory of labels is well over 18 months. The comment noted that the period to use labels that state ''manufactured for'' and ''distributed by'' could be easily as long.

FDA is persuaded by the majority of the comments that it is appropriate to have the effective date of this final rule be 18 months from the date of its publication, consistent with the time period allowed for the labels of conventional foods to comply with the 1990 amendments. FDA is addressing the issues raised by these comments in greater detail in the final rule entitled ''Food Labeling: Statement of Identity, Nutrition Labeling and Ingredient Labeling of Dietary Supplements'' published elsewhere in this issue of the **Federal Register**.

IV. Other Provisions

FDA did not receive any comments that dealt specifically with the other provisions of the proposal. In the absence of any basis for doing otherwise, FDA is adopting those provisions as proposed.

V. Environmental Impact

The agency has previously considered the environmental effects of this rule as announced in the proposed rule (60 FR 67176). No new information or comments have been received that would affect the agency's previous determination that there is no significant impact of the human environment and that an environmental impact statement is not required.

VI. Paperwork Reduction Act

In the dietary supplement proposal, FDA stated its tentative conclusion that the proposed rule contains no reporting, recordkeeping, labeling, or other third party disclosure requirements and asked for comments on whether the proposed rule imposed any paperwork burden. No comments were received addressing the question of paperwork burden. FDA concludes that the labeling requirement in this document are not subject to review by the Office of Management and Budget because they do not constitute a ''collection of information'' under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). Rather, the labeling statements are a ''public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public'' (5 CFR 1320.3(c)(2)).

VII. Analysis of Impacts

FDA has examined the economic implications of the final rule as required by Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select the regulatory approach that maximizes net benefits (including potential economic, environmental, public health and safety effects; and other advantages; distributive impacts; and equity). Executive Order 12866 classifies a rule as significant if it meets any one of a number of specified conditions, including having an annual effect on the economy of $100 million or adversely affecting in a material way a sector of the economy, competition, or jobs, or if it raises novel legal or policy issues. If a rule has a significant impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze options that would minimize the economic impact of that rule on small entities. FDA finds that this final rule is not a significant rule as defined by Executive Order 12866, and finds under the Regulatory Flexibility Act, that the final rule will not have a significant impact on a substantial number of small entities. Similarly, it has been determined that this rule is not a major rule for the purpose of congressional review (Pub. L. 104–121).

The final rule does not significantly change the way in which claims are made with three exceptions: (1) Percentage claims for dietary supplements that do not have RDI's or DRV's are no longer prohibited; (2) dietary supplements of vitamins and minerals may now highlight an ingredient that is not a vitamin or mineral; and (3) labels or labeling of dietary supplements may include the types of statements listed in 403(r)(6) of the act so long as those statements are made in accordance with requirements of that section. With regards to these actions, costs of redesigning labels will be incurred only by those firms wishing to take advantage of the DSHEA. With respect to the third, firms who wish to make the statements provided for in section 403(r)(6) of the act will incur the additional cost of redesigning labels to include the disclaimer.

FDA is unable to quantify the benefits from this final rule. Some consumers will benefit from the additional information about dietary ingredients that will become available. However, because statements may now be made under section 403(r)(6) of the act for some dietary ingredients without any information being submitted to FDA to demonstrate that the dietary ingredient is safe, or that it will have its claimed effect, it is uncertain whether this final rule will have any significant health benefits.

This rule provides small entities with the opportunity to use certain claims that were previously prohibited. Small entities will incur the cost of redesigning labels to include claims only if making the claim will be profitable to the firm. In the proposed rule (60 FR 67176), FDA certified that this rule will not have a significant impact on a substantial number of small entities. FDA received no objections to that certification.

VIII. References

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

1. The Research Department, Food Marketing Institute, ''Trends in the United States: Consumer Attitudes & the Supermarket,'' 1996.

2. Levy, A. S., and B. M. Derby, ''The Impact of the NLEA on Consumer: Recent Findings from FDA's Food Label and Nutrition Tracking System. Executive Summary, January 23, 1996.

3. Levy, A. S., memorandum to Camille Brewer: Likely Effectiveness of Proposed Format Requirements for Disclaimer Statement on Dietary Supplement Products, January 16, 1997.

List of Subjects in 21 CFR Part 101

Food labeling, Nutrition, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, CFR part 101 is amended as follows:

PART 101—FOOD LABELING

1. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: Secs. 4, 5, 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs. 201, 301, 402, 403, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 371).

2. Section 101.13 is amended by revising paragraph (a), the introductory text of paragraph (b), and redesignating paragraph (q)(3) as paragraph (q)(3)(i), and adding new paragraph (q)(3)(ii) to read as follows:

§ 101.13 Nutrient content claims—general principles.

(a) This section and the regulations in subpart D of this part apply to foods that are intended for human consumption and that are offered for sale, including conventional foods and dietary supplements.

(b) A claim that expressly or implicitly characterizes the level of a nutrient of the type required to be in nutrition labeling under § 101.9 or under § 101.36 (that is, a nutrient content claim) may not be made on the label or in labeling of foods unless the claim is made in accordance with this regulation and with the applicable regulations in subpart D of this part or in part 105 or part 107 of this chapter.

* * * * *

(q) * * *

(3) * * *

(ii) Percentage claims for dietary supplements. Under section 403(r)(2)(F) of the act, a statement that characterizes the percentage level of a dietary ingredient for which a reference daily intake (RDI) or daily reference value (DRV) has not been established may be made on the label or in labeling of dietary supplements without a regulation that specifically defines such a statement. All such claims shall be accompanied by a referral or disclosure statement in accordance with paragraphs (g) or (h) of this section.

(A) *Simple percentage claims.* Whenever a statement is made that characterizes the percentage level of a dietary ingredient for which there is no RDI or DRV, the statement of the actual amount of the dietary ingredient per serving shall be declared next to the percentage statement (e.g., ''40 percent omega-3 fatty acids, 10 mg per capsule'').

(B) *Comparative percentage claims.* Whenever a statement is made that characterizes the percentage level of a dietary ingredient for which there is no RDI or DRV and the statement draws a comparison to the amount of the dietary ingredient in a reference food, the reference food shall be clearly identified, the amount of that food shall be identified, and the information on the actual amount of the dietary ingredient in both foods shall be declared in accordance with paragraph (j)(2)(iv) of this section (e.g., ''twice the omega-3 fatty acids per capsule (80 mg) as in 100 mg of menhaden oil (40 mg)'').

* * * * *

3. Section 101.14 is amended by removing paragraph (a)(4), by redesignating paragraphs (a)(5) and (a)(6) as paragraphs (a)(4) and (a)(5), respectively; and by revising paragraphs (b)(3)(i) and (d)(3) to read as follows:

§ 101.14 Health claims: general requirements.

* * * * *

(b) * * *

(3) * * *

(i) The substance must, regardless of whether the food is a conventional food or a dietary supplement, contribute taste, aroma, or nutritive value, or any other technical effect listed in § 170.3(o) of this chapter, to the food and must retain that attribute when consumed at levels that are necessary to justify a claim; and

* * * * *

(d) * * *

(3) Nutrition labeling shall be provided in the label or labeling of any food for which a health claim is made in accordance with § 101.9; for restaurant foods, in accordance with § 101.10; or for dietary supplements, in accordance with § 101.36.

* * * * *

4. Section 101.54 is amended by revising paragraphs (b)(1), (c)(1), and the introductory text of paragraph (e)(1) to read as follows:

§ 101.54 Nutrient content claims for ''good source,'' ''high,'' and ''more.''

* * * * *

(b) ''*High*'' *claims.* (1) The terms ''high,'' ''rich in,'' or ''excellent source of'' may be used on the label and in the labeling of foods, except meal products as defined in § 101.13(l) and main dish products as defined in § 101.13(m), provided that the food contains 20 percent or more of the RDI or the DRV per reference amount customarily consumed.

* * * * *

(c) ''*Good Source*'' *claims.* (1) The terms ''good source,'' ''contains,'' or ''provides'' may be used on the label and in the labeling of foods, except meal products as defined in § 101.13(l) and main dish products as defined in § 101.13(m), provided that the food contains 10 to 19 percent of the RDI or the DRV per reference amount customarily consumed.

* * * * *

(e) ''*More*'' *claims.* (1) A relative claim using the terms ''more,'' ''fortified,'' ''enriched,'' and ''added'' may be used on the label or in labeling of foods to describe the level of protein, vitamins, minerals, dietary fiber, or potassium, except as limited by § 101.13(j)(1)(i) and except meal products as defined in § 101.13(l) and main dish products as defined in § 101.13(m), provided that:

* * * * *

5. New § 101.93 is amended by adding paragraphs (b) through (e) to read as follows:

§ 101.93 Notification procedures for certain types of statements on dietary supplements.

(a) * * *

(b) *Disclaimer.* The requirements in this section apply to the label or labeling of dietary supplements where the dietary supplement bears a statement that is provided for by section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the act), and the manufacturer, packer, or distributor wishes to take advantage of the exemption to section 201(g)(1)(C) of the act that is provided by compliance with section 403(r)(6) of the act.

(c) *Text for disclaimer.* (1) Where there is one statement, the disclaimer shall be placed in accordance with

paragraph (d) of this section and shall state:

This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

(2) Where there is more than one such statement on the label or in the labeling, each statement shall bear the disclaimer in accordance with paragraph (c)(1) of this section, or a plural disclaimer may be placed in accordance with paragraph (d) of this section and shall state:

These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

(d) *Placement.* The disclaimer shall be placed adjacent to the statement with no intervening material or linked to the statement with a symbol (e.g., an asterisk) at the end of each such statement that refers to the same symbol placed adjacent to the disclaimer specified in paragraphs (c)(1) or (c)(2) of this section. On product labels and in labeling (e.g., pamphlets, catalogs), the disclaimer shall appear on each panel or page where there such is a statement. The disclaimer shall be set off in a box where it is not adjacent to the statement in question.

(e) *Typesize.* The disclaimer in paragraph (c) of this section shall appear in boldface type in letters of a typesize no smaller than one-sixteenth inch.

Dated: September 11, 1997.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 97–24730 Filed 9–22–97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket Nos. 95N–0245, 95N–0282, and 95N–0347]

RIN 0905–AD96

Food Labeling; Nutrient Content Claims: Definition for ''High Potency'' and Definition of ''Antioxidant'' for Use in Nutrient Content Claims for Dietary Supplements and Conventional Foods

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations to: Define the term ''high potency'' as a nutrient content claim; define nutrient content claims using the term ''antioxidant'' (e.g., ''good source of antioxidants,'' ''high in antioxidants,'' ''more antioxidants''); and to correct an omission pertaining to the use of ''sugar free'' claims on dietary supplements. FDA is taking these actions to provide for the use of additional nutrient content claims on labels or in labeling in accordance with provisions of the Nutrition Labeling and Education Act of 1990.

EFFECTIVE DATE: March 23, 1999.

FOR FURTHER INFORMATION CONTACT: Camille E. Brewer, Center for Food Safety and Applied Nutrition (HFS–165), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5483.

I. Background

On June 18, 1993 (58 FR 33731), FDA published a proposal entitled ''Food Labeling; Requirements for Nutrient Content Claims for Dietary Supplements of Vitamins, Minerals, Herbs, and Other Similar Nutritional Substances'' (hereinafter referred to as the 1993 nutrient content claims proposal). In that proposal FDA requested comment on several terms, including ''high potency'' that are often encountered on labels or in labeling of dietary supplements and that seem to imply that the dietary supplement will contribute to good health (58 FR 33731 at 33748). The agency requested comment on whether there were established meanings for these terms, and, if so, whether they characterized the level of the nutrients in the food and thus should be considered to be nutrient content claims. In 1994, in its final rule in the nutrient content claims proceeding (hereinafter referred to as the 1994 nutrient content claims final rule), based on the comments that it received, FDA determined that ''high potency'' is a claim that characterizes the level of a nutrient or nutrients and, therefore, meets the definition of a nutrient content claim in § 101.13(b) (21 CFR 101.13(b)) (59 FR 378 at 391, January 4, 1994).

One comment to the 1993 nutrient content claims proposal stated that FDA failed to address whether certain claims regarding antioxidants were within the scope of the proposed regulation. In the 1994 nutrient content claims final rule, the agency stated that while such claims were not explicitly discussed in the 1993 nutrient content claims proposal, they also are nutrient content claims (59 FR 378 at 389).

However, given the time constraints under which FDA prepared the 1994 nutrient content claims final rule, the agency was not able to adopt a definition either for ''high potency'' or for nutrient content claims for antioxidants. FDA announced its intention to review the suggestions for a definition of ''high potency'' and ''antioxidant'' claims and, based on information received in the comments, to propose an appropriate definition for these terms (59 FR 378 at 391). In the **Federal Register** of December 28, 1995 (60 FR 67184), the agency published a proposed rule entitled ''Nutrient Content Claims: Definition for 'High Potency' Claim for Dietary Supplements and Definition of 'Antioxidant' for Use in Nutrient Content Claims for Dietary Supplements and Conventional Foods'' (hereinafter referred to as the high potency/antioxidant proposal).

The agency received approximately 70 comments in response to the high potency/antioxidant proposal. A number of comments supported the proposal, while others disagreed with various aspects of the proposal. A few comments addressed issues that are outside the scope of this rulemaking. A summary of the comments, the agency's responses to the comments, and a discussion of the agency's conclusions follow.

II. High Potency

In the high potency/antioxidant proposal, FDA proposed that the term ''high potency'' may be used on the labels or in the labeling of dietary supplements to describe a nutrient that is present at 100 percent or more of the Reference Daily Intake (RDI) for vitamins and minerals, or of the Daily Reference Value (DRV) for protein and dietary fiber, per reference amount customarily consumed. To describe multinutrient products as ''high potency,'' FDA proposed that at least two-thirds of the nutrients in a product must be present at 100 percent of the RDI for vitamins and minerals or of the DRV for protein and dietary fiber per reference amount customarily consumed.

A. ''High Potency'' as a Nutrient Content Claim

1. The majority of the comments agreed that ''high potency'' is a nutrient content claim. These comments stated that the agency's definition has a basis in the labeling practices of the dietary supplement industry, and that consumers are already familiar with this definition. Some comments stated that the term ''high potency'' is commonly understood to describe the level of a nutrient or nutrients in a product, particularly on dietary supplements of vitamins and minerals.

On the other hand, a few comments stated that ''high potency'' is not a

nutrient content claim. One comment suggested that the agency should limit the scope of its nutrient content claim regulation of the term ''high potency'' to uses involving dietary supplements containing nutrients with RDI's or DRV's. The comment noted, however, that the term ''potency'' has other meanings used in conjunction with products containing dietary ingredients for which no RDI's or DRV's have been established, and that use of the term on such products should continue to be allowed, subject to the general misbranding provisions of the Federal Food, Drug, and Cosmetic Act (the act).

Other comments stated that the agency should withdraw the proposal because ''potency'' has an alternative meaning that FDA did not consider. One comment stated that for botanicals, equivalent amounts of the same dietary ingredient from different plants may differ in the magnitude of the biological responses they produce. The comment stated that, if the term ''potency'' is incorrectly used to describe the level of a dietary ingredient, the proper definition would not be available for correct use in a manner that would provide truthful and accurate information for consumers. The comment also maintained that the use of the term ''potency'' for botanicals should be reserved for those cases where biological assays exist. The comment stated that there would be no way of verifying the claim for a dietary ingredient in the absence of a biological assay for that dietary ingredient.

One comment requested that the agency prohibit ''high potency'' claims for protein and fiber because the ingestion of 100 percent of the Daily Value (DV) for these nutrients in single servings may lead to deleterious health effects.

As noted in several of the comments, the term ''high potency'' is commonly used to describe the level of a nutrient or nutrients, particularly for dietary supplements of vitamins and minerals and, therefore, meets the definition in § 101.13(b) of a nutrient content claim. Thus, FDA rejects the suggestion that it withdraw the proposal to define ''high potency.'' FDA acknowledges that there are other meanings for the term ''high potency.'' However, these meanings are not appropriate for consideration in this proceeding because they do not describe the level of a nutrient. For example, for pharmaceuticals, ''potency'' is a means of comparing the relative activities of drugs in a series (Ref. 1). The comment that discussed the potency of botanicals seemed to be ascribing to ''potency'' a meaning that is closer to the pharmaceutical use of the term than to its use as a nutrient content claim. This rulemaking is about foods, not pharmaceuticals.

Before terms like ''potency'' can be used to describe the level of dietary ingredients other than vitamins and minerals, standards would have to be developed that provide a basis for characterizing the level of these substances. Claims regarding the potency of constituents other than vitamins or minerals would be misleading or false if made without the benefit of standards that establish the validity of such claims. The agency encourages the dietary supplement industry to participate in developing such standards.

Moreover, the Commission on Dietary Supplement Labels (the Commission) is conducting a study on, and will provide the agency with a report containing recommendations for the regulation of label claims and statements for dietary supplements. Issues relating to the ''potency'' of botanicals and other dietary ingredients may be addressed in the Commission's final report. Therefore, the agency believes that consideration of the issue of alternate uses for the term ''potency'' should be delayed at least until issuance of a final report from the Commission.

For dietary supplements of vitamins and minerals, comments supported the agency's tentative view that the term ''high potency'' unambiguously suggests that the nutrients are present at a certain level. However, such support was not as obvious for ''high potency'' claims on products containing protein or fiber. The agency acknowledges the concern raised by one of the comments about the long-term health effects of the ingestion of 100 percent of the DV for protein or fiber in single servings. In recognition of this concern, and because manufacturers who wish to highlight the level of protein or fiber in a product may use other defined terms (e.g., ''good source,'' ''high,'' ''more'') or amount or percent statements as described in § 101.13(i) (e.g., ''30% of the DV for protein''), the agency concludes that it is appropriate to limit the scope of this definition to nutrients with RDI's (i.e., vitamins and minerals). Manufacturers also may use other descriptive terms for protein and fiber (e.g., terms that describe the quality of protein or the solubility of fiber), as long as such claims are truthful and not misleading. Accordingly, FDA is modifying proposed § 101.54(f)(1) (redesignated as paragraph (f)(1)(i)) and (f)(2) to reflect that the definition of ''high potency'' is limited to vitamins or minerals. This definition of ''high potency'' precludes the use of this nutrient content claim for protein and fiber.

B. Application to Conventional Foods

2. Several comments from the conventional food industry opposed the provision that limited use of the term ''high potency'' to the labels and labeling of dietary supplements. These comments argued that the proposal would establish an elite nutrient content claim offering attractive marketing opportunities available only to dietary supplements. The comments maintained that this policy would send the misleading message that nutrients obtained from dietary supplements are an especially efficacious way of achieving a balanced diet. The comments also stated that, given current consumer awareness of nutrition, the term ''high potency'' may be appropriate for conventional foods.

The comments pointed out that there are several conventional foods that achieve 100 percent of the DV of a single nutrient without fortification (e.g., vitamin C in orange juice, vitamin A in carrots) as well as a number of foods that achieve 100 percent DV for the majority of nutrients through fortification. The comments stated that the options for describing 100 percent of the RDI or DRV are limited (e.g., ''100 percent DV of Vitamin C,'' ''100 percent DV of 'X' vitamins and minerals''). One comment suggested that FDA define synonyms for ''high potency'' that would be more appropriate for conventional foods (e.g., ''ultra high,'' ''naturally ultra high''). The comment suggested that FDA establish an ''extra high'' claim for which any food providing at least 30 percent of the DV of a nutrient would qualify. The comment stated that such a claim would enable such foods as fluid milk to be labeled as ''extra high'' in calcium. Another comment suggested that ''superior source of'' or ''outstanding source of'' may be appropriate synonyms for ''high potency'' for conventional foods (e.g., see 56 FR 60366, November 27, 1991; 58 FR 33715, June 18, 1993; 59 FR 354, January 4, 1994; and 59 FR 395, January 4, 1994).

FDA does not wish to foster the notion that dietary supplements are a superior (or an inferior) source of nutrients or to promote disparate marketing opportunities for dietary supplements and conventional foods. With regard to labels and labeling, the agency is committed to supporting as much parity between conventional foods and dietary supplements as is possible consistent with the act (e.g., see 56 FR 60366, November 27, 1991; 58 FR

33715, June 18, 1993; and 59 FR 354, January 4, 1994).

The agency is persuaded that the term ''high potency'' can be meaningful and helpful to consumers in constructing healthy daily diets. If FDA were to adopt the same definition of ''high potency'' for conventional foods as for dietary supplements, given the acceptance and understanding of this term from its use on supplements, there is little likelihood that consumers would be confused about the meaning of the claim were it to appear on conventional foods. The agency concludes that the term will likely be useful in highlighting for consumers those products (either dietary supplements or conventional foods) that contain 100 percent or more of the DV for specific nutrients in one serving. Therefore, FDA is not adopting proposed § 101.13(b)(6), which would have limited the use of ''high potency'' to dietary supplements. FDA also is revising proposed § 101.54(f)(1) (redesignated as paragraph (f)(1)(i)) and (f)(2) to remove the restriction that the term ''high potency'' be used only on dietary supplements.

The possibility of foods achieving 100 percent of the DV for certain nutrients through fortification was raised in one of the comments. FDA has considered the appropriateness of fortifying a food to meet the requirements for bearing the nutrient content claims in consideration of the terms ''more'' (56 FR 60421, November 27, 1991 and 58 FR 2302, January 6, 1993) and ''healthy'' (59 FR 24232, May 10, 1994). The agency stated that, although random fortification could lead to deceptive and misleading claims, fortification of foods in accordance with the policy set out in § 104.20 (21 CFR 104.20) would ensure that the fortification was rational, and that the resultant claims would not be misleading.

FDA has previously stated that fortifying a food of little or no nutritional value for the sole purpose of qualifying that food for a health claim is misleading for several reasons. First, there is great potential to confuse consumers if foods like sugars, soft drinks, and sweet desserts are fortified to qualify for a claim, when, at the same time, dietary guidance as contained in the U.S. Department of Agriculture's (USDA's) and U.S. Department of Health and Human Services' (DHHS') 1995 *Dietary Guideline for Americans*, for example, states that these foods provide calories and little else nutritionally (Ref. 2). Indiscriminate fortification of such foods with one nutrient would not make such foods consistent with dietary guidelines and may encourage overfortification of the food supply (e.g., vitamin or mineral addition to soft drinks). Consistent with the provisions for ''more'' and ''healthy'' claims, the agency concludes that adherence to the principles stated in its fortification policy in § 104.20 will ensure that a food is not indiscriminately fortified for the sole purpose of making a ''high potency'' claim. Accordingly, the agency is adding new § 101.54(f)(3) which states that, where compliance with the definition of ''high potency'' is based on a nutrient that has been added to the food (other than a dietary supplement), fortification shall be in accordance with the policy on fortification of foods in § 104.20.

The agency points out that it is in the process of reviewing its policy on fortification for the purpose of making health claims. Currently, no expressed or implied health claims may be made on the label or in labeling for a food unless the food contains 10 percent or more of the RDI or DRV for vitamin A, vitamin C, iron, calcium, protein, or fiber per reference amount customarily consumed before any nutrient addition (see § 101.14(e)(6) (21 CFR 101.14(e)(6)). In response to petitions from the National Food Processors Association and the American Bakers Associations, FDA proposed modifications to § 101.14(e)(6) to allow fruit and vegetable products comprised solely of fruits and vegetables, enriched grain products that conform to a standard of identity, and certain other products that do not contain 10 percent of one of the six listed nutrients, to bear health claims if they meet all other requirements for the claim. FDA is reviewing comments on this proposal (60 FR 66206, December 21, 1995).

With regard to synonyms for nutrient content claims, the agency has stated (58 FR 2302 at 2320):

> Because a goal of the 1990 amendments is to make nutrition information on the label or labeling of foods available in a form that consumers can use to follow dietary guidelines (H. Rept. 101–538, supra, 10), and the act envisions that synonyms for defined terms can be an appropriate means to communicate such information, the agency will evaluate synonyms according to the standard in the 1990 amendments, i.e., that the term is commonly understood to have the same meaning as a defined term. In doing so, FDA intends to be open to considering terms that meet this standard. However, FDA does not intend to permit any synonym that it believes would be unclear in meaning to consumers with respect to characterizing the level of a nutrient in a food.

The agency has no evidence that terms such as ''superior source of'' or ''outstanding source of'' are commonly understood to have the same meaning as ''high potency.'' Likewise, FDA is not aware of any basis on which it could find that terms such as ''very,'' ''ultra,'' or ''extra'' would be understood by consumers to be synonymous with ''high potency.'' Furthermore, terms such as ''ultra'' do not signify the quantity present and therefore may not provide meaningful information to the consumer. Therefore, FDA is not authorizing these terms for use as synonyms to the ''high potency'' nutrient content claim. Interested parties may petition the agency to authorize synonyms or new nutrient content claims under the procedures described in § 101.69 (21 CFR 101.69).

The agency also points out that, on October 25, 1994, the National Food Processors Association (NFPA) petitioned FDA to initiate rulemaking for the adoption of amendments to the regulations governing nutrient content claims and health claims. Among other things, the petition requested that the agency allow manufacturers to tie or ''anchor'' an undefined term (e.g., ''loads of'') to a defined nutrient content claim (e.g., ''high'') as a synonym for that defined term, without FDA preclearance of the undefined term, when the terms are understood by consumers to have the same meaning, when such claims are made in accordance with the requirements for the defined term, and when the defined term also appears in the product's labeling. The proposal responding to the NFPA petition published on December 21, 1995 (60 FR 66206). FDA is currently evaluating comments to that proposal.

C. 100 Percent Criterion

3. Many comments supported the proposal to define ''high potency'' as 100 percent of the DV.

One comment from a trade association for dietary supplement manufacturers objected to the basis for selecting 100 percent of the DV as the requirement for high potency. The association argued that 100 percent is not sufficient to meet the needs of practically all healthy persons, at least for some nutrients, and that this amount is not necessarily the amount that some consumers require to meet what they consider optimal targets for nutrient intake.

One comment stated that consumers will understand ''full potency'' to equal 100 percent of the DV, but that the term ''high potency'' conveys the impression that the nutrient content is above 100 percent. The comment stated that to avoid confusion and protect consumers from misleading information, FDA should not adopt a definition for ''high potency'' until it has conducted a

survey of consumers of dietary supplements concerning public understanding of the meaning of the terms ''high potency'' and ''full potency.'' The comment recommended that FDA adopt not one but two nutrient content claims, one for ''full potency'' and another for ''high potency.'' Other comments stated that ''full potency'' is not an appropriate synonym for ''high potency'' but offered no explanation.

A couple of comments suggested that the proposed regulations be revised to define ''high potency'' for the B vitamins as well as vitamins C and E as above 100 percent of their respective DV's to be consistent with current marketing practices that typically package these nutrients in amounts well above 100 percent of the DV for each nutrient.

The agency rejects the comment that objected to the basis for the definition of ''high potency.'' The RDI's are based on the National Academy of Sciences' Recommended Dietary Allowances (NAS RDA's) and are the cornerstone for several nutrient content claims. Since the inception of the nutrition labeling program (37 FR 6493, March 30, 1972), FDA has relied on the judgment of the NAS' Food and Nutrition Board concerning the essentiality of particular nutrients in human nutrition and for recommendations regarding the required levels of those nutrients to meet the needs of practically all healthy persons. The NAS' RDA's remain the most widely accepted and respected source of information on human nutrient requirements.

The NAS is in the process of revising the basis for the RDA's and may consider optimal nutrition and the prevention of chronic disease in developing a future edition of the RDA's (Ref. 3). FDA expects that label reference values and nutrient content claims will evolve in tandem with the RDA's. In the interim, the agency concludes that the RDA's, and the principles on which they are based, form a firm foundation on which to establish certain label reference values and their derivatives, the nutrient content claims.

FDA did not propose a definition for ''full potency.'' In the high potency/antioxidant proposal, FDA requested comment on whether the term ''full potency'' is generally viewed by consumers as a synonym to ''high potency'' (60 FR 67184 at 67189). The agency is not persuaded by the comment that suggested that consumers interpret ''full potency'' to mean 100 percent of the DV and ''high potency'' to mean more than 100 percent because the comment did not supply any support for its assertions. In fact, FDA did not receive comments supporting ''full potency'' as a synonym for ''high potency.'' Therefore, the agency is not defining ''full potency'' as a synonym for ''high potency.''

FDA does not consider that it is necessary to adopt a separate definition for ''full potency'' because of the lack of evidence that this term describes the level of a nutrient, and that it should be considered a nutrient content claim. Further, the agency is not persuaded that consumer research is necessary to define ''high potency'' at 100 percent of the RDI given that most of the comments supported this definition.

The agency sees no reason to alter the definition of ''high potency'' to require higher levels of certain nutrients because the definition of ''high potency'' does not preclude manufacturers of the B vitamins, vitamin C, or vitamin E from marketing these vitamins at levels above 100 percent of the RDI. The comment did not include an alternate recommendation for a definition, nor did it include any data in support of its assertion regarding the current levels of the B vitamins or vitamins C and E marketed in dietary supplements.

D. Multinutrient Products

4. The majority of comments supported the criterion that two-thirds of the nutrients present in a multinutrient product must be present at 100 percent of the DV to bear a ''high potency'' claim.

One comment stated that FDA's tally of the nutrients likely to be present at levels less than 100 percent of the DV is incomplete, and, therefore, the requirement that 2/3 of the nutrients be present at 100 percent of the RDI may be more rigid than was actually intended. The comment stated that biotin is an extremely expensive ingredient and is seldom included at 100 percent of the RDI. The comment maintained that some trace minerals are commonly present at less than 100 percent of the RDI, and that the definition of ''high potency'' should not require uniformly high levels of these nutrients. The comment stated that some products intended for men or for the elderly now provide less than the RDI levels of iron which represents a desirable trend. The comment stated that requiring that one-half of the nutrients be present at 100 percent of the RDI is more appropriate than requiring that two-thirds be present at 100 percent to bear the ''high potency'' claim.

One comment suggested that the term ''high potency'' be used on the label or in the labeling of a dietary supplement to describe the product if all of the nutrients with RDI's or DRV's in the product are at 100 percent or more, with the exception of: (a) The 11 nutrients deemed impractical or imprudent in the high potency/antioxidant proposal to include at 100 percent of RDI or DRV levels; and (b) the essential nutrient iron, because daily supplementation at 100 percent of the RDI level is not deemed prudent for all people.

One comment recommended that FDA permit multinutrient products that contain one or more nutrients to use the term ''high potency'' along with a specific nutrient referenced in the nutrient content claim. As an example, the comment suggested that if the multinutrient product contains 100 percent of the RDI for vitamin C, the product should be allowed to bear the claim ''high potency vitamin C.'' The comment also suggested that if the multinutrient product contains 50 percent or more nutrients that are above RDI levels, the product should be allowed to declare ''high potency'' with an asterisk. The comment stated that the asterisk would correspond with a same panel reference that lists the nutrients with RDI's or DRV's at 100 percent of their label reference values. Alternatively, the comment suggested that a company could use a phrase such as ''See Supplement Facts Panel for a complete listing, 7 of 12 nutrients in this product exceed RDI/DRV levels'' to draw attention to the number of nutrients present at 100 percent of the RDI or DRV.

The agency points out that the number of nutrients eligible to bear a ''high potency'' nutrient content claim has changed from what was proposed because the claim is now limited to the vitamin or mineral content of the food product. However, two-thirds is a reasonable proportion of nutrients that should be present for a multinutrient product to bear the ''high potency'' claim. To be able to characterize a dietary supplement or conventional food as ''high potency,'' that claim ought to reflect the nature of the food. For a product to bear this claim, it is reasonable to expect that significantly more than half of the RDI nutrients in the food meet the ''high potency'' standard. The two-thirds requirement appropriately captures this expectation. Hence, FDA rejects the suggestion that only 50 percent of the nutrients in a multinutrient product be present at the requisite level to qualify for a ''high potency'' claim.

FDA concludes that the provision that two-thirds of the nutrients be present at 100 percent of the RDI for a

multinutrient product to bear the term ''high potency''is sufficiently flexible to account for the presence at less than 100 percent of the DV for iron, biotin, and those trace minerals that are typically not found at 100 percent of the DV. Because this final rule revises the proposed definition of ''high potency'' to include conventional foods, FDA has revised § 101.54(f)(2) to refer to all multinutrient products, not just dietary supplements.

There is nothing in the high potency/antioxidant proposal that precludes use of such terms as ''high potency vitamin C'' or the use of asterisks that refer to a listing of nutrients that are present at 100 or more percent of the RDI, either for a single or a multinutrient product. To emphasize the fact that the vitamins or minerals present at 100 percent or more of the DV can be described by the term ''high potency,'' FDA is revising proposed § 101.54(f)(1) (redesignated as paragraph (f)(1)(i)) to state that the term ''high potency'' can be used to describe individual vitamins or minerals that are present at 100 percent or more of the RDI. However, if the term ''high potency'' is used on the label of a multinutrient product to refer to the entire product, the two-thirds criterion must be met. There is nothing in § 101.54(f) that precludes other descriptive statements (e.g., ''7 of 12 nutrients in this product exceed RDI/DRV levels'') as long as they are truthful and not misleading.

FDA recognizes that there are ''combination'' products that contain, in addition to vitamins and minerals, dietary ingredients for which no label reference value has been established (e.g., botanicals). (See comment 1 of this document.) FDA advises that the label or labeling of such products must clearly identify which dietary ingredients are being described by the term ''high potency'' (e.g., ''botanical 'X' with high potency vitamin D''), so that FDA can evaluate the appropriateness of the claim under the definition for high potency in § 101.54. Where there is any ambiguity regarding the use of the term ''high potency,'' the agency will evaluate the claim on a case-by-case basis in the context of the entire label and labeling to determine whether the claim is being used to describe the level of a nutrient or to describe the product. Accordingly, FDA is adding new § 101.54(f)(1)(ii) to state that products that contain vitamins or minerals as well as other nutrients or dietary ingredients shall clearly identify which ingredients are described by the term ''high potency.''

5. A couple of comments stated that it is possible that some substances that are technically vitamins and minerals are present in multingredient products at less than 2 percent of the DV (and hence are excluded from nutrition labeling) but perform technological functions in the finished supplement. The comments suggested that these ingredients should not be part of the denominator in determining whether a product meets the two-thirds criterion for a ''high potency'' claim. The comment recommended that proposed § 101.54(f)(2) be revised to clarify that vitamins or minerals present at less than 2 percent of the DV are excluded from being counted with the one-third of the nutrients that may be present to qualify for the claim.

FDA agrees that nutrients present in insignificant amounts should be excluded from being counted in the denominator for determining the ratio of nutrients present at 100 percent of the RDI as long as they are used for technological purposes only and are declared only in the ingredient statement. These same criteria are used in § 101.9(c)(8)(ii)(B) (21 CFR 101.9(c)(8)(ii)(B)) to define vitamins and minerals that may be omitted from nutrition labeling. For vitamins and minerals in conventional foods and dietary supplements, the agency defines any amount less than 2 percent of the RDI as insignificant (see § 101.9(c)(8)(iii)). Accordingly, the agency is revising proposed § 101.54(f)(2) to state that the term ''high potency'' may be used on the label or in the labeling of a food product to describe the product if it contains 100 percent or more of the RDI for at least two-thirds of the vitamins and minerals that are listed in § 101.9(c)(8)(iv) and that are present in the product at 2 percent or more of the RDI (e.g., ''High potency multivitamin, multimineral dietary supplement tablets'').

III. Antioxidants

In the high potency/antioxidant proposal, FDA proposed that the term ''antioxidant'' be defined as a collective term inclusive of vitamin C, vitamin E, and beta-carotene when used as part of a nutrient content claim (e.g., ''good source of antioxidants''). The agency proposed that the levels of these nutrients must be sufficient to qualify for a nutrient content claim that characterizes the level of antioxidants in a food without further specifying the antioxidant nutrient. For example, to qualify for a ''high in antioxidants'' claim, FDA proposed that the product must contain 20 percent or more of the RDI for vitamin C and for vitamin E per reference amount customarily consumed, and that 20 percent or more of the RDI for vitamin A must be present as beta-carotene per reference amount customarily consumed. The agency proposed that if the food does not contain all three antioxidants at the requisite level, the claim must specify which antioxidants in the food meet the required level (e.g., ''high in antioxidant vitamins C and E''). FDA proposed that nutrient content claims for antioxidants be authorized for both conventional foods and dietary supplements. Finally, the agency proposed that a collective term (e.g., ''complete antioxidant complex,'' ''antioxidant complex'') may be used on the labels or in labeling provided that vitamin C and vitamin E are present at 10 percent or more of the RDI per reference amount customarily consumed, and that 10 percent or more of the RDI for vitamin A is present as beta-carotene per reference amount customarily consumed.

A. Underlying Concepts

6. A few comments requested that the agency withdraw the proposal. One comment stated that the proposal did not discuss the characteristics of botanicals or other nonnutrients that act as antioxidants in the human body. Another comment suggested that the agency broaden its definition to encompass all vitamins, minerals, and plant compounds involved in antioxidant processes. This comment suggested that FDA rely on the 20 percent criterion (i.e., 20 percent or more of the DV, the definition for ''high'' claims) for those nutrients with RDI's but permit the use of the content claim using the term ''antioxidants'' with an asterisk for all other such substances when present in any cognizable amount in food. For example, the comment suggested that the asterisk correspond with the same panel reference to the following statement: ''This product contains————, an antioxidant. An RDI reference amount has not been established for this nutrient.'' One comment stated that only RDI nutrients should be permitted to claim ''high in antioxidants'' or ''good source of antioxidants'' but argued that terms such as ''contains'' or ''provides antioxidants'' should be available for use with other proven antioxidants.

The agency rejects the suggestion that the antioxidant proposal be withdrawn. The purpose of this rulemaking is to define a term used in nutrient content claims that characterize the level in foods of certain antioxidant nutrients. Without such a definition, claims on the label or in labeling of food that describe the level of ''antioxidants'' would, under section 403(r)(1)(A) of the act (21

U.S.C. 343(r)(1)(A)), misbrand the products on which they appear.

Under section 403(r)(1)(A) of the act, a claim that characterizes the level of any nutrient which is of the type required by section 403(q)(1) or (q)(2) to be listed in nutrition labeling may not be made unless the claim is made in accordance with a regulation that FDA adopts under section 403(r)(2) to define the claim. This rulemaking is intended to define the circumstances in which claims can be made that characterize the level of ''antioxidant'' substances in food. Unless FDA completes this rulemaking, labels of dietary supplements, as well as of other foods, cannot contain statements that characterize the levels of ''antioxidants.''

The agency is not persuaded that the term ''antioxidants,'' when used in defined nutrient content claims, should be broadened to include all substances involved in antioxidant processes. The purpose of this rulemaking is not to delineate all known antioxidants. The comments that stated that there are other dietary ingredients that act as antioxidants reflect a misinterpretation of FDA's intent. FDA is not restricting all label and labeling statements about antioxidants to statements about only a limited number of nutrients. Rather, the agency is defining the circumstances in which claims that characterize the level of nutrients that have antioxidant activity, such as ''high in antioxidants'' can be made in compliance with the requirements of the act. As stated above, manufacturers cannot make label statements that characterize the level of a nutrient unless FDA has defined such statements by regulation (see section 403(r)(1)(A) of the act), and FDA cannot define such statements unless it has a reference point, that is an RDI or DRV, against which to measure the nutrient levels. Many of the plant compounds referred to in the comments as antioxidants (e.g., lycopene, lutein, polyphenols) do not have RDI's, and thus it is not possible to characterize the level of these substances because there is no standard against which to do so. Consequently, they cannot be the subject of nutrient content claims at this time. However, FDA did not intend in this rulemaking to decide whether these substances have, or do not have, antioxidant activity.

The agency is not limiting truthful and nonmisleading statements about the properties or the effects of antioxidants. Manufacturers may, for example, craft a statement, subject to section 403(a) of the act, that describes how a nutrient or dietary ingredient that does not have an RDI participates in antioxidant processes. Likewise, claims that describe the effect of a nutrient or dietary ingredient on the structure or function of the body may be made as long as such claims are not false or misleading and, if appropriate, are made in accordance with section 403(r)(6) of the act (see comment 8 of this document). However, irrespective of how many antioxidant substances there are, claims characterizing levels of nutrients or dietary ingredients are not permitted unless authorized by a regulation.

To address the misinterpretation of the agency's intentions, that is evident in the comments, and to clarify the scope of this rulemaking, FDA is changing the paragraph heading in § 101.54(g) from ''Antioxidant claims'' to ''Nutrient Content Claims Using the Term 'Antioxidant'.'' In addition, to emphasize that this regulation concerns the level of certain nutrients, FDA is inserting new text in § 101.54(g) that states that nutrient content claims that characterize the level of one or more antioxidant nutrients present in a food may be used on the label or in the labeling of that food when the nutrients meet the conditions that are established in this regulation. Among the conditions set out in § 101.54(g)(1) is the requirement that an RDI must have been established for each nutrient that is to be subject of a claim.

Regarding the comment that argued that terms such as ''contains'' or ''provides'' antioxidants be available for use with antioxidants without established RDI's, the agency points out that ''contains'' and ''provides'' are synonyms for the defined nutrient content claim ''good source'' (see § 101.54(c)) and, thus, under section 403(r)(1)(A) of the act, can only be used with nutrients for which RDI's have been established. Consequently, a claim such as ''contains lycopene'' would be an unauthorized nutrient content claim because lycopene does not have an RDI. Nonetheless, a statement such as '''x' mg of lycopene per serving'' is permitted under § 101.13(i)(3), which allows for the use of amount or percentage statements that do not implicitly characterize the level of the nutrient in a food (e.g., claims that do not imply whether the amount is high or low based on an established RDI or DRV value), so long as the statement is not misleading in any way. (See Ref. 4, p. 36, C23). For dietary supplements, certain other statements (i.e., simple and comparative percentage claims) can be made under new § 101.13(q)(3)(ii) (see the document entitled ''Food Labeling; Requirements for Nutrient Content Claims, Health Claims, and Statements of Nutritional Support for Dietary Supplements'' (hereinafter referred to as ''the nutrient content claims document'') published elsewhere in this issue of the **Federal Register** for further discussion of this issue). Further, as discussed fully under comment 8 of this document, other statements about antioxidant properties of food substances may appear on the labels of foods, provided that they are made in accordance with the statutory requirements.

7. One comment stated that the proposal lacked a scientific definition of the term ''antioxidant'' and suggested that the agency repropose and include a definition for this term. Other comments stated that the distinction between direct and indirect antioxidants made by the agency in the proposal was not useful. These comments argued that consumers are unlikely to distinguish between direct and indirect antioxidants, and that research shows that minerals such as copper, magnesium, zinc, and selenium have known antioxidant effects. The comments asserted that these nutrients should be grouped with vitamin C, vitamin E, and beta-carotene for the purpose of making nutrient content claims about antioxidants.

One comment stated that the endorsement of vitamin C, vitamin E, and beta-carotene could send a misleading message to consumers that these nutrients will prevent disease, that scientists have reached a consensus on the mechanisms underlying disease prevention, and that the consumption of a few common antioxidants in and of itself provides health benefits. The comment stated that, as a result, consumers may be tempted to take supplements of individual antioxidants, which may have deleterious health consequences or at least no significant benefits.

One comment requested that FDA establish criteria for determining the biological endpoints to be achieved by the use of antioxidants. The comment also suggested that FDA establish a definition for the total antioxidant activity of whole foods.

In the high potency/antioxidant proposal and in an earlier rulemaking (56 FR 60624, November 27, 1991), the agency summarized the antioxidant properties of vitamin C, vitamin E, and beta-carotene. The agency stated that there was scientific evidence that these nutrient substances were able to trap and deactivate reactive oxygen molecules and, thus, prevent the damage caused by these reactive molecules (also called free radicals).

No evidence was presented in the comments that nutrient content claims for vitamin C, vitamin E, and beta-carotene will be construed by consumers to be an endorsement that the nutrients that are the subject of such claims will prevent disease or, by themselves (that is, in the absence of a healthy total daily diet), provide inordinate health benefits. Therefore, there is no basis for the agency not to confirm its proposal that these nutrients can be subjects of nutrient content claims for antioxidants.

In the high potency/antioxidant proposal, the agency tentatively concluded that only vitamin C, vitamin E, and beta-carotene possessed direct antioxidant activity. The agency tentatively concluded that nutrients such as zinc, manganese, copper, selenium, riboflavin, and niacin should not be classed as antioxidants for the purpose of making nutrient content claims (60 FR 67184). This tentative conclusion was based on the fact that these nutrients are precursors of coenzymes that are involved in oxidative reactions but do not have direct antioxidant activities, and that they may have effects that are both antioxidant and pro-oxidative in character.

FDA acknowledges that there is new literature on antioxidants, some of which calls into question the relevance of the distinction between direct and indirect antioxidants (e.g., see Refs. 5 through 15). Based on the comments and a review of this literature (e.g., see Refs. 5 through 15), FDA is persuaded that it is reasonable to allow all nutrients that have antioxidant activity or that participate in antioxidant reactions to be the subject of nutrient content claims for antioxidants, so long, of course, as an RDI has been established for the nutrient. Based on the state of the science, FDA is not able to justify establishing a more limited list of nutrients.

However, FDA is not specifying the nutrients that may be the subject of the claim in the codified language of § 101.54 because some nutrients with reported antioxidant activity (e.g., copper, manganese, iron) are pro-oxidative at certain levels (60 FR 67184). A manufacturer making an antioxidant claim for a nutrient must have substantiation that the nutrient functions as an antioxidant at the levels present and under the intended conditions of use. The agency advises that antioxidant claims on products that contain levels of a nutrient sufficient to cause the nutrient to act as a pro-oxidant are false and misleading under section 403(a) of the act.

Based on its conclusion that nutrients that exhibit antioxidant activity through an indirect mechanism in fact have an antioxidant function when present at certain levels, and that manufacturers should be able to inform consumers about their presence, FDA is broadening the number of nutrients that can be the subject of a nutrient content claim that characterizes the level of antioxidants. Accordingly, the agency is revising proposed § 101.54(g)(1) and (g)(2) to delete the language that would have limited the nutrients that could be the subject of antioxidant content claims to vitamin C, vitamin E, and beta-carotene and to include in its stead general language that refers to nutrients that have recognized antioxidant activity.

The agency is defining the conditions for the use of the term ''antioxidant'' in nutrient content claims in § 101.54(g). This section provides that the term antioxidant may be used for a substance for which there is scientific evidence that, following absorption from the gastrointestinal tract, the substance participates in physiological, biochemical, or cellular processes that inactivate free radicals or that prevent free radical-initiated chemical reactions. This definition captures the attributes of those nutrients that the agency has previously concluded are direct antioxidants (i.e., vitamin E, vitamin C, and beta-carotene) (56 FR 60624 and 60 FR 67184), as well as the attributes of those nutrients that the agency has described as indirect antioxidants (60 FR 67184).

While the agency believes that this definition for antioxidant, which responds to comments and which is based on available scientific discussions, is the most appropriate definition at this time, it is clear that a widely accepted and well-established definition for antioxidants has not been developed within the scientific community. In the near future, the NAS Institute of Medicine (IOM) will be conducting a comprehensive assessment of human nutrient requirements for dietary antioxidants. This review will consider both the nature of the definition of a dietary antioxidant as well as the linkage between dietary reference intakes and antioxidant activity. FDA expects to carefully review the outcomes and final report of the IOM to the extent that they are relevant to this final rulemaking. The agency may consider reexamining its conclusions on nutrient content claims for antioxidants based on discussions provided in the IOM report when it becomes available. The agency will consider proposing an affirmative list of antioxidant nutrients and limiting nutrient content claims to such a list following the release of the IOM report.

The agency is revising proposed § 101.54(g)(3) to specify the levels of nutrients needed to qualify for antioxidant nutrient content claims. Section 101.54(g)(3) states that the level of each nutrient that is the subject of the claim must be sufficient to qualify for the claim (e.g., to bear the claim ''high in antioxidant vitamin C,'' the product must contain 20 percent or more of the RDI for vitamin C). Beta-carotene may be a subject of the claim when the level of vitamin A present as beta-carotene in the food that bears the claim is sufficient to qualify for the claim. For example, to bear the claim ''good source of antioxidant beta-carotene,'' 10 percent or more of the RDI for vitamin A must be present in the food as beta-carotene per reference amount customarily consumed. When a product contains more than one antioxidant nutrient, each antioxidant nutrient that is being described must meet the level of nutrient specified in the nutrient content.

It is important that the antioxidant nutrients be identified as part of a nutrient content claim for antioxidants because the names are facts that are material in light of the antioxidant representation. The comments reveal that a variety of nutrients and dietary ingredients could be considered antioxidants. Since these final rules allow the manufacturer to determine what nutrients in a product meet the definition in § 101.54(g) for antioxidants and are to be the subject of the nutrient content claim, the claim would be confusing to consumers without a clear identification of which nutrients in the product are being described. Consumers cannot be expected to know which nutrients are antioxidants. There are no regulatory provisions for providing this information in the nutrition label, and it will not necessarily be revealed in the ingredient statement. In addition, some products may contain several antioxidants, with only a few of them being present at levels appropriate for the claim. In this case, the claim clearly needs to identify which nutrients meet the criteria for the claim being made.

The agency concludes that without the disclosure of the nutrients proximate to the claim, a claim on the label or in labeling of food that describes the level of antioxidants would be misleading under section 201(n) of the act. Accordingly, FDA is adding new § 101.54(g)(4) that states that the names of the nutrients that are the subject of the claim must be included as part of the claim (e.g., ''high in antioxidant vitamins C and E'').

For flexibility, the agency concludes that the names of the nutrients may be included as part of the claim either directly, by mentioning them in the claim, or indirectly, by use of an asterisk. Because the claim may refer to many nutrients, and space constrains may make it difficult to fit the entire list within the claim, FDA is willing to provide the same flexibility in how antioxidant claims are made that it is allowing for the disclaimer required with statements made under section 403(r)(6) of the act. (For further discussion of the placement of the disclaimer, see the nutrient content claims document published elsewhere in this issue of the **Federal Register**.) As with the disclaimer, the agency concludes that the list of nutrients should be on the same panel or page as the claim. This placement establishes an obvious relationship between the claim and the list of antioxidant nutrients. The placement of the list of nutrients on another panel would obscure material facts necessary for understanding the claim.

With respect to type-size requirements, section 403(r)(2)(A)(iii) through (r)(2)(A)(v) of the act requires that statements that disclose the level of fat, saturated fat, or cholesterol, which must be presented in conjunction with certain nutrient content claims, ''have appropriate prominence which shall be no less than one-half the size of the claim.'' The agency concludes that, for consistency in identifying material information, the standard embodied in these provisions should be applied to the disclosure of the antioxidant nutrients.

The agency recognizes that sometimes claims may be small, particularly in labeling, and one-half the type size of the claim may result in a type size that is too small to be easily read. Thus, there is a need for a minimum type size for the list of antioxidant nutrients. One-sixteenth of an inch is specified in § 101.2(c) (21 CFR 101.2(c)) as the minimum type size for most mandatory information on the principal display panel or information panel, e.g., designation of ingredients, name and place of business, and warning and disclaimer statements. Further, one-sixteenth of an inch is the minimum size required in § 101.105(i) for net quantity of contents statements. Consequently, the agency concludes that a minimum type size of one-sixteenth of an inch for the disclosure of the antioxidant nutrients is necessary to ensure that it is prominently displayed. However, for the sake of increased prominence, it is preferable to use one-half the size of the claim when it results in a type size of larger than one-sixteenth of an inch.

Accordingly, FDA is adding new § 101.54(g)(4) which permits the term ''antioxidant'' or ''antioxidants'' (as in ''high in antioxidants'') to be linked by a symbol (e.g., an asterisk) that refers to the same symbol that appears elsewhere on the same panel of the product label followed by the name or names of the nutrients with recognized antioxidant activity. The list of nutrients must appear in letters of type size of no smaller than the larger of one-half of the type size of the largest nutrient content claim or 1/16 inch.

The issue of biological endpoints, raised by one of the comments, is beyond the scope of this rulemaking. It was not clear whether the comment that requested that FDA establish criteria for biological endpoints to be achieved by the use of antioxidants was asking FDA to establish a standard biological measurement (or biomarker) to determine whether a substance has antioxidant activity in vivo, or asking FDA to set forth criteria for establishing when the use of antioxidants provides protection from disease. In either case, such issues are outside the scope of what FDA proposed to do in this rulemaking.

The same comment also suggested that FDA establish a definition for the total antioxidant activity of whole foods. FDA recognizes that foods may contain a mixture of substances, both nutrients and nonnutrients, that participate in antioxidant processes. However, there are no reliable methods available that measure the antioxidant activity of all substances that participate in antioxidant reactions when an entire food is consumed. The development of a definition of total antioxidant activity of whole foods is beyond the scope of this regulation, which is intended to permit the use of the term ''antioxidants'' in claims that characterize the level of these nutrients in a food, including a dietary supplement.

8. A couple of comments stated that the term ''antioxidant'' is a statement provided for under section 403(r)(6) of the act. These comments requested clarification on whether the use of the term ''antioxidant'' is part of a statement about a product's biological function. The comments stated that factual statements about the biological function of antioxidants should be permitted, provided that the labeling does not include unauthorized health or nutrient content claims.

Another comment stated that FDA lacks authority to define the term ''antioxidant'' for use in nutrient content claims under section 403(r)(2)(A)(i) or (r)(2)(F) of the act. The comment argued that dietary ingredients without established RDI's are expressly excluded by section 7(c) of the Dietary Supplement Health and Education Act of 1994 (the DSHEA) from the nutrient content claims provisions found in section 403(r)(2)(A)(i) of the act. The comment interpreted section 7(c) of the DSHEA to mean that nutrient content claims can be made for dietary ingredients that do not have RDI's.

One comment suggested that the codified language be revised to state clearly that the term ''antioxidant'' is being described solely as part of a nutrient content claim. For example, the comment suggested that proposed § 101.54(g) be revised to read ''the term 'antioxidants,' *when used as part of a nutrient content claim,* may only be used on the label or in labeling * * *.'' (Emphasis added.) The comment also suggested that proposed § 101.54(g) be revised to include the statement ''This section does not apply to dietary supplement statements of nutritional support.''

FDA agrees with the first comment that ''antioxidant'' describes the biological activity of a substance. As stated above, FDA has defined ''antioxidant activity'' in § 101.54(g)(2) (under its authority under sections 403(r)(2) and 701(a) of the act). However, FDA does not agree that ''antioxidant'' is necessarily a statement that is made under section 403(r)(6) of the act. If an antioxidant effect is a nutritional effect, that is, if it is attributable to the nutritional value of consuming a substance, a claim about that substance's antioxidant effect may be made as long as it is truthful and not misleading and not made in violation of section 403(r)(1)(A) (on nutrient content claims) or (r)(1)(B) (on health claims) of the act.

Section 403(r)(6) of the act is relevant only if the antioxidant effect is not attributable to the nutritive value of the dietary ingredient, or if a manufacturer chooses to take advantage of this provision even though the antioxidant effect is attributable to a substance's nutritive value (see discussion on section 403(r)(6) of the act in the nutrient content claims document published elsewhere in this issue of the **Federal Register**.) Section 403(r)(6) of the act, which was added by the DSHEA, encompasses label statements on dietary supplements that claim a benefit related to a classical nutrient deficiency disease, describes how a nutrient or dietary ingredient affects the structure or function in humans, characterizes the documented

mechanism by which a nutrient or dietary ingredient acts to maintain the structure or function, or describes general well-being from consumption of a nutrient or dietary ingredient. Manufacturers may make claims regarding the antioxidant properties (or biological properties) of a substance under section 403(r)(6) of the act as long as all of the requirements of this section of the act are met (e.g, notification, substantiation, disclaimer).

The agency rejects the comment that suggested that section 403(r)(2)(F) of the act is relevant to this rulemaking. Section 403(r)(2)(F) of the act creates a narrow exception to section 403(r)(2)(A)(i) of the act. Section 403(r)(2)(F) of the act pertains only to claims about the percentage of a dietary ingredient for which FDA has not established a reference value. Thus, section 403(r)(2)(F) of the act has no relevance to this proceeding. (See the nutrient content claims document published elsewhere in this issue of the **Federal Register** for further discussion of percentage claims.)

As discussed in comment 6 of this document, FDA is persuaded to revise the paragraph heading for § 101.54(g) to state that the section refers to nutrient content claims using the term ''antioxidants'' to clarify that the section addresses nutrient content claims for antioxidants. The agency concludes that this revision clarifies that the scope of § 101.54(g) is limited to nutrient content claims without making the additional changes in codified language suggested by the comment.

B. Beta-carotene

9. Several comments agreed with the inclusion of beta-carotene in the antioxidant definition. Several other comments opposed its inclusion. The latter comments provided two reasons for their opposition: (1) There is little scientific evidence that beta-carotene functions as an antioxidant in the human body, and (2) findings from clinical prevention trials suggest potential harm to smokers from the consumption of beta-carotene supplements. One comment stated that in the Alpha-Tocopherol, Beta Carotene (ATBC) Lung Cancer Prevention Trial (the ATBC Trial), an intake of 20 milligrams (mg)/day synthetic beta-carotene over a 5- to 8-year period was associated with an 18 percent increased incidence of lung cancer and an 8 percent increase in total mortality in male smokers (Ref. 16). The comment also noted that the Beta-Carotene and Retinol Efficacy Trial (CARET) was terminated early because interim results indicated that beta-carotene and vitamin A supplements provided no benefit and may have caused harm to participants (Ref. 17). The comment reported that in the CARET trial, 30 mg beta-carotene and 25,000 International Units (IU) vitamin A were administered daily to male and female smokers and former smokers or to men exposed to asbestos. The comment noted that the interim result, a 28 percent increased lung cancer risk in the treatment group, was consistent with the results of the ATBC Trial. The comment asserted that results of these studies do not support the hypothesis that beta-carotene provides any beneficial disease prevention or antioxidant effect in these populations. Furthermore, the comment maintained that the evidence from the Physician's Health Study, which showed no protective effect from beta-carotene supplementation against cancer or cardiovascular disease (Ref. 18), clearly does not support an antioxidant role for beta-carotene in the prevention of these diseases.

Another comment argued that the scientific evidence does not support the hypothesis that beta-carotene supplements are effective in the prevention of cancer or cardiovascular disease in well-nourished populations. The comment, however, asserted that the question of a possible increase in risk of disease among smokers who take beta-carotene supplements had not been definitively proven.

One carotenoid expert asserted that carotenoids are more appropriately defined as ''physiologic modulators'' rather than as ''antioxidants.'' An antioxidant expert contended that there is inadequate scientific evidence to support the hypothesis that beta-carotene functions as an antioxidant in the human body and urged FDA not to include beta-carotene in this classification until scientific evidence is available to support its purported action as an antioxidant.

A couple of comments stated that there is no evidence demonstrating a significant in vivo antioxidant function for beta-carotene, compared to the demonstrated in vivo antioxidant function for vitamins C and E. The comments stated that the results of the beta-carotene intervention trials do not support an antioxidant function for beta-carotene but, instead, indicate that beta-carotene supplementation may cause harm to smokers, possibly through a pro-oxidant mechanism. These comments stated that there is no consensus among experts that beta-carotene has in vivo antioxidant activity.

Another comment cited the findings of the ATBC trial and suggested that beta-carotene may act as a pro-oxidant at high levels. The comment further stated that negative health effects or pro-oxidant activity results have not been attributed to high intakes of mixed carotenoids provided from fruits and vegetables. The comment also stated that foods with naturally occurring beta-carotene contain a mixture of carotenoids and carotenoid isomers that may confer a health protective effect to foods compared to supplements containing only beta-carotene. The comment agreed with the inclusion of beta-carotene in the antioxidant definition but suggested that the agency prohibit dosages that would result in pro-oxidant stress. The comment suggested that when beta-carotene is the subject of the claim, the product should contain at least 20 percent, but no more than 100 percent, of the RDI for vitamin A as added beta-carotene.

As discussed in the previous comment, FDA is not specifically identifying beta-carotene as an antioxidant in this final rule. However, FDA does not agree with the comments that stated that beta-carotene should not be considered a recognized antioxidant and therefore should be ineligible to be included in nutrient content claims for antioxidants. There is substantial scientific evidence that beta-carotene, in addition to its established metabolic role as a precursor to vitamin A, acts as an antioxidant (Refs. 19 through 22). The agency is aware, however, that most of the scientific evidence for beta carotene having antioxidant activity is from in vitro, rather than in vivo, studies. Although there is no direct scientific evidence that beta-carotene has in vivo antioxidant activity, or that it may have a beneficial health outcome that is directly attributable to its antioxidant capacity, the in vitro antioxidant activity of beta-carotene suggests mechanisms for how it and other antioxidant substances may act in the body. For example, the results from a recent study suggest that vitamin E, vitamin C, and beta-carotene collaborate to deactivate free radicals (Ref. 23). Investigators reported that, using an in vitro model, free radicals are passed from one antioxidant molecule to the next in the following sequence: From vitamin E to beta-carotene to vitamin C. These investigators hypothesized that the resulting water-soluble, vitamin C radical would be voided from the body before causing harm. According to this scheme, smokers, who tend to have lower levels of vitamin C than nonsmokers, do not have sufficient vitamin C to scavenge the carotenoid radicals. The investigators raised the

possibility of low vitamin C levels in smokers as an explanation for the increased risk of lung cancer following beta-carotene supplementation that was found in the ATBC and CARET trials.

Findings from clinical trials do not reveal the exact mechanism of action of substances in vivo, but they do provide information on whether a compound can achieve a particular clinical outcome or endpoint. Clinical trials can provide clues on whether the substance acted in the hypothesized fashion.

Because of the adverse results of the ATBC and CARET trials, the agency recognizes that beta-carotene may have other than antioxidant effects in certain situations. It may be that beta-carotene acts as a pro-oxidant in certain situations, e.g., in smokers given large doses of supplemental beta-carotene, but as an antioxidant in others, e.g., in nonsmoking, healthy adults who consume diets high in beta-carotene.

The agency believes that additional research on the in vivo antioxidant mechanism of beta-carotene is needed, and if future scientific evidence does not support an in vivo antioxidant effect for beta-carotene, the agency is prepared to reconsider whether this substance meets the definition of antioxidant. Thus, while the results from in vitro studies do not conclusively prove that beta-carotene is an in vivo antioxidant, they provide enough scientific evidence that the agency concludes that it is reasonable, at this time, to permit beta-carotene to be the subject of nutrient content claims about the level of antioxidants in food.

FDA agrees with those comments that stated that the results of the ATBC and CARET trials raise serious concerns about the safety of beta-carotene supplementation for smokers and others at high risk of lung cancer. Based on the comments discussed above and on FDA's review of the scientific literature, the agency advises that it has serious concerns about the safety of dietary supplements that are intended to provide 20 mg or more beta-carotene daily, the lowest dose for which an adverse effect was observed in the ATBC trial. The agency encourages manufacturers and distributors of dietary supplements containing beta-carotene to consider the safety of dosages in excess of this amount in developing and marketing such products and to consider including cautionary label statements to ensure that such high-dose beta-carotene dietary supplements do not present a significant or unreasonable risk of injury or illness to consumers under the conditions of use recommended or suggested in labeling or under ordinary conditions of use. FDA points out that it agrees with the comment that stated no negative health effects have been attributed to high intakes of carotenoids, including beta-carotene, from fruits and vegetables.

C. Complete and Complex

10. Several comments objected to the proposed definition of ''complete'' and ''complex.'' One comment recommended that the proposed standard for ''complete'' or ''complex'' antioxidant formula be strengthened by mandating that vitamin C and vitamin E be present at 100 percent or more of RDI levels, and that at least 100 percent of the RDI for vitamin A be present as beta-carotene.

One comment recommended that FDA permit the use of the term ''antioxidant complex'' with an asterisk to refer to another asterisk next to a list of all antioxidant ingredients other than vitamin E, vitamin C, and beta-carotene. The comment suggested that the asterisk correspond with a same panel reference to the following statement: ''This product contains ————, which are antioxidants. An RDI reference amount has not been established for these nutrients.'' The comment stated that ''complete antioxidant complex'' is inherently misleading, and that only ''antioxidant complex'' should be used as a collective term. The comment maintained that ''complete antioxidant complex'' conveys the impression that the product contains all known antioxidant compounds and contains those compounds at 100 percent of their RDI's.

One comment stated that the purpose of the definition is limited solely to define nutrient content claims, and FDA is not purporting to define what other dietary ingredients play an antioxidant role in the body and which claims (other than defined nutrient content claims) may be made. For this reason, the comment objected to the proposed definitions of ''complex'' and ''complete'' because they do not characterize a level, which is the prerequisite for a claim under section 403(r)(1)(A) of the act. The comment maintained that limiting the use of these terms to even an expanded list of nutrients with RDI's would be misleading in light of the growing scientific recognition of the antioxidant capabilities of a number of other dietary ingredients.

Another comment stated that authorizing a claim such as ''complete antioxidant formula'' will result in an infringement of a federally-registered trademark. Several associations of advertising agencies stated that the use of such terms undercuts the value of certain trademarked terms.

Based on the comments, FDA is persuaded that terms such as ''complete antioxidant complex'' and ''complete antioxidant formula,'' discussed in the high potency/antioxidant proposal (60 FR 67184 at 67191), may convey the impression that all known antioxidants are present in a product. The agency is persuaded that products bearing the term ''complete'' in association with the term ''antioxidants'' may be misleading given the dictionary definition of ''complete'' (i.e., having all necessary parts, whole) (Ref. 24). This term might be misleading because a complete list of antioxidants would be difficult to compile and would likely be controversial because of lack of consensus of which substances are antioxidants. On the other hand, the term ''complex'' means composed of interconnected or interwoven parts (Ref. 24) and conceivably might be applied to a number of antioxidants in the same product. Additionally, FDA is persuaded that such terms do not necessarily describe the level of a nutrient and therefore are outside the realm of nutrient content claims.

As mentioned, the agency recognizes that there are dietary ingredients that are antioxidants, but for which label reference values have not been established. Because nutrient content claims can only be made for those dietary ingredients for which reference values have been established, antioxidants without such reference values could not be the subject of a nutrient content claim.

Although nutrient content claims can only be made for those dietary ingredients for which reference values have been established, the agency has no objection to manufacturer's grouping these substances parenthetically next to the term ''antioxidants'' or to listing them in association with an asterisk elsewhere on the product label. However, as discussed in comment 6 of this document, there are constraints on the use of the word ''contains'' because it is a synonym for ''good source,'' a defined nutrient content claim.

In light of the conclusion that ''complete'' and ''complex'' do not necessarily describe a nutrient level, the potential for misunderstanding these claims (i.e., for assuming that all antioxidants are present), and because of possible, unanticipated trademark issues, FDA is withdrawing proposed § 101.54(g)(3) on collective nutrient content claims. If such terms are used on a food label, FDA will evaluate whether their use is false or misleading

under sections 403(a) and 201(n) of the act.

D. Referral Statements

11. One comment argued that while referral statements are required on conventional foods, such statements are not necessary on dietary supplements, especially when the lack of space on most labels is considered. The comment argued that, unlike conventional foods, almost all dietary supplements are purchased specifically for their ingredients, and that consumers can be expected to analyze nutrition information without being reminded to do so.

FDA is not persuaded to change the requirement for the referral statement, nor does it have the authority to do so. Section 403(r)(2)(B) of the act states that if a nutrient content claim is made, the label or labeling of the food shall contain, prominently and in immediate proximity to such claim, the following statement: ''See ———— for nutrition information.'' Under section 403(r)(2)(B)(i) of the act, the blank must identify the panel on which the information described in the statement may be found. While the DSHEA implicitly recognizes that statements that characterize the percentage level of a dietary ingredient for which FDA has not established a reference value are nutrient content claims, and thus exempts them from the requirement in section 403(r)(2)(A)(i) of the act, it does not exempt such statements from the requirement in section 403(r)(2)(B) for referral statements. Further, because the use of nutrient content claims is entirely voluntary, the agency is not persuaded to establish special provisions for small package size. Therefore, FDA has made no change in its regulations in response to this comment.

E. Ingredient Statements

12. One comment requested clarification on the use of the term ''antioxidant'' in an ingredient statement. The comment stated that an ingredient statement should be allowed to include the term ''antioxidant mix'' or ''antioxidant formula'' within appropriate limits because it is the common or usual name of a mixture of vitamins C and E and beta carotene. The comment maintained that food manufacturers can purchase prepackaged mixtures containing these three nutrients. The comment suggested that the term ''antioxidant mix'' has become an established common or usual name of a mixture of these vitamins and argued that the ingredient statement should be permitted to identify an antioxidant mixture followed by the individual ingredients in parenthesis, ''Antioxidant mix (ascorbic acid (vitamin C), DL–Alpha-tocopherol Acetate (vitamin E), Beta Carotene)''.

Section 403(i)(1) of the act states that a food is misbranded unless its label states the common or usual name of the food. The comment did not provide any information to persuade the agency that the term ''antioxidant mix'' is an established common or usual name. Therefore, FDA rejects the suggestion that the term ''antioxidant mix'' be allowed in ingredient labeling. Interested parties may petition the agency to consider the term ''antioxidant mix'' as a common or usual name. FDA points out that any such petition should include substantiation that the term is recognized by consumers as a common or usual name.

IV. Effective Date

13. Several comments requested that the date of application be 18 months after publication of the final rule. One comment requested 12 months; another suggested 24 months. The comments expressed concern that manufacturers have adequate time to bring products into compliance.

This final rule is one of four final rules on food labeling published in this issue of the **Federal Register**. Three of the final rules pertain to dietary supplements, the fourth final rule pertains to the uniform compliance date for food regulations. Comments were received on the three dietary supplement rulemakings requesting an extension of their respective dates of application. Because FDA wishes to minimize the impact of label changes on manufacturers, the agency is persuaded that it is reasonable to extend the effective date for these rulemakings to 18 months following the publication date. This amount of time is consistent with the time period allowed for the labels of conventional foods to comply with the 1990 amendments. FDA is addressing the issue of the effective date in greater detail in the final rule entitled ''Food Labeling: Statement of Identity, Nutrition Labeling and Ingredient Labeling of Dietary Supplements'' published elsewhere in this issue of the **Federal Register**.

V. Other Provisions

FDA did not receive any comments that dealt specifically with the other provisions of the proposal. In the absence of any basis for doing otherwise, FDA is adopting those provisions, in particular, the amendment to § 101.60(c)(1)(iii)(A) (21 CFR 101.60(c)(1)(iii)(A)), as proposed.

VI. Environmental Impact

The agency has previously considered the environmental effects of this rule as announced in the high potency/antioxidant proposal (60 FR 67184). No new information or comments have been received that would affect the agency's previous determination that there is no significant impact on the human environment and that an environmental impact statement is not required.

VII. Paperwork Reduction Act

In the high potency/antioxidant proposal, FDA stated its tentative conclusion that the proposed rule contains no reporting, recordkeeping, labeling or other third party disclosure requirements and asked for comments on whether the proposed rule imposed any paperwork burden. No comments were received addressing the question of paperwork burden. FDA concludes that the labeling requirements in this document are not subject to review by the Office of Management and Budget because they do not constitute a ''collection of information'' under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). Rather, the labeling statements are a ''public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public'' (5 CFR 1320(c)(2)).

VIII. Benefit-Cost Analysis

FDA has examined the economic implications of the final rule as required by Executive Order 12866. 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). Executive Order 12866 classifies a rule as significant if it meets any one of a number of specified conditions, including having an annual effect on the economy of $100 million or adversely affecting in a material way a sector of the economy, competition, or jobs, or if it raises novel legal or policy issues. FDA finds that this final rule is not a significant rule as defined by Executive Order 12866.

FDA believes that many dietary supplements currently marketed use the terms ''high potency'' and ''high in antioxidants'' to describe the level of nutrients in the products. Without rulemaking to define these terms, manufacturers will not be able to

continue to use them. This regulation will require that any manufacturer of dietary supplements currently using the terms ''high potency'' or ''antioxidant'' bear the costs of removing such statements from their labels only if the products do not meet the definition that the agency is adopting. FDA has information on the use of the terms ''high potency'' and ''antioxidant'' on the labels of dietary supplements provided by A. C. Nielsen. Using the item names in the Nielsen data base, FDA can determine products using the terms for the following Nielsen product categories: ''Nutritional Supplements'' (94); ''Vitamins-Tonic-Liquid & Powder'' (3); ''Vitamins-Multiple'' (217); ''Vitamins-B Complex with Vitamin C'' (46); and ''Minerals'' (98). Although FDA does not have information on the Nielsen category ''Vitamins-Remaining,'' the agency can make some plausible assumptions. Although FDA does not know the exact size of the missing product category, based on other information provided by Nielsen, it does know that this category is at least as big as the largest of the other categories. Therefore, it is reasonable to assume that the number of products using the terms ''high potency'' or ''antioxidant'' is at least equal to the greatest of the other categories. Therefore, FDA estimates that there are at least 675 supplements of vitamins and minerals that use these terms in their labeling.

FDA has no information to determine how many of those products will be reformulated, nor how many labels will be redesigned, as a result of this regulation. Firms whose labels do not meet the definitions for the claims established in this rulemaking will decide between reformulation and relabeling based on the relative costs of each. FDA cannot predict the cost of reformulating because it will depend on the nutrients involved and, in the case of ''high potency'', the degree to which the level of the nutrient is below the definition for the claim. FDA estimates that the cost of a label redesign for these types of products is approximately $2,200 per label. If the labels of all 675 products are redesigned, then the costs of this regulation will be $1.5 million. However, to the extent that firms can combine label changes attributable to this rule with those attributable to the dietary supplement nutrition labeling regulations (and the fact that FDA has made those regulations effective on the same day as the regulations in this rulemaking means that firms will have a complete ability to do so), then the costs of this rule will be greatly reduced. Based on these estimates, FDA concludes that the costs of this rule will not be significant.

By defining the terms ''high potency'' and ''high in antioxidants,'' this rule will benefit consumers by ensuring the consistent use of these claims. However, because FDA cannot predict the extent to which manufacturers will take advantage of the opportunity to use these claims nor the value that consumers place on the consistent use of these claims, FDA cannot quantify the benefits of this final rule.

IX. Small Entity Analysis

FDA has examined the economic implications of the final rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–612). If a rule has a significant impact on a substantial number of small entities, the Regulatory Flexibility Act requires that agencies analyze options that would minimize the economic impact of that rule on small entities. Pursuant to the Regulatory Flexibility Act (5 U.S.C. 605(b)), the Secretary of Health and Human Services certifies that this final rule might have a significant impact on a substantial number of small entities.

A. Estimate and Description of the Small Entities

According to the Regulatory Flexibility Act, the definition of a small entity is a business independently owned and operated and not dominant in its field. The Small Business Administration has set size standards for most business categories through use of four-digit Standard Industrial Classification codes. For dietary supplements of vitamins and minerals, a business is considered small if it has fewer than 750 employees.

As stated in the previous section, FDA has determined that there are approximately 675 products that may require label redesign or product reformulation if they do not meet the definitions established by this regulation. Using Dun's Market Identifiers, FDA has determined that half of these products are produced by 120 small entities.

B. Description of the Impacts

As stated earlier, FDA has no information to determine how many of these products will be reformulated, nor how many labels will be redesigned as a result of this regulation. Firms whose labels do not meet the definitions for the claims established in this rulemaking will decide between reformulation and relabeling based on the relative costs of each. In addition, affected firms may choose to reformulate the product if the loss of the claim will result in a significant reduction in sales. FDA cannot predict the cost of reformulating because it will depend on the nutrients involved and, in the case of ''high potency,'' the degree to which the level of the nutrient is below the definition for the claim. As stated in section VIII of this document, FDA has determined the cost of redesigning each label to be $2,200.

The smallest affected entity for which FDA has information has three employees, annual sales of $120,000, and produces one product potentially affected by this regulation. If the product will require label redesign, then the cost of this regulation to that firm will be a one-time cost of $2,200, or 1.8 percent of the firm's annual sales. FDA considers this potential cost to be significant.

C. Compliance Requirements and Necessary Skills

The Regulatory Flexibility Act also requires agencies to describe the projected reporting, recordkeeping, and other compliance requirements of the rule and the type of professional skills necessary for preparation of the report or record. As stated elsewhere in this preamble, there are no reporting or recordkeeping requirements of this rule. Manufacturers desiring to use ''high potency'' or ''antioxidant'' claims on the labels of their products are only required to ensure that the products meet the definitions of the claims.

In the case of ''high potency,'' manufacturers must review the levels of the nutrients for which the claim is made and ensure that they are sufficient. Because manufacturers are required to report the levels in the nutrition facts panel, no further analysis of the product is necessary. If the levels of the relevant nutrients are insufficient, then the firm must either avoid using the claim or alter the levels of the nutrient to meet the established definition.

In the case of the term ''antioxidant'' when used in nutrient content claims, firms must simply know whether or not the nutrient is one of the nutrients that may be labeled ''antioxidant'' when used in a nutrient content claim. No special skills are required in this case.

D. Alternatives

FDA has examined the following alternatives to the rule which may minimize the significant economic impact on small entities consistent with the stated objectives.

1. Exempt Small Entities

One alternative for alleviating the burden for small entities would be to

exempt them from the provisions of this rule. However, the majority of the firms engaged in the manufacture of vitamin or mineral supplements are small. Even accounting for the fact that large firms produce more products on average than small firms, exempting small firms would exempt a large proportion of products. Although this option would clearly eliminate the burden on small firms, it would also result in a significant reduction in the value to consumers of standardizing these terms. Therefore, FDA concludes that selecting this alternative would defeat the purpose of the regulation.

2. Lengthen the Compliance Period

As discussed elsewhere, the agency is persuaded to make this final rule effective 18 months following its publication date because the agency wishes to minimize the impact of label changes on manufacturers. FDA considered establishing a longer compliance period for small entities. However, within the 18-month compliance period, all but the very smallest entities will be required to change their labels in response to nutrition labeling and ingredient labeling requirements. Thus, lengthening this compliance period will not result in any reduction in costs to these firms because they are not likely to opt to relabel their products twice when they have the ability to combine the necessary changes into one relabeling effort.

X. References

The following references have been placed on file in the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

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List of Subjects in 21 CFR Part 101

Food labeling, Nutrition, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 101 is amended as follows:

PART 101—FOOD LABELING

1. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: Secs. 4, 5, 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs. 201, 301, 402, 403, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 371).

2. Section 101.54 is amended by revising the section heading and adding new paragraphs (f) and (g) to read as follows:

§ 101.54 Nutrient content claims for ''good source,'' ''high,'' ''more,'' and ''high potency.''

* * * * *

(f) ''*High potency*'' claims. (1)(i) The term ''high potency'' may be used on the label or in the labeling of foods to describe individual vitamins or minerals that are present at 100 percent or more of the RDI per reference amount customarily consumed.

(ii) When the term ''high potency'' is used to describe individual vitamins or minerals in a product that contains

other nutrients or dietary ingredients, the label or labeling shall clearly identify which vitamin or mineral is described by the term ''high potency'' (e.g., ''Botanical 'X' with high potency vitamin E'').

(2) The term ''high potency'' may be used on the label or in the labeling of a multiingredient food product to describe the product if the product contains 100 percent or more of the RDI for at least two-thirds of the vitamins and minerals that are listed in § 101.9(c)(8)(iv) and that are present in the product at 2 percent or more of the RDI (e.g., ''High potency multivitamin, multimineral dietary supplement tablets'').

(3) Where compliance with paragraphs (f)(1)(i), (f)(1)(ii), or (f)(2) of this section is based on a nutrient that has been added to a food (other than a dietary supplement), that fortification shall be in accordance with the policy on fortification of foods in § 104.20 of this chapter.

(g) *Nutrient content claims using the term ''antioxidant.''* A nutrient content claim that characterizes the level of antioxidant nutrients present in a food may be used on the label or in the labeling of that food when:

(1) An RDI has been established for each of the nutrients;

(2) The nutrients that are the subject of the claim have recognized antioxidant activity; that is, when there exists scientific evidence that, following absorption from the gastrointestinal tract, the substance participates in physiological, biochemical, or cellular processes that inactivate free radicals or prevent free radical-initiated chemical reactions;

(3) The level of each nutrient that is the subject of the claim is sufficient to qualify for the § 101.54(b), (c), or (e) claim (e.g., to bear the claim ''high in antioxidant vitamin C,'' the product must contain 20 percent or more of the RDI for vitamin C). Beta-carotene may be a subject of the claim when the level of vitamin A present as beta-carotene in the food that bears the claim is sufficient to qualify for the claim. For example, for the claim ''good source of antioxidant beta-carotene,'' 10 percent or more of the RDI for vitamin A must be present as beta-carotene per reference amount customarily consumed; and

(4) The names of the nutrients that are the subject of the claim are included as part of the claim (e.g., ''high in antioxidant vitamins C and E''). Alternatively, when used as part of a nutrient content claim, the term ''antioxidant'' or ''antioxidants'' (as in ''high in antioxidants'') may be linked by a symbol (e.g., an asterisk) that refers to the same symbol that appears elsewhere on the same panel of a product label followed by the name or names of the nutrients with recognized antioxidant activity. The list of nutrients shall appear in letters of a type size height no smaller than the larger of one-half of the type size of the largest nutrient content claim or 1/16 inch.

3. Section 101.60 is amended by revising paragraph (c)(1)(iii)(A) to read as follows:

§ 101.60 Nutrient content claims for the calorie content of foods.

* * * * *

(c) * * *

(1) * * *

(iii)(A) It is labeled ''low calorie'' or ''reduced calorie'' or bears a relative claim of special dietary usefulness labeled in compliance with paragraphs (b)(2), (b)(3), (b)(4), or (b)(5) of this section, or, if a dietary supplement, it meets the definition in paragraph (b)(2) of this section for ''low calorie'' but is prohibited by §§ 101.13(b)(5) and 101.60(a)(4) from bearing the claim; or

* * * * *

Dated: September 11, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–24732 Filed 9–22–97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Chapter I

[Docket No. 96N–0094]

Uniform Compliance Date for Food Regulations

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; response to comments.

SUMMARY: The Food and Drug Administration (FDA) is responding to comments that were submitted in response to a final rule establishing January 1, 2000, as the uniform compliance date for food labeling regulations that the agency issues between January 1, 1997, and December 31, 1998. FDA received three comments in response to that final rule. The agency is not making any changes in the final rule in response to these comments. January 1, 2000, remains the uniform compliance date for food labeling regulations that are issued between January 1, 1997, and December 31, 1998.

EFFECTIVE DATE: December 27, 1996.

FOR FURTHER INFORMATION CONTACT: Gerad L. McCowin, Center for Food Safety and Applied Nutrition (HFS–150), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–4561.

SUPPLEMENTARY INFORMATION:

I. Background

FDA has periodically announced uniform compliance dates for new food labeling requirements to minimize the economic impact of label changes. In 1992, FDA suspended this practice pending the issuance of regulations implementing the Nutrition Labeling and Education Act of 1990 (the 1990 amendments). In the **Federal Register** of December 24, 1996 (61 FR 67710), FDA issued a final rule (hereinafter referred to as the December 24, 1996, final rule) establishing January 1, 1998, as its new uniform compliance date for all food labeling regulations that are issued after its publication and before January 1, 1997. FDA announced that it was reinstating its previous practice of periodically announcing, as final rules, uniform compliance dates for food labeling regulations. In the **Federal Register** of December 27, 1996 (61 FR 68145) (hereinafter referred to as the December 27, 1996, final rule), FDA established January 1, 2000, as the uniform compliance date for food labeling regulations that are issued between January 1, 1997, and December 31, 1998. Because FDA had already provided notice and opportunity for comment on the practice of establishing uniform compliance dates by issuance of a final rule announcing the date (see 61 FR 67710, December 24, 1996), the agency found any further rulemaking unnecessary. Nonetheless, under 21 CFR 10.40(e)(1), FDA provided an opportunity until March 13, 1997, for interested persons to comment on whether the uniform compliance date of January 1, 2000, should be modified or revoked. In the December 27, 1996, final rule, FDA advised that it would publish a notice setting out the agency's conclusions concerning any comments that it received in response to the final rule or initiate notice and comment rulemaking to modify or revoke the uniform compliance date that the final rule established.

FDA received three letters, each containing one or more comments, from trade associations in response to the December 27, 1996, final rule. A summary of these comments and the

agency's responses are provided as follows:

II. Comments

A. Dietary Supplements

One of the comments asked the agency to confirm that the final rule for a uniform compliance date of January 1, 2000, will apply to the proposed regulations for dietary supplement labels that FDA published in the **Federal Register** of December 28, 1995 (60 FR 67176 and 67194). The comment noted that the December 28, 1995, proposals specified a compliance date of December 31, 1996, and that obviously that date had come and gone and the final regulations had yet to be issued. The comment agreed with FDA's statements concerning the use of a uniform compliance date and stated that the uniform compliance date of January 1, 2000, should be applied to the final rule issued in response to the December 28, 1995, proposed regulations concerning dietary supplements. The comment explained that the dietary supplement labeling regulations will have a massive impact on the entire industry. It stated that every single dietary supplement label will need to be revised, and that many products that do not currently bear nutrition labeling will be required to do so. The comment concluded that, based on the passage of time and the need for the industry to have adequate time to reprint and replace label stock, the uniform compliance date of January 1, 2000, is the appropriate effective date for the final labeling regulations for dietary supplements.

As stated in the December 27, 1996, final rule, ''The new uniform compliance date will apply only to final FDA food labeling regulations that require changes in the labeling of food products and that publish after January 1, 1997, and before January 1, 1999'' (61 FR 68145). The Dietary Supplement Health and Education Act of 1994 (DSHEA) amended the Federal Food, Drug, and Cosmetic Act (the act) to establish a new definition for ''dietary supplement'' in section 201(ff) of the act (21 U.S.C. 321(ff)). The last sentence of section 201(ff) of the act states, ''Except for purposes of section 201(g), a dietary supplement shall be deemed to be a food within the meaning of this Act.'' Therefore, the agency confirms that the uniform compliance date will generally apply to regulations that establish requirements for the labeling of dietary supplements.

In the December 27, 1996, final rule (61 FR 68145 at 68146), however, FDA advised that if any food labeling regulation, including one concerning dietary supplements, involves special circumstances that justify a compliance date other than January 1, 2000, the agency will determine for that regulation an appropriate compliance date and will specify that compliance date in the final rule that resolves the proceeding. Elsewhere in this issue of the **Federal Register**, FDA is publishing final rules in response to proposals on dietary supplements that it published in the **Federal Register** of December 28, 1995. As discussed in those final rules, FDA has concluded that a compliance date of March 23, 1999, is responsive to the directives of DSHEA, and that extending the compliance date to January 1, 2000, for those final rules would not be appropriate. Therefore, FDA is adopting March 23, 1999, as the effective date for the final regulations for the labeling of dietary supplements, rather than January 1, 2000.

B. Bakery Industry

Although two letters from trade associations for the bakery industry agreed with the concept of a uniform compliance date, these letters disagreed with establishing January 1, 2000, as the uniform compliance date for regulations issued between January 1, 1997, and December 31, 1998. One comment stated that the uniform compliance date of January 1, 1998, should be extended to January 1, 1999, and that the uniform compliance date of January 1, 2000, should be extended to January 1, 2001. The comment stated that this extra year would allow firms to do laboratory analyses-reformulations, use existing inventory, and release new products and packaging to consumers. The comment explained that it is hard to foresee what types of new final regulations will materialize by December 31, 1998, and that 2 years would not be sufficient time for all of the changes needed. The comment suggested that all future uniform compliance dates allow a 3-year timeframe to make changes. The comment stated that, while some types of labeling changes may be more swiftly implemented than others, FDA should consider the more complicated cases like folic acid in establishing these dates.

The second comment stated that a compliance period of 1 year is not sufficient for the small and medium, mostly family owned, wholesale bakers that it represents to implement labeling changes in a manner that would minimize economic impact. The comment stated that the least amount of time needed for bakers to efficiently and effectively implement new labeling regulations would be 24 months. The comment expressed its concern that the rule would constrict a company's method of implementing FDA's rules, particularly for slow selling items, where labels are ordered for an extended length of time.

These two comments raise concerns similar to some that were raised in response to the uniform compliance date proposal of April 15, 1996 (61 FR 16422), and that were addressed in the December 24, 1996, final rule. In that proceeding, there were comments that objected to establishing January 1, 1998, as the uniform compliance date for food labeling regulations issued between January 1, 1995, and December 31, 1996, on the grounds that it resulted in a ''compliance period'' that at its shortest possible length would be only 12 months long. FDA disagreed with those comments, stating that a compliance period that is 18 months or 2 years at its shortest is too long. The agency pointed out that it must consider the costs and benefits to both the food producer and the consumer (61 FR 67710). A compliance period of 6 months would increase the benefit to the consumer but would result in even greater costs to the food producers than are caused by a compliance period of 12 months. Although a lengthier compliance period would reduce the costs to food producers, it would delay implementation of the labeling changes, thus decreasing the value of any benefits to the consumer.

As the agency pointed out in the December 24, 1996, final rule, the minimum compliance period of 1 year is the same compliance period that it has used for all of its uniform effective date final rules dating back to the 1970's, until it issued the labeling regulations that implemented the 1990 amendments. The agency is unaware of, nor has anyone submitted, including in the comments in this proceeding, any information to demonstrate any problems with respect to bringing labels into compliance with the various uniform effective dates that it had established over the period of approximately 20 years during which it has announced uniform compliance dates. While there have been instances where the agency has granted extensions beyond the uniform compliance date, generally firms have come into compliance with little complaint to the agency. The agency is merely reinstating its former practice.

The agency concludes that the comments on the December 27, 1996, final rule do not provide a basis on which to initiate rulemaking to revoke or modify the uniform compliance date

established therein. Therefore, FDA confirms that January 1, 2000, will be the uniform compliance date for food labeling regulations issued between January 1, 1997, and December 31, 1998.

Dated: September 11, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–24731 Filed 9–22–97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 96N–0240]

Food Labeling; Notification Procedures for Statements on Dietary Supplements

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations to establish the notification procedures for manufacturers, packers, or distributors of dietary supplements who are marketing dietary supplement products that bear statements under a provision of the Federal Food, Drug, and Cosmetic Act (the act). The agency is adopting this procedure to ensure that notification is accomplished efficiently. FDA instituted this proceeding to help the industry comply with the Dietary Supplement Health and Education Act of 1994 (the DSHEA).

EFFECTIVE DATE: October 23, 1997.

FOR FURTHER INFORMATION CONTACT: Robert J. Moore, Center for Food Safety and Applied Nutrition (HFS–456), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–4605.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of September 27, 1996 (61 FR 50771), FDA published a proposed rule entitled ''Food Labeling; Dietary Supplement; Nutritional Support Statement; Notification Procedure'' (hereinafter referred to as ''the September 1996 proposal''). FDA issued this proposal in response to section 6 of the DSHEA (Pub. L. 103–417). This section of the DSHEA amended the act by adding section 403(r)(6) (21 U.S.C. 343(r)(6)). This section of the act allows for statements to be made on the label or in the labeling of a dietary supplement that does the following:

(1) Claims a benefit related to a classical nutrient deficiency disease and discloses the prevalence of such disease in the United States,

(2) describes the role of a nutrient or dietary ingredient intended to affect the structure or function in humans,

(3) characterizes the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function, or

(4) describes general well-being from consumption of a nutrient or dietary ingredient if the statements are made in accordance with certain requirements. The manufacturer of the dietary supplement must:

(1) Substantiate that the statement is truthful and not misleading;

(2) Include, prominently displayed and in boldface type, the following: ''This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease;'' and

(3) Notify the Secretary of Health and Human Services (the Secretary) (and by delegation FDA) no later than 30 days after the first marketing of a dietary supplement bearing such a statement that the statement is being made. The statement may not claim to diagnose, mitigate, treat, cure, or prevent a disease or class of diseases.

In the September 1996 proposal, FDA outlined the procedure by which manufacturers would comply with the requirements that they notify the Secretary when they make a claim under section 403(r)(6) of the act. FDA received eight responses to the proposal. Each response contained one or more comments. Some comments supported the proposal generally or supported aspects of the proposal. Other comments addressed issues outside the scope of the proposal (e.g., guidelines differentiating health claims from structure/function claims, health information to consumers, types of claims that can be made, the form and amount of substantiation FDA will require, when the disclaimer should or should not be required, and the use of classical nutrient deficiency claims) and will not be addressed in this document. Several comments suggested modifications or revisions of various aspects of the proposal. A summary of the comments and the agency's responses to the comments follow.

II. Notification of ''Products'' or ''Brands''

1. One comment objected to proposed § 101.93(b)(4) (redesignated as § 101.93(a)(2)(iv)) requiring that the brand name of the product be included in the notification. The comment argued that providing this information would be unnecessarily burdensome, and that the DSHEA did not require this information. The comment cited the fact that a dietary supplement product, such as vitamin C 500 milligrams (mg), may be marketed under a variety of brand names, but that the product (i.e., the dietary supplement) could be the same from brand ABC to brand XYZ. The comment argued that if a notification has been made for a claim on one brand of this dietary supplement, it should not be necessary for every manufacturer of this type of supplement to file a notification.

FDA is not persuaded to modify the regulation in response to this comment. If a manufacturer makes a type of dietary supplement, such as a vitamin C supplement, under a number of different brand names, under § 101.93(a)(2)(iv), a manufacturer may list all of the brands on which the claim is to appear, and thus for which it is providing notification, in a single submission. The regulation does not require that a separate notice be submitted for each individual product or brand.

FDA finds that the brand name of a dietary supplement is a necessary part of the notification that a statement of nutritional support is being made on the label or in the labeling of the dietary supplement. Including the brand is necessary to efficiently enforce the act. If the notification does not include the relevant brand name, FDA will not know which products are in compliance with the notification requirement of section 403(r)(6) of the act. This is particularly important because there is no requirement that a manufacturer submit to FDA its substantiation that establishes that its claim is truthful and not misleading (section 403(r)(6)(B) of the act). Thus, it cannot be assumed that the first submission for a claim under section 403(r)(6) of the act establishes that adequate substantiation exists to support that claim for all products that may contain that substance. Each manufacturer must have its own substantiation that any statement it makes in the labeling of a dietary supplement product under section 403(r)(6) of the act is truthful and not misleading, and the manufacturer must submit a notice to FDA that attests to this fact.

III. Signature of Person Who Can Certify that Firm has Substantiation

2. Several comments objected to proposed § 101.93(c) (redesignated as

§ 101.93(a)(3)), which requires that the notice be signed by a responsible individual or by the person authorized to certify that the information presented and contained in the notice is accurate. Other comments objected to proposed § 101.93(c) (redesignated as § 101.93(a)(3)) which requires that the individual certify that the information contained in the notice is complete and accurate, and that the notifying firm has substantiation that the statement is truthful and not misleading. These comments argued that the DSHEA does not require that the notification be signed by anyone, and that it does not require that an individual certify that the information contained in the notice is complete and accurate, or that the notifying firm have substantiation that the statement is truthful and not misleading.

One comment agreed that the company must have substantiation that statements made in accordance with section 403(r)(6)(B) of the act are truthful and not misleading. However, this comment maintained that section 403(r)(6)(B) of the act does not require, or provide any basis for requiring, signature and certification as part of the notification. Another comment stated that the DSHEA's requirement that manufacturers of dietary supplements have substantiation that such statements are truthful and not misleading is independent of the notification requirement.

Several comments also disagreed with FDA's explanation that the requirement for a signature will ensure that the statutory requirements have been met, and that the certification is necessary to provide assurance that a notifying firm has fully complied with the requirement of section 403(r)(6) of the act.

Several comments contended that neither the courts nor FDA have established procedures, guidelines, or standards for identifying the type and amount of evidence needed to support substantiation, and therefore, the manufacturer who is giving notification cannot know whether the evidence it has meets FDA's expectations and has no basis to provide certification. One comment stated that general dictionary definitions for ''substantiation'' are of no help because, in the relevant legal context, the question requires detailed legal analysis, which at best can only identify possible interpretations and does not even begin to predict what the agency's ultimate interpretation of ''substantiation'' might be. One comment stated that ''substantiation'' under the DSHEA might be interpreted by regulated supplement companies to mean a number of different things (e.g., near scientific certainty, significant scientific agreement, or reasonable basis). The comment requested that FDA acknowledge that it will not attempt to set a substantiation standard under the DSHEA comparable to new drug or health claims requirements, and that it will not adopt the Federal Trade Commission's ''reasonable basis'' standard that is currently applied in dietary supplement advertising cases.

Several comments maintained that the requirement that manufacturers certify that the notifying firm has substantiation that the statement is truthful and not misleading goes beyond the authority of the act because it imposes potential liability under the False Statements Act (18 U.S.C. 1001) if FDA does not agree that the substantiation relied upon by the person making the notification meets the requirements of the act. Another comment contended that the objective of § 101.93(a)(3) is accomplished by existing Federal statutes (i.e., 18 U.S.C. 1001) that prohibit the knowing and willful false representation of any statement to a Government agency. Another comment objected to the agency subjecting both a manufacturer and the person representing the company to potential criminal sanctions for making false statements, and this comment argued that, in doing so, FDA would be acting in a manner that is inconsistent with the intent of Congress.

FDA disagrees with these comments and finds that they are without merit. First, FDA does not agree that the requirement that manufacturers have substantiation that statements made in accordance with section 403(r)(6) of the act are truthful and not misleading is independent of the notification requirement. The last sentence of section 403(r)(6) of the act states that if a manufacturer of a dietary supplement proposes to make a ''statement described in the first sentence of this subparagraph,'' it is to notify the Secretary (that is, FDA). A ''statement described in the first sentence of [section 403(r)(6)]'' is one for which (among other things) ''the manufacturer of the dietary supplement has substantiation that such statement is truthful and not misleading.'' In section 403(r)(6) of the act, thus, contrary to the assertion in the comment, there is a direct connection between the substantiation requirement and the notification requirement in section 403(r)(6) of the act.

Second, FDA also finds no merit to the argument made with respect to 18 U.S.C. 1001. Because the act on its face connects the notification requirement to the substantiation requirement, a manufacturer who submits a notification under section 402(r)(6) of the act without being in possession of substantiation that the claim that it intends to make, or is making, is truthful and not misleading is making a false statement to the Government, in violation of 18 U.S.C. 1001. This is true without regard to whether a responsible individual has signed a certification or not.

FDA is requiring that the notification be signed by a responsible individual, and that individual certify the accuracy of the information presented in the notice, for efficient enforcement of the act under sections 403(r)(6) and 701(a) of the act (21 U.S.C. 371(a)). The person signing the notice, and the company on whose behalf he or she signs it, must recognize that there are significant consequences to their action, including potential liability under 18 U.S.C. 1001. Signing a certification that the information in the notice is accurate will likely cause the person who is doing so to check the information in the notice. Such a check should minimize any problems under this section of the act and thus will contribute to its efficient enforcement.

Third, FDA finds no merit to the comments that claim that firms have no basis to determine what level of substantiation is necessary. In this regard, the act is clear on its face: The manufacturer must have substantiation that the statement is truthful and not misleading. If the manufacturer has any doubts as to whether it has substantiation to meet this standard, it should not make the statement in question on its label or in its labeling. Claims that manufacturers are unable to interpret this standard are belied by the fact that since the passage of the DSHEA, FDA has received literally hundreds of notices under section 403(r)(6) of the act. FDA assumes that these notifications have been made in good faith, and the submitters were confident that they were in possession of adequate substantiation. Thus, FDA finds no need for it to elaborate on the substantiation standard that appears in the act.

IV. Recommended Compliance With the Proposed Rule

3. One comment stated that FDA indicated in the preamble to the September 1996 proposal that it ''recommends'' that manufacturers follow the proposed regulation immediately. The comment requested that FDA make clear that failure to follow ''recommendations'' that are not final rules carries no penalty or sanction and generates no prejudice.

FDA made this recommendation in the September 1996 proposal because of the many requests from manufacturers to FDA asking for guidance on how to make a statement of nutritional support notification. However, the comment is correct that no penalty or sanction applies to manufacturers who do not make their notification according to these rules until the effective date of this regulation. It should, however, be noted that dietary supplement manufacturers do not have the option of not notifying FDA if they are making statements of nutritional support on the label or in the labeling of their products. The requirement to make the notification to FDA no later than 30 days after the first marketing of the dietary supplement that bears such a statement became effective with the signing into law of the DSHEA on October 25, 1994.

V. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(8) 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

A. Benefit-Cost Analysis

FDA has examined the economic implications of this final rule as required by Executive Order 12866. 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). Executive Order 12866 classifies a rule as significant if it meets any one of a number of specified conditions, including: Having an annual effect on the economy of $100 million; adversely affecting some sector of the economy in a material way; adversely affecting jobs or competition; or raising novel legal or policy issues.

In the economic analysis of the proposed rule, FDA stated that the costs of this regulation consisted of the costs of preparing and submitting notification to FDA regarding statements of nutritional support. FDA concluded that because the information should already have been gathered in order to prepare the nutritional support statement itself, the additional cost incurred for notification would be small and in many instances negligible. One comment said that the costs of notification could be burdensome for a manufacturer producing many different brands and products. FDA is not persuaded that this additional burden would be large, for the same reasons as stated in the economic analysis of the proposed rule—the notification cost will be negligible to manufacturers who have borne the labeling costs associated with nutritional support statements for several different brands or products. This final rule is procedural and implements the statutory notification requirement at minimal cost. Other requirements associated with nutritional support statements will be dealt with by other rules.

FDA finds that this final rule does not constitute a significant rule as defined by Executive Order 12866. Furthermore, it has been determined that this rule is not a major rule for the purpose of congressional review (Pub. L. 104–121).

B. Small Business Analysis

FDA has examined the economic implications of this final rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–612). If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would lessen the economic effect of the rule on small entities.

For purposes of defining industry size standards, the Small Business Administration (SBA) classifies industries according to four-digit Standard Industrial Classification (SIC) codes. SBA does not define ''small'' for the dietary supplement industry, because no SIC code corresponds to the industry—dietary supplements encompass a wide range of products. The industry's products come closest to the industry groups Food Preparations N.E.C. (SIC code 2099) and Medicinal Chemicals and Botanical Products (SIC code 2833). The SBA size standards for small businesses are 500 or fewer employees for food preparations and 750 or fewer employees for medicinal and botanical products. Under either employee-based size standard, virtually all firms in the dietary supplement industry could be classified as small, including some firms that are among the leaders in sales revenues.

For the dietary supplement industry, FDA is basing size classifications on sales revenue rather than employees. According to the *Nutrition Business Journal*, of the 850 firms manufacturing dietary supplements, 11 firms have total revenues over $100 million, accounting for 53 percent of total sales; 30 firms have sales revenues between $20 and $100 million, accounting for 28 percent of total sales; and 809 firms have sales under $20 million, accounting for 19 percent of total sales. The 809 firms in the under $20 million category have an average sales revenue of $800,000 and will be considered small businesses by FDA. Because the total includes some firms making functional foods that are not dietary supplements and other products, such as sports nutrition products, that are not considered dietary supplements, the estimate may overstate the number of small firms affected by this final rule.

The number of small businesses affected by this final rule could include all small businesses in the dietary supplement industry, if they choose to use nutritional support statements. As FDA concluded in the benefit-cost analysis, the additional costs imposed by the notification provisions will be negligible to small firms once the labeling provisions have been carried out. This final rule requires only that the manufacturer notify FDA within 30 days of marketing a supplement that bears a nutritional support statement on its label. The information required in the notification is either on the label itself (e.g., the text of the statement) or readily available (e.g., the name of the ingredient that is the subject of the statement).

FDA finds that this final rule will not have a significant economic impact on a substantial number of small entities. Accordingly, under the Regulatory Flexibility Act (5 U.S.C. 605(b)), the agency certifies that this final rule will not have a significant impact on a substantial number of small entities.

VII. The Paperwork Reduction Act of 1995

This final rule contains information collection requirements 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 title, description, and respondent description of the information collection provisions are shown below with an estimate of the annual reporting and recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

Title: Food Labeling; Notification Procedures for Statements on Dietary Supplements.

Description: FDA is, by regulation, requiring manufacturers, packers, and distributors of dietary supplements to

notify FDA that they are marketing a dietary supplement product that bears on its label or in its labeling a statement provided for in section 403(r)(6) of the act. Section 403(r)(6) of the act requires that the agency be notified, with a submission about such statements, no later than 30 days after the first marketing of the dietary supplement. Information that is required in the submission includes: (1) The name and address of the manufacturer, packer, or distributor of the dietary supplement product; (2) the text of the statement that is being made; (3) the name of the dietary ingredient or supplement that is the subject of the statement; (4) the name of the dietary supplement (including the brand name); and (5) a signature of a responsible individual who can certify the accuracy of the information presented.

In § 101.93, the agency is establishing procedures for submitting required information. Section § 101.93 provides details of the procedures associated with the submission and identifies the information that must be included in the submission in order to meet the requirements of section 403 of the act.

Description of Respondents: Businesses or other for-profit organizations.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
101.93	420	1	420	0.5–1	210–420

(Through inadvertent error, the agency misreported the number of respondents and the annual frequency per response and omitted the total annual response in the proposal. Hours per response and total hours were reported correctly. In this final rule, FDA is correcting the inadvertent errors that it made in the proposal).

Individuals and organizations may submit comments on these burden estimates or on any other aspect of these information collection provisions, including suggestions for reducing the burden, and should direct them to the Office of Special Nutritionals (HFS–450), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204.

The information collection provisions in this final rule have been approved under OMB control number 0910–0331. This approval expires on October 31, 1999. 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.

List of Subjects in 21 CFR Part 101

Food labeling, Nutrition, Reporting and recordkeeping requirements.

PART 101—FOOD LABELING

1. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: Secs. 4, 5, 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs. 201, 301, 402, 403, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 371).

2. Section 101.93 is added to subpart F to read as follows:

§ 101.93 Notification procedures for certain types of statements on dietary supplements.

(a)(1) No later than 30 days after the first marketing of a dietary supplement that bears one of the statements listed in section 403(r)(6) or the Federal Food, Drug, and Cosmetic Act, the manufacturer, packer, or distributor of the dietary supplement shall notify the Office of Special Nutritionals (HFS–450), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204, that it has included such a statement on the label or in the labeling of its product. An original and two copies of this notification shall be submitted.

(2) The notification shall include the following:

(i) The name and address of the manufacturer, packer, or distributor of the dietary supplement that bears the statement;

(ii) The text of the statement that is being made;

(iii) The name of the dietary ingredient or supplement that is the subject of the statement, if not provided in the text of the statement; and

(iv) The name of the dietary supplement (including brand name), if not provided in response to paragraph (a)(2)(iii) on whose label, or in whose labeling, the statement appears.

(3) The notice shall be signed by a responsible individual or the person who can certify the accuracy of the information presented and contained in the notice. The individual shall certify that the information contained in the notice is complete and accurate, and that the notifying firm has substantiation that the statement is truthful and not misleading.

(b) through (e) [Reserved]

Dated: August 20, 1997.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 97–24738 Filed 9–22–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 190

[Docket No. 96N–0232]

Premarket Notification for a New Dietary Ingredient

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is establishing the procedure by which a manufacturer or distributor of dietary supplements or of a new dietary ingredient is to submit under the Federal Food, Drug, and Cosmetic Act (the act) the information on which it has concluded that a dietary supplement containing a new dietary ingredient will reasonably be expected to be safe. FDA is issuing this regulation to enable industry to comply with the requirements of the Dietary Supplement Health and Education Act of 1994 (the DSHEA).

EFFECTIVE DATE: October 23, 1997.

FOR FURTHER INFORMATION CONTACT: Carolyn W. Miles, Center for Food Safety and Applied Nutrition (HFS–456), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–401–9858.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of September 27, 1996 (61 FR 50774), FDA published

a proposed rule, entitled ''Premarket Notification for a New Dietary Ingredient'' (hereinafter referred to as ''the September 1996 proposal''). FDA issued this proposal in response to section 8 of the DSHEA (Pub. L. 103–417). This section of the DSHEA amended the act by adding, among other provisions, section 201(ff) (21 U.S.C. 321(ff)), which defines a dietary supplement, and by adding section 413(a) (21 U.S.C. 350b(a)), which provides, among other things, for the notification of the Secretary of Health and Human Services (the Secretary) (and by delegation FDA) at least 75 days before the introduction or delivery for introduction into interstate commerce of a dietary supplement that contains a new dietary ingredient. Section 413(a) of the act states that a dietary supplement that contains a new dietary ingredient shall be deemed adulterated unless it meets one of two requirements. One requirement is that ''the dietary supplement contains only dietary ingredients which have been present in the food supply as an article used for food in a form in which the food has not been chemically altered.'' The alternative requirement is that:

[T]here is a history of use or other evidence of safety establishing that the dietary ingredient when used under the conditions recommended or suggested in the labeling of the dietary supplement will reasonably be expected to be safe and, at least 75 days before being introduced or delivered for introduction into interstate commerce, the manufacturer or distributor of the dietary ingredient or dietary supplement provides the Secretary with information, including any citation to published articles, which is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such dietary ingredient will reasonably be expected to be safe.

FDA published the September 1996 proposal to establish a procedure that would enable industry to comply with this notification requirement in an efficient manner. Adoption of this procedure will help to facilitate compliance with the notification required by section 413(a)(2) of the act. Interested persons were given until December 26, 1996, to comment on the proposal.

FDA received four letters each containing one or more comments from consumer groups, a trade association, and industry in response to the proposal. All of the comments generally supported the proposal. Several comments suggested modifications or revisions of various aspects of the proposal. A summary of the comments and the agency's responses follows.

II. New Dietary Ingredients Subject to Notification Requirements

1. Several comments expressed concern that proposed § 190(a), published in the September 1996 proposal, implied that any ''new dietary ingredient'' is subject to the notification requirements. The comments argued that the statutory requirement for notification under section 413(a)(2) of the act does not apply to those new dietary ingredients that have been present in the food supply as an article used for food in a form in which the food has not been chemically altered, as described in section 413(a)(1) of the act.

FDA agrees with the comments that the notification requirements of this regulation apply only to new dietary ingredients described in section 413(a)(2) of the act. Section 413(a)(1) of the act applies to dietary supplements that contain only dietary ingredients that have been present in the food supply as an article used for food in a form in which the food has not been chemically altered, and the statute does not require that FDA be notified before these products are marketed. To make clear which new dietary ingredients are subject to the notification requirement in section 413(a)(2) of the act, FDA is modifying proposed § 190.6(a) by incorporating the phrase ''that has not been present in the food supply as an article used for food in a form in which the food has not been chemically altered'' to define which new dietary ingredients are subject to the notification requirement.

III. The Notification

2. One comment opposed the requirement in proposed § 190.6(b)(3)(i) that the notification include the level of the new dietary ingredient in the dietary supplement. The comment claimed that notices may be submitted by vendors who will not know the level of the new ingredient in the supplement and argued that these vendors should not be barred from the sale of these ingredients.

FDA does not agree that it would be appropriate to remove the requirement that the notification include the level of the new dietary ingredient in the dietary supplement. First, § 190.6(b)(3)(i) responds to section 413(a)(2) of the act that states that the manufacturer or the distributor is to provide the information on a dietary supplement that contains a new dietary ingredient. Both of these parties would have access to information on the level of the new dietary ingredient. If a vendor wants to stand in the position of a manufacturer or distributor, it needs to be able to provide the information that they can provide.

Second, section 413(a) of the act also states that a dietary supplement that contains a new dietary ingredient is adulterated unless there is a history of use or other evidence of safety establishing that the dietary ingredient, when used under the conditions recommended or suggested in the labeling of the dietary supplement, will reasonably be expected to be safe, and that the notification must include the information on which the manufacturer or distributor has determined that the dietary supplement containing the dietary ingredient will meet this standard. It is not possible to have a reasonable expectation of safety without knowledge of the level of the new dietary ingredient in the supplement. The dietary ingredient may be safe under certain conditions of use, but it may be unsafe under other conditions of use. For example, the essential trace mineral selenium is safe when consumed in amounts necessary to meet a person's nutrient requirements, but it is toxic when consumed at high levels. Some dietary ingredients contain constituents that have potent pharmacologic actions that could cause the dietary ingredient to present a significant or unreasonable risk of injury or illness under the labeled conditions of use. The bark of *Pausinystalia yohimbe* (K. Schumann) (commonly called yohimbe) contains the indolalkylamine alkaloid yohimbine, which is a potent alpha-2-adrenergic antagonist that may be toxic when ingested in high doses.

Thus, if the notification does not contain the level of the dietary ingredient in the product, the notification would not contain a piece of information that is necessary if the manufacturer or distributor is to conclude that the dietary supplement will reasonably be expected to be safe under the conditions of use recommended or suggested in its labeling. Without this information, the dietary supplement would be adulterated under section 402(f)(1)(B) of the act (21 U.S.C. 342(f)(1)(B)). Therefore, FDA is not persuaded to remove or revise proposed § 190.6(b)(3)(i). This provision is necessary to ensure that a manufacturer has considered information that directly bears on the safety of the new dietary ingredient of interest.

3. One comment stated that FDA's proposed rule on the notification for a new dietary ingredient is a procedural regulation when what is needed is a substantive regulation that provides adequate guidance to the manufacturer

as to the quality and quantity of the information necessary to meet the requirements of section 413(a)(2) of the act. The comment disagreed with FDA's assertion that the manufacturer is only required to provide the basis on which it has concluded that the dietary supplement will reasonably to expected to be safe and that the manufacturer or distributor is not required to do a complete search of all available sources of information on the new dietary ingredient. The comment maintained that under the proposed regulation, manufacturers could knowingly market products with documented deleterious effects as long as they provide FDA with articles citing only a product's benefits.

The comment requested that FDA examine how the DSHEA amended section 402 of the act as well as section 413 of the act. Section 402(f)(1)(B) of the act states that a ''food shall be deemed to be adulterated if it is a dietary supplement or contains a dietary ingredient that is a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury.'' The comment argued that without a minimal safety data requirement, FDA risks that its interpretation of the DSHEA could cause a manufacturer to challenge the validity of the DSHEA on the grounds that the statute is void for vagueness because it does not provide fair warning to the manufacturer of what is expected. The comment requested that FDA issue regulations that elaborate on omissions in the statute by Congress.

The comment further suggested that FDA should require that a new dietary ingredient, when used under the conditions recommended or suggested in the labeling of the dietary supplement, be generally recognized as safe (GRAS); that is, that FDA apply to a new dietary ingredient the standard that there is general recognition that a dietary supplement containing the new dietary ingredient ''will reasonably be expected to be safe.'' The comment further suggested that FDA should provide industry with examples of publications that are acceptable as evidence of safety and a list of sources to search for evidence of adverse effects associated with a new dietary ingredient. Further, the comment maintained that manufacturers should be required to provide FDA with a summary of studies and scientific data, including known adverse effects. The comment stated that, in the absence of an appropriate scientific standard of evidence, manufacturers would be free to submit articles from questionable publications or unpublished materials to establish the safety of the new dietary ingredient. The comment argued that reliance on a GRAS standard would not be contrary to the statute or to congressional intent because it would still permit the marketing of dietary supplements without prior approval.

FDA disagrees with the comment that a substantive, rather than a procedural, regulation is necessary to respond to section 413(a)(2) of the act. The comment appears to be opposed to proposed § 190.6(b)(4), which sets out the substantive information that the notification must include. Significantly, § 190.6(b)(4) simply tracks the language of section 413(a)(2) of the act. It is appropriate that the regulation do so because, contrary to what the comment asserts, the manufacturer or distributor is not required to do a complete literature search. It is required only to provide ''the basis on which [it] has concluded that a dietary supplement containing such dietary ingredient will reasonably be expected to be safe'' (section 413(a)(2) of the act). That is all that the regulation requires.

FDA agrees with the comment that sections 402(f)(1)(B) and 413 of the act are related in that they both relate to new dietary ingredients. FDA also acknowledges that Congress has provided in section 413(a) of the act that a failure to provide the information under section 413(a) of the act would render the dietary supplement adulterated under section 402(f) of the act. The agency, however, in deciding what information needs to be provided, is bound by the standard in the act. It is not free to rewrite the law, as the comment appears to suggest.

The fact that Congress did not create a minimal safety data requirement in section 413(a)(2) of the act does not render the DSHEA void for vagueness. The manufacturer's or distributor's obligation under section 413(a)(2) of the act is clear. It must make a showing as to why it considers that consumption of a new dietary ingredient will be safe.

FDA also does not agree that the GRAS concept has relevance here. The concept of GRAS was adopted by Congress in 1958, as a limitation on the scope of the ''food additive'' definition (section 201(s) of the act). Congress excluded from the definition of ''food additive'' substances that are generally recognized, among experts qualified by scientific training and experience to evaluate their safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through experience based on common use in food) to be safe under the conditions of their intended use. However, dietary ingredients, which are used in dietary supplements, are not food additives. Congress excluded them from the definition of a ''food additive'' in the DSHEA (section 201(s)(6) of the act, which was added by section 3(b) of the DSHEA). Thus, the concept of GRAS is not relevant to how dietary ingredients are regulated.

Furthermore, there is a fundamental difference between who is to make at least the initial judgment as to the safety of an ingredient under section 413(a)(2) of the act and whose judgment is relevant to a determination that an ingredient is GRAS. Whether an ingredient is GRAS is based on the judgment of ''experts qualified by scientific training and experience to evaluate'' the ingredient's safety. In contrast, the requirement in section 413(a)(2) of the act that a notification be made for a new dietary ingredient provides that the manufacturer or distributor is to determine whether a dietary supplement containing such dietary ingredient will reasonably be expected to be safe. While this determination is subject to review by FDA, section 413(a) of the act does not specify that the manufacturer or distributor must rely on any specified third party in making its judgment. For these reasons, FDA is not requiring in § 190.6(b)(4) that the notification for a new dietary ingredient include information establishing that the new dietary ingredient is GRAS or the subject of any other type of general recognition.

Furthermore, FDA is not persuaded that it is necessary for the agency to provide examples of scientific publications that are adequate to provide the information that can be the basis on which the manufacturer or distributor has concluded that a dietary supplement containing the new dietary ingredient will reasonably be expected to be safe. The agency also is not persuaded that the act requires that a manufacturer or distributor provide to FDA information on all known adverse effects attributable to the new dietary ingredient that is the subject of the submission. Section 413(a)(2) of the act requires only that the notification provide information ''which is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such dietary ingredient will reasonably be expected to be safe when used under the conditions recommended or suggested in the labeling.'' Thus, the statute does not specify or limit what evidence a manufacturer or distributor may rely on in determining whether the use of the

ingredient will reasonably be expected to be safe. Nonetheless, FDA expects that, in making a determination that a new dietary ingredient is reasonably expected to be safe and does not present a significant or unreasonable risk of illness or injury, a manufacturer or distributor will consider the evidence of safety that is available in the scientific literature and from examination of reports of adverse effects associated with the use of a new dietary ingredient.

FDA does not find that the statute requires that the agency determine the relative merit of different types of evidence of safety, and therefore, the agency is not modifying § 190.6 to specify specific safety requirements for new dietary ingredients or to establish standards that the evidence of safety must meet.

4. One comment opposed the proposed requirement in § 190.6(b)(4) that the premarket notification for a ''new dietary ingredient'' contain reprints or photostatic copies, including, if necessary, English translations of all references to published information offered in support of the notification. The comment stated that with FDA's diminished resources the handling, cataloging, and storage of such copies could place a substantial burden on the agency and that this requirement for submission of copies of cited articles would be expensive and cumbersome for the manufacturer. The comment suggested that the requirement for submission of copies of references should not become a part of the final rule on new dietary ingredient notifications because of the availability of scientific data through electronic data bases.

FDA is not persuaded to delete proposed § 190.6(b)(4). FDA finds that it would take significantly more agency resources to find and obtain copies of references than would be expended to managing them as a part of each notification. Furthermore, FDA has found in reviewing the notifications that have been received since the passage of the DSHEA that many of the references cited in the notifications are not readily available in the United States or are not easily obtained electronically. In some cases, English translations are not available unless provided by the party making the notification. On the other hand, the manufacturer or distributor, who has reviewed the published information in concluding that there is a reasonable expectation of safety, will have ready access to the articles and thus would be in a position to supply them to FDA.

Thus, FDA is not persuaded that the requirement that the new ingredient notification include copies of all references used to support the notification will impose an excessive or unnecessary burden on FDA or on manufacturers or distributors who make a notification. Consequently, it is not revising § 190.6(b)(4).

5. Several comments opposed the proposed § 190.6(b)(5) requirement that the premarket notification of the marketing of a new dietary ingredient include the signature of an authorized official of the manufacturer or distributor of the dietary supplement that contains the new dietary ingredient.

One comment asked that the regulation be changed to require the signature of the person who is directly responsible for assimilating and submitting the premarket notification. The comment stated that in its company, an ''authorized official'' usually means an officer of the company, but that the assimilation and submission of documents such as premarket notifications to FDA is the responsibility of someone who is not an officer of the company.

Another comment stated that it had no objection to the requirement in proposed § 190.6(b)(5) that the notification be signed by an authorized official of the manufacturer or distributor. The comment did state, however, that such a signature does not constitute a certification of the accuracy or completeness of the data set out in the notification. The comment argued that section 8 of the DSHEA is entirely silent with respect to the signature or certification of notices, and that the agency's proposal creates an administrative amendment to DSHEA and is, therefore, inappropriate.

In the preamble to the September 1996 proposal, FDA stated that it was ''including this provision to ensure that the individual that is responsible for the accuracy, completeness, and understandability of the notification is identified'' (61 FR 50774 at 50775). Section 8 of the DSHEA does not designate a specific employee or representative of a manufacturer or distributor who is to submit the notice on behalf of a manufacturer or distributor. FDA did not intend by its use of the word ''authorized'' to designate a particular person that the firm must assign the responsibility of preparing the notification required under section 413(a)(2) of the act. Instead, the agency only intended that § 190.6(b)(5) provide that the person who signs the notification be familiar with the information contained in it and be available to answer questions or provide additional information to FDA if questions about a notification arise. Therefore, FDA is modifying § 190.6(b)(5) by replacing the term ''authorized official'' with the word ''person.'' This change will make clear that a manufacturer or distributor may assign responsibility for the notification to a person without concern about that person's official capacity within the management structure of the firm.

The September 1996 proposal did not represent that the signature of the individual that is responsible for the accuracy, completeness, and understandability of the notification constitutes a ''certification.'' However, the person signing the notice, and the company on whose behalf he or she signs it, should recognize that there are significant consequences to their action, including potential liability under 18 U.S.C. 1001. The intent of section 413(a)(2) of the act is for the firm to provide to FDA the information that is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such dietary ingredient will reasonably be expected to be safe. A firm must have such information, or the dietary supplement may well be adulterated under section 402(f)(1)(B) of the act. The notification is intended to be the mechanism by which that information is made available to FDA, so that the agency is aware of the basis that a manufacturer or distributor has for concluding that there is reasonable assurance that a new dietary ingredient is safe. Consequently, the information in the notification must be a fair and accurate representation of the information that a firm used in developing its conclusion that a new dietary ingredient is safe. A notification that intentionally omitted information that would indicate that a new dietary ingredient presents a significant or unreasonable risk of illness or injury or that contained false or misleading information would be a knowing and willful submission of false information to the Federal Government and could subject the parties involved to criminal sanctions under 18 U.S.C. 1001.

However, the person who signs the notification need not certify the information in the notification. The signature is intended to identify the person to whom FDA may address questions to concerning the notification. However, such persons should be cognizant of their responsibility in providing this notification and of the consequences of submitting of false or misleading information to the Federal Government.

IV. Administrative Procedures

6. One comment requested that proposed § 190.6(c) be revised to state that FDA will send an acknowledgment of the receipt of the premarket notification of the marketing of a new dietary ingredient noting the filing date, so that manufacturers will know when the 75-day notice period expires.

FDA is persuaded to make this revision. However, the agency cautions that the acknowledgment of the receipt of the premarket notification of the marketing of a new dietary ingredient does not constitute a finding by FDA that the new dietary ingredient, or the dietary supplement that contains the new dietary ingredient, is safe, or that it is not adulterated under section 402 of the act. Therefore, FDA has required § 190.6(c) by adding the sentence: ''FDA will acknowledge the receipt of the notification made pursuant to section 412(a) of the act and will notify the submitter of the date of receipt of such a notification.''

7. One comment asked that proposed § 190.6(c) be revised by removing the last sentence which states: ''For 75 days after the filing date, the manufacturer or distributor of a dietary supplement that contains a new dietary ingredient shall not introduce or deliver for introduction, into interstate commerce the dietary supplement that contains the new dietary ingredient.'' The comment stated that this language is not found in the act, and that the language is unnecessarily restrictive. The comment argued that if the agency completes its review and decides there is no concern, the manufacturer should not be prohibited from marketing the dietary supplement when such a determination by FDA is made prior to the 75th day after the notification was filed.

FDA does not agree that this sentence should be removed from the regulation. While the comment is correct that the language in the regulation is not stated in the law, section 413(a)(2) of the act states, as stated in the previous paragraph, that at least 75 days before introducing or delivering for introduction, a new dietary ingredient into interstate commerce, the manufacturer or distributor is to provide information that the dietary ingredient will reasonably be expected to be safe. The comment is based on a misunderstanding of the notification process. Because there is no requirement that the notification provide a comprehensive safety review of the new dietary ingredient, it is not likely to provide the agency with a basis to find that there is no concern. Rather, the process is more likely to identify those new dietary ingredients that do present a concern. Thus, it is the people who have provided a notice that raises concerns, rather than one that does not, who are likely to hear from the agency. Given this fact, and to ensure that the system runs smoothly, FDA is codifying its expectation based on the act that manufacturers and distributors that submit a notification to FDA will not market their product for 75 days from the date of submission of the notice. Consequently, FDA has not modified proposed § 190.6(c) as requested by this comment.

8. One comment asked that proposed § 190.6(d) be changed to state that:

> * * * if additional information is provided in support of the new ingredient notification, the agency will determine whether the additional information is a substantive amendment to the submission. If the agency determines that the new submission is a substantive amendment, FDA will assign a new filing date. FDA will acknowledge receipt of the additional information and, when applicable, notify the manufacturer of the new filing date, which is the date of receipt by FDA of the information that constitutes the substantive amendment.

The comment argued that proposed § 190.6(d) would require that any additional information, regardless of how significant (for example, a single response to an inquiry from the agency about a submission), would reset the 75-day period. Furthermore, the comment stated that its suggested language would provide flexibility for submitting additional information without unnecessarily prolonging the 75-day period.

FDA agrees with the substance of this comment that the agency should be flexible in its handling of the submission of additional materials. Therefore, FDA has revised § 190.6(d) to reflect that if it receives additional information, the agency will review all submissions pertaining to the notification in question, including responses made to inquires from the agency, to determine whether they are significant and whether they require that the 75-day period be reset.

V. Environmental Impact

The agency had determined under 21 CFR 25.24(a)(8) 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

A. Benefit-Cost Analysis

FDA has examined the economic implications of this final rule as required by Executive Order 12866. 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, safety, distributive, and equity effects). Executive Order 12866 classifies a rule as significant if it meets any one of a number of specified conditions, including: Having an annual effect on the economy of $100 million, adversely affecting some sector of the economy in a material way, adversely affecting jobs or competition, or raising novel legal or policy issues.

In the economic analysis of the proposed rule, FDA estimated the number of new ingredients to be 0 to 12 per year and the cost per notification to be $410, for an annual cost range of $0 to $4,920 per year. In the most recent year, the industry introduced six new ingredients for an estimated cost of $2,460. FDA received no comments on these estimates and consequently concludes that the actual costs of this rule will not be significant.

FDA finds that this final rule does not constitute a significant rule as defined by Executive Order 12866. Furthermore, it has been determined that this rule is not a major rule for the purpose of Congressional Review (Public Law 104–121).

B. Small Business Analysis

FDA has examined the economic implications of this final rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–612). If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would lessen the economic effect of the rule on small entities.

FDA received no comments on the regulatory flexibility analysis of the proposed rule. As the agency stated in the analysis of the proposed rule, the dietary supplement industry does not have its own standard industrial classification code. The industry's products come closest to the industry groups Food Preparations (not elsewhere classified) (Standard Industrial Classification code 2099) and Medicinal Chemicals and Botanical Products (Standard Industrial Classification code 2833). The Small Business Administrations' (SBA) size standards for ''small'' are 500 or fewer employees for food preparations and 750 or fewer employees for medicinal and botanical products. The use of this size standard will cause the majority of

firms in the dietary supplement industry to be classified as small businesses.

Without further information on the identity of the businesses introducing new ingredients, FDA concludes that the total number of businesses affected by the proposed rule will be no more than the number of new ingredients (estimated to be 0 to 12 per year). Before the event, FDA cannot determine the sizes of firms that introduce new dietary ingredients. Small businesses could introduce all new ingredients or none. The annual number of small businesses potentially affected by the proposed rule will therefore be the same as the annual number of new ingredients, 0 to 12.

Whether the cost of notification, approximately $410 per submission, will be a substantial burden depends partly on the revenues of the smallest businesses in the dietary supplement industry. For the smallest businesses in the industry, the cost of notification considered alone could be a significant burden. This cost, however, cannot be considered in isolation from the total cost of introducing a new dietary ingredient. A dietary supplement firm introducing a new ingredient must first determine that the ingredient can reasonably be expected to be safe. Technical, legal, and marketing costs of introducing a new dietary ingredient and ensuring its safety will be much larger than the cost of providing the information required under this rule. The costs of notification are therefore not likely to be a substantial part of the total cost of introducing a new dietary ingredient. Small businesses capable of bearing the cost of introducing new ingredients, then, would be highly unlikely to find the additional cost imposed by the 75-day premarket notification procedure to be an economically significant burden.

FDA finds that this final rule will not have a significant economic impact on a substantial number of small entities. Accordingly, under the Regulatory Flexibility Act (5 U.S.C. 605(b)), the Secretary certifies that this final rule will not have a significant impact on a substantial number of small entities.

VII. Paperwork Reduction Act of 1995

This final rule contains information collection requirements 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 following title, description, and respondent description of the information collection provisions are shown with an estimate of the annual reporting and recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

Title: Dietary supplements; dietary ingredients; premarket notification.

Description: FDA is requiring, by regulation, the submission to the agency of information that is the basis on which a manufacturer or distributor of a new dietary ingredient or a dietary supplement containing a new dietary ingredient has concluded that the dietary supplement containing such dietary ingredient will reasonably be expected to be safe. This information must be submitted to the agency at least 75 days prior to the first commercial distribution of a dietary supplement containing a new dietary ingredient. FDA will review the submitted information to determine whether the submission meets the requirements of section 413 of the act. The agency is establishing § 190.6 as the procedural regulation for this program. This regulation provides details of the administrative procedures associated with the submission and identifies the information that must be included in the submission in order to meet the requirements of section 413 of the act and to show the basis on which a manufacturer or distributor of a new dietary ingredient or a dietary supplement containing a new dietary ingredient has concluded that the dietary supplement containing such dietary ingredient will reasonably be expected to be safe.

Description of Respondents: Businesses or other for-profit organizations.

ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
190.6	6	1	6	20	120
Total					120

There are no capital or operating and maintenance costs associated with this collection of information.

Individuals and organizations may submit comments on these burden estimates or on any other aspect of these information collection provisions, including suggestions for reducing the burden, and should direct them to the Office of Special Nutritionals (HFS–450), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204.

The information collection provisions in this final rule have been approved under OMB control number 0910–0330. This approval expires October 31, 1999. 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.

List of Subjects in 21 CFR Part 190

Food ingredients, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, title 21 CFR chapter I is amended by adding new part 190 to read as follows:

PART 190—DIETARY SUPPLEMENTS

Subpart A—[Reserved]

Subpart B—New Dietary Ingredient Notification

Sec.

190.6 Requirement for premarket notification.

Authority: Secs. 201(ff), 301, 402, 413, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(ff), 331, 342, 350b, 371).

Subpart A—[Reserved]

Subpart B—New Dietary Ingredient Notification

§ 190.6 Requirement for premarket notification.

(a) At least 75 days before introducing or delivering for introduction into interstate commerce a dietary supplement that contains a new dietary ingredient that has not been present in the food supply as an article used for food in a form in which the food has not been chemically altered, the manufacturer or distributor of that supplement, or of the new dietary ingredient, shall submit to the Office of Special Nutritionals (HFS–450), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204, information including any citation to published articles that is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such dietary ingredient will reasonably be expected to be safe. An original and two copies of this notification shall be submitted.

(b) The notification required by paragraph (a) of this section shall include:

(1) The name and complete address of the manufacturer or distributor of the dietary supplement that contains a new dietary ingredient, or of the new dietary ingredient;

(2) The name of the new dietary ingredient that is the subject of the premarket notification, including the Latin binomial name (including the author) of any herb or other botanical;

(3) A description of the dietary supplement or dietary supplements that contain the new dietary ingredient including:

(i) The level of the new dietary ingredient in the dietary supplement; and

(ii) The conditions of use recommended or suggested in the labeling of the dietary supplement, or if no conditions of use are recommended or suggested in the labeling of the dietary supplement, the ordinary conditions of use of the supplement;

(4) The history of use or other evidence of safety establishing that the dietary ingredient, when used under the conditions recommended or suggested in the labeling of the dietary supplement, will reasonably be expected to be safe, including any citation to published articles or other evidence that is the basis on which the distributor or manufacturer of the dietary supplement that contains the new dietary ingredient has concluded that the new dietary supplement will reasonably be expected to be safe. Any reference to published information offered in support of the notification shall be accompanied by reprints or photostatic copies of such references. If any part of the material submitted is in a foreign language, it shall be accompanied by an accurate and complete English translation; and

(5) The signature of the person designated by the manufacturer or distributor of the dietary supplement that contains a new dietary ingredient.

(c) FDA will acknowledge its receipt of a notification made under section 413 of the Federal Food, Drug, and Cosmetic Act (the act) and will notify the submitter of the date of receipt of such a notification. The date that the agency receives the notification submitted under paragraph (a) of this section is the filing date for the notification. For 75 days after the filing date, the manufacturer or distributor of a dietary supplement that contains a new dietary ingredient shall not introduce, or deliver for introduction, into interstate commerce the dietary supplement that contains the new dietary ingredient.

(d) If the manufacturer or distributor of a dietary supplement that contains a new dietary ingredient, or of the new dietary ingredient, provides additional information in support of the new dietary ingredient notification, the agency will review all submissions pertaining to that notification, including responses made to inquiries from the agency, to determine whether they are substantive and whether they require that the 75-day period be reset. If the agency determines that the new submission is a substantive amendment, FDA will assign a new filing date. FDA will acknowledge receipt of the additional information and, when applicable, notify the manufacturer of the new filing date, which is the date of receipt by FDA of the information that constitutes the substantive amendment.

(e) FDA will not disclose the existence of, or the information contained in, the new dietary ingredient notification for 90 days after the filing date of the notification. After the 90th day, all information in the notification will be placed on public display, except for any information that is trade secret or otherwise confidential commercial information.

(f) Failure of the agency to respond to a notification does not constitute a finding by the agency that the new dietary ingredient or the dietary supplement that contains the new dietary ingredient is safe or is not adulterated under section 402 of the act.

Dated: August 22, 1997.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 97–24737 Filed 9–22–97; 8:45 am]

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Federal Register

Tuesday
September 23, 1997

Part IV

Department of Labor

Pension and Welfare Benefits Administration

29 CFR Part 2580

Health Care Continuation Coverage; Proposed Rule

DEPARTMENT OF LABOR

Pension and Welfare Benefits Administration

29 CFR Part 2580

Health Care Continuation Coverage

AGENCY: Pension and Welfare Benefits Administration, Labor.

ACTION: Request for information.

SUMMARY: This document is a request for information to assist the Department of Labor (the Department) in assessing the need for a regulation clarifying certain statutory notice requirements set forth in section 606 of Title I of the Employee Retirement Income Security Act (ERISA) and in section 4980B of the Internal Revenue Code (the Code). These statutory notice requirements were enacted as part of the continuation coverage provisions included in the Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA). The continuation coverage provisions, commonly referred to as the COBRA provisions, generally require group health plans to provide participants and beneficiaries who under certain circumstances would otherwise lose coverage (qualified beneficiaries) with the opportunity to elect to continue coverage under the plan at group rates for a limited period of time.

The Department anticipates that information and views provided by plan sponsors, plan fiduciaries, service providers to plans, plan participants and beneficiaries, and other interested persons will aid it in assessing the need for issuing a regulation to explicate the notice requirements of the COBRA provisions and the appropriate scope and content of any such regulation. A regulation on the notice requirements of the COBRA provisions would affect participants and beneficiaries (including qualified beneficiaries) of certain group health plans, as well as the sponsors and fiduciaries of such plans.

DATES: Written comments should be received by the Department of Labor on or before November 24, 1997.

ADDRESSES: Comments (preferably, at least six copies) should be addressed to the Office of Regulations and Interpretations, Pension and Welfare Benefits Administration, Room N–5669, U.S. Department of Labor, 200 Constitution Ave., NW, Washington, DC 20210. Attn: COBRA RFI. All comments received will be available for public inspection at the Public Disclosure Room, Pension and Welfare Benefits Administration, U.S. Department of Labor, Room N–5507, 200 Constitution Ave., NW, Washington, DC 20210.

FOR FURTHER INFORMATION CONTACT: David Lurie, Office of Regulations and Interpretations, Pension and Welfare Benefits Administration, (202) 219–7461. This is not a toll-free number.

SUPPLEMENTARY INFORMATION:

A. Background

1. The COBRA Provisions

The COBRA provisions, sections 601 to 608 of Title I of ERISA, and the related portions of section 4980B of the Code,[1] establish the requirement that any ''group health plan'' [2] maintained by an employer that employs 20 or more employees must offer ''qualified beneficiaries'' [3] the opportunity to elect ''continuation coverage'' under the plan following certain events (qualifying events) that would otherwise result in the loss of coverage.[4]

Under section 602(2)(A), the nature of the qualifying event determines the length of continuation coverage that an employer must make available to a qualified beneficiary. If the qualifying event is either a termination or a reduction in the hours of the covered employee's employment, the period of continuation coverage is up to 18 months from the date of the qualifying event.[5] This period is extended for an additional 11 months, to make a total period of 29 months of continuation coverage, for all qualified beneficiaries with respect to a covered employee, if any of such qualified beneficiaries has been determined, pursuant to Title II or Title XVI of the Social Security Act, to have been disabled at any time within the first 60 days of continuation coverage.[6] Furthermore, in cases involving a termination or reduction of hours of employment, the occurrence of another qualifying event during the initial 18 months of continuation coverage will extend the continuation coverage period to up to 36 months from the date of the original qualifying event. In all other cases, the period of continuation coverage is generally up to 36 months from the date of the qualifying event. The occurrence of certain events subsequent to election of continuation coverage can cause the period of continuation coverage to end prior to the end of the otherwise applicable continuation coverage period.[7]

The COBRA provisions specify the nature of the continuation coverage that must be offered, the premiums that a qualified beneficiary may be required to pay as a predicate for such continuation coverage, and the manner in which plan administrators must provide qualified

[1] All references herein to ERISA sections 601–608 should be read to refer also to corresponding provisions in Code section 4980B.

[2] The term *group health plan* is defined in section 607(1) to mean an employee welfare benefit plan providing medical care (as defined in section 213(d) of the Code) to participants or beneficiaries directly or through insurance, reimbursement, or otherwise. Plans that provide substantially only long-term care services (as defined in section 7702B(c) of the Code, however, are not included. Further, although governmental plans are excepted from coverage under Title I of ERISA, *see* ERISA section 4(b)(1), COBRA amended the Public Health Service Act, 42 U.S.C. § 300bb–1 *et seq.,* to impose requirements for the provision of health care continuation coverage similar to those contained in Part 6 of Title I on certain State and local employers.

[3] Section 607(3) defines *qualified beneficiary* generally as any person, other than a covered employee, who, on the day before the qualifying event for that employee, was a beneficiary under the plan as the spouse or dependent child of the covered employee. In the case of a qualifying event that is the termination or reduction of hours of the covered employee, the term also includes the covered employee. In the case of a qualifying event that is the bankruptcy of the plan sponsor, the term *qualified beneficiary* includes the covered employee if he or she had retired on or before the date of substantial elimination of coverage, and any individual who, on the day before the qualifying event, was a beneficiary under the plan as the surviving spouse of the covered employee. The Health Insurance Portability and Accountability Act of 1996 (HIPAA) expanded the definition of qualified beneficiary contained in section 607(3) to include children who are born to or placed for adoption with the covered employee during the duration of continuation coverage.

[4] Section 603 defines a *qualifying event* as any of the following: 1) the death of the covered employee; 2) the termination (other than by reason of gross misconduct) or reduction in hours of the covered employee's employment; 3) the divorce or legal separation of the covered employee from the employee's spouse; 4) the covered employee's becoming entitled to benefits under Medicare; 5) a dependent child's ceasing to be a dependent under the terms of the plan; or 6) the bankruptcy of the employer from which the covered employee retired. Section 607 defines other relevant terms, such as ''covered employee'' and ''group health plan,'' for the purposes of the COBRA provisions.

[5] A group health plan may, pursuant to section 607(5), provide instead that the period of continuation coverage (and the period during which the employer must notify the plan administrator of a qualifying event) will begin on the date the qualified beneficiary loses coverage, rather than the date of the qualifying event.

[6] Prior to enactment of HIPAA, section 602(2) provided that a qualified beneficiary would be entitled to the 11-month disability extension only if he or she was disabled at the time that the covered employee suffered the termination or reduction in hours of employment. HIPAA also amended section 602(2) to clarify that the 11-month disability extension applies to the non-disabled family members of a disabled qualified beneficiary who meets the requirements for the extension, provided those family members are also entitled to continuation coverage.

[7] For example, a qualified beneficiary's right to continuation coverage will cease if an employer ceases to provide group health coverage to its employees, if the qualified beneficiary fails to pay required premiums in a timely fashion, or if the qualified beneficiary becomes covered under another group health plan that does not contain any invalidating pre-existing condition exclusions or limitations. *See* § 602(2) (B), (C), (D).

beneficiaries with the opportunity to elect continuation coverage and to pay any required premiums. *See* sections 602, 604, 605.

Section 606 establishes a series of related notice requirements that ultimately trigger, under section 605, the beginning of the period of time during which the qualified beneficiary may elect continuation coverage (the election period). These notice requirements are described in detail in Section 2, below.

Section 608 grants the Secretary of Labor generally the authority to issue regulations to carry out the provisions of Part 6 of Title I of ERISA. In order to avoid duplicate and perhaps inconsistent regulations, the Conference Report accompanying COBRA [8] provides that the Secretary of Labor is authorized to promulgate regulations implementing the disclosure and reporting requirements of COBRA, while the Secretary of the Treasury is authorized to issue regulations defining the required continuation coverage.[9] The Conference Report further stated that pending the promulgation of regulations, employers would be required to operate ''in good faith compliance with a reasonable interpretation of the substantive rules and notice requirements' H. Rep. 99–453 at 562–63.

2. COBRA Notices

Section 606 of ERISA provides for a series of related notices, beginning with the requirement for a general notice of the rights provided under COBRA and culminating with an individualized notice to a qualified beneficiary entitled to elect continuation coverage.

(a) *Initial Notice.* Section 606(a)(1) requires a group health plan to provide to each covered employee and spouse of the employee (if any) at the time of commencement of coverage under the plan [10] a written notice describing the rights provided under COBRA.[11]

(b) *Notice of Qualifying Event.* Section 606 (a)(2) and (a)(3) require that the plan administrator of a group health plan be notified that a qualifying event has occurred. The nature of the qualifying event determines whether this notice obligation falls on the employer of a covered employee or on the covered employee or qualified beneficiary. If the qualifying event is the death of the covered employee, the termination or reduction of hours of the covered employee's employment,[12] the covered employee's becoming entitled to Medicare, or a bankruptcy proceeding of the employer, section 606(a)(2) requires the employer of the covered employee to provide notice of the qualifying event to the plan administrator. The employer must provide this notice within 30 days of the date the event occurs.[13] If the qualifying event is the divorce or legal separation of the covered employee or a dependent child's ceasing to be a dependent under the terms of the plan, section 606(a)(3) requires the covered employee or qualified beneficiary to provide the notice of qualifying event to the plan administrator.[14] The covered employee or qualified beneficiary must provide this notice within 60 days of the date the qualifying event occurs.[15]

(c) *Notice of Right to Elect Continuation Coverage.* Section 606(a)(4) requires a plan administrator to notify qualified beneficiaries of their right to elect continuation coverage.[16] This notice must be provided within 14 days of the date on which the administrator receives the notice that a qualifying event has occurred.[17] Pursuant to section 605(1), a qualified beneficiary must be provided a period of at least 60 days, beginning on the later of the date of the loss of coverage due to the qualifying event or the date the notice of the right to elect continuation coverage was sent, within which to elect continuation coverage.

(d) *Social Security Disability Notice.* Section 602 provides that, if a qualified beneficiary becomes disabled, as determined under Title II or XVI of the Social Security Act, at any time during the first 60 days of continuation coverage, he or she is entitled to a total of up to 29 months of continuation coverage, rather than only 18 months of continuation coverage. Section 606(a)(3) provides that, in order to obtain the 11-month extension, such a qualified beneficiary must notify the plan administrator of the determination of disability within 60 days after the date of such determination. Section 602 also requires that this notice be provided before the end of the original 18-month period of continuation coverage. The qualified beneficiary must also notify the plan administrator of any final determination that the qualified beneficiary is no longer disabled. This notice must be provided within 30 days of the date of such determination.

[8] H. Rep. No. 99–453, 99th Cong., 1st Sess. (December 18, 1995).

[9] The Conference Report indicates further that the Secretary of Health and Human Services, who is to issue regulations implementing the continuation coverage requirements for State and local governments, must conform the actual requirements of those regulations to the regulations issued by the Secretaries of Labor and the Treasury. *Id.* at 562–63. Pursuant to its authority, the Treasury Department has proposed certain regulations relating to continuation coverage. *See* Prop. Treas. Reg. § 1.162–26 (52 Fed. Reg. 22716, June 15, 1987).

[10] Advisory Opinion 94–17 (April 9, 1994) states that a group health plan is required to provide the initial notice required by section 606(a)(1) only to individuals who may at some time become entitled to elect continuation coverage under the plan, *i.e.*, someone who is or becomes covered under the plan. Accordingly, a group health plan is required to provide the initial notice to a covered employee's spouse only if, and at the time, the spouse commences coverage under the plan.

[11] On June 26, 1986, the Department issued ERISA Technical Release 86–2 (TR 86–2), ''Guidance on Group Health Continuation Coverage Notification Provisions,'' to provide for use by employers a model initial notice satisfying the requirements of section 606(a)(1). TR 86–2 emphasizes that use of the model notice is not the only method of achieving good faith compliance with a reasonable interpretation of the initial notice requirement. Additionally, TR 86–2 provides guidance with respect to certain procedural issues not addressed by the statute and the Department's view of good faith compliance in the absence of regulations. First, TR 86–2 states that sending a notice by first-class mail to the last known address of a covered employee and his or her spouse (if any) would evince a good faith effort at compliance. Second, TR 86–2 states that, if a spouse's last known address is the same as the covered employee's, a single mailing addressed to both would be considered to be in good faith compliance with the requirement set forth in 606(a)(1). Finally, TR 86–2 states that if an employer (or plan administrator) determines that a spouse no longer resides with the covered employee, good faith compliance could be achieved by a separate, first-class mailing to the last known address of the spouse.

[12] In the case of a multiemployer plan, the requirement that the employer notify the plan administrator of the termination or reduction in hours of the covered employee's employment is satisfied if the plan provides that the plan administrator will determine the occurrence of such a qualifying event.

[13] If the plan is a multiemployer plan, this notice must be given within the time period set by the plan.

[14] Prop. Treas. Reg. § 1.162–26, Q&A 33, states that this notice is to be provided to the ''employer or other plan administrator.''

[15] Prop. Treas. Reg. § 1.162–26, Q&A 33, states that if the notice is not sent to the employer or other plan administrator within 60 days after the later of the date of the qualifying event or the date that the qualified beneficiary would lose coverage, the group health plan does not have to offer the qualified beneficiary continuation coverage.

[16] Advisory Opinion 90–16 (May 3, 1990) states that the administrator of a group health plan cannot be relieved, by delegation, contract, or otherwise, of responsibility for providing the notice required by section 606(a)(4).

[17] In an information letter dated April 11, 1995, the Department stated that, in cases in which the employer of employees covered by a group health plan is also the plan administrator, both the 30-day notice period for the employer's notice of a qualifying event and the 14-day period for the administrator's notice of the right to elect continuation coverage would continue to apply. Accordingly, an employer who is also the plan administrator has a maximum period of 44 days from the date on which the qualifying event occurred to provide such notice.

3. Statutory Sanctions for Failure to Comply With COBRA Notice Requirements

The COBRA provisions impose sanctions for failure to comply with certain of the notice requirements of ERISA section 606.

a. ERISA Section 502

Section 502(a)(1)(A) of ERISA permits participants and beneficiaries to bring a civil action for the relief provided in section 502(c). Section 502(c)(1) provides that a plan administrator that fails to provide an initial notice or a notice of the right to elect continuation coverage may, in the court's discretion, be held liable to the participant or beneficiary for up to $100 per day from the date of the failure to provide notice and for any other relief that the court deems proper.

b. Code Section 4980B

Code section 4980B imposes excise taxes on the employer,[18] and, in certain circumstances, a person (other than an employee) who is responsible for administering or providing benefits under the plan and whose act or failure to act caused the failure, for the failure of a group health plan to meet any of the requirements of the COBRA provisions, including the relevant notice requirements. Pursuant to section 4980B(b)(1), the amount of the tax on any failure with respect to a qualified beneficiary is $100 per day [19] for each day of non-compliance. Code section 4980B(b) establishes a number of standards relating to minimum and maximum amounts of tax and specifies situations in which the tax will not be imposed.

4. Health Insurance Portability and Accountability Act (HIPAA)

HIPAA, which was signed into law on August 21, 1996, made certain substantive changes to the COBRA provisions. Those changes became effective January 1, 1997, regardless of the date of any qualifying event. Among other changes,[20] HIPAA amended section 602(2)(D)(i), with respect to circumstances under which a group health plan may cease providing continuation coverage to a qualified beneficiary because that qualified beneficiary has become covered under another group health plan, to reflect the changes made by HIPAA with respect to preexisting condition exclusions and limitations. Specifically, the COBRA provisions mandate that, if the new plan limits or excludes coverage for any preexisting condition of the qualified beneficiary, the plan providing continuation coverage cannot cease making continuation coverage available solely due to the coverage under the new plan. However, HIPAA provides that, if the new group health plan limits or excludes coverage for preexisting conditions, but those limits or exclusions would not apply to or would be satisfied by a qualified beneficiary under the HIPAA rules limiting pre-existing coverage exclusions, the plan providing continuation coverage may cease providing it. As a separate matter, HIPAA provides that the amount of an individual's ''creditable coverage'' (*see* footnote 21) must include any period of time during the relevant look-back period for which the individual was covered by a group health plan as a result of the individual's having elected continuation coverage.

5. Interim HIPAA Regulations

On April 8, 1997, the Department, in conjunction with the IRS and the Health Care Financing Administration of the Department of Health and Human Services, published in the **Federal Register** interim rules and a proposed rule implementing certain provisions of HIPAA (62 FR 16894). The Department's interim regulation relating to certificates of creditable coverage,[21] 29 CFR 2590.701–5 (62 FR 16946, 16947), provides that a qualified beneficiary is entitled to a certificate both at the time that coverage would be lost in the absence of continuation coverage and, if the qualified beneficiary has elected continuation coverage, at the time that the continuation coverage ceases. In addition, in cases in which the person is entitled to elect continuation coverage, the first certificate must be furnished no later than the time a notice of the right to elect continuation coverage is required to be provided. The second certificate, after continuation coverage ceases, must be provided within a reasonable time after continuation coverage ceases.

B. Circumstances Suggesting a Need for Regulatory Guidance

As discussed herein, the COBRA provisions of ERISA impose obligations on employers, plan administrators, plan participants, and qualified beneficiaries regarding disclosure of information through notices and the ensuing right to elect continuation coverage. Section 606 of ERISA provides a statutory framework within which these notices have significance as a means of providing affected parties with adequate notice at appropriate times of the rights granted under the statutory scheme. The delivery of notices also delineates limited time periods during which such rights must be exercised. Failure to comply with any of the notice requirements carries consequences for the party failing to provide notice, whether in the form of potential liability to provide coverage under the group health plan, sanctions imposed on employers or plan administrators, or a loss of coverage or an opportunity to elect continuation coverage on the part of qualified beneficiaries. The Department believes the following factors suggest a possible need for guidance concerning the COBRA notice provisions.

First, a significant amount of the relevant litigation that has occurred since enactment of the COBRA provisions has involved failures or alleged failures to comply with the notice requirements.[22] Second, many of the numerous requests that the Department has received from participants for assistance with the COBRA provisions have involved

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[18] In the case of a multiemployer plan, the tax is imposed on the plan.

[19] If there is more than one qualified beneficiary with respect to the same qualifying event, the maximum amount of tax that may be imposed on all failures on any day with respect to such qualified beneficiaries is $200.

[20] As described in footnotes 2 and 4, above, HIPAA clarified the definition of ''qualified beneficiary'' and the scope of the 11-month extension for disabled qualified beneficiaries. In addition, section 421(e) of HIPAA required group health plans subject to COBRA to notify individuals who have elected continuation coverage no later than November 15, 1996, of the changes to COBRA enacted by HIPAA. The Department issued Technical Release 96–1 on October 15, 1996, to inform employers and plan administrators of the changes in the COBRA rules made by HIPAA and of their obligation under HIPAA to notify qualified beneficiaries of such changes. The Department, as a matter of enforcement policy, deemed that supplying qualified beneficiaries with a written copy of the information contained in TR 96–1, or with a copy of TR 96–1, would constitute compliance with the notice requirement contained in section 421(e) of HIPAA if the information was sent to each qualified beneficiary by first class mail at the last known address of the qualified beneficiary by November 1, 1996.

[21] Pursuant to ERISA section 701, which was added by HIPAA, certificates of creditable coverage are required to be provided to participants and beneficiaries under group health plans under certain circumstances. These certificates serve to establish a participant's or beneficiary's period of ''creditable coverage,'' which will reduce or eliminate the period for which a group health plan can limit or exclude coverage of a preexisting condition of such participant or beneficiary.

[22] *See, e.g., Underwood* v. *Fluor Daniel, Inc.*, No. 95–3036 (4th Cir. 1997); *Stanton* v. *Larry Fowler Trucking, Inc.*, 52 F.3d 723 (8th Cir. 1995); *Bixler* v. *Central Pennsylvania Teamsters Health & Welfare Fund*, 12 F.3d 1292 (3rd Cir. 1993); *Meadows* v. *Cagle's, Inc.*, 954 F.2d 686 (11th Cir. 1992); *Kidder* v. *H&B Marine, Inc.*, 932 F.2d 347 (5th Cir. 1991); *Truesdale* v. *Pacific Holding Co./ Hay Adams Division*, 778 F. Supp. 77 (D.D.C. 1991).

allegations that employers' and plan administrators' notices have been not forthcoming or have been inadequate or confusing. Third, the COBRA provisions have been amended several times since publication of TR 86–2, reducing its value as a model for good faith compliance. Fourth, the obligations imposed on group health plans by HIPAA and other legislation with respect to coordination of continuation coverage with other statutory rights have further increased the importance of proper implementation of the COBRA notice provisions. For these reasons, the Department believes that regulatory guidance clarifying the notice requirements may aid employers and plan administrators in complying with the COBRA notice requirements and may also provide participants and beneficiaries with a better understanding of their rights and obligations.

C. Issues on Which Information is Requested

To assist the Department in assessing the need for guidance concerning the COBRA notice requirements, the Department invites interested parties to submit information relating to whether the Department should promulgate standards with regard to the content of the notices, the delivery and timing of these notices, and the consequences of either satisfying or failing to satisfy the notice requirements, and what such standards should be.

In order to assist interested parties in responding, this notice contains a list of specific questions the answers to which the Department believes would be helpful in considering guidance in this area. It is requested that the public, in responding to specific questions presented by this Notice, refer to the question number listed in this Notice. Reference to the appropriate question number will aid the Department in analyzing submissions.

The questions provided herein may not address all issues relevant to the development of the regulation. Accordingly, the Department further invites interested parties to submit additional comments on any other matters that they believe may be pertinent to the Department's consideration of guidance on this subject.

Specific areas with respect to which the Department is interested include:

I. Initial Notice to Covered Employees and Spouses

A. What information should be required to be included in the initial notice to covered employees and spouses?

B. Would ''model'' language with respect to any of the required information be helpful?

C. Should the Department provide an updated, revised ''model'' notice to replace that published in TR 86–2?

D. In TR 86–2, the Department indicated that furnishing one initial notice to participants and spouses residing at the same address would be adequate. Should the Department continue to view this method of furnishing information to a spouse residing with a participant as sufficient?

II. Notice of Qualifying Event

A. What information should be required to be included in the notice of qualifying event?

B. In what form should this notice be required to be provided?

C. Should the required information or the required form in which this information is conveyed vary depending on whether the notice is being given by the employer or by the covered employee (or qualified beneficiary)?

D. Should the Department provide rules under which notice of a qualifying event is deemed to have been given when an employer is also the plan administrator of a group health plan, or should some formality of communications be required under such circumstances?

E. Should the Department provide a ''model'' notice of qualifying event for use by employers and qualified beneficiaries?

F. What, if any, problems have arisen in connection with compliance with this notice requirement?

III. Notice of Right to Elect Continuation Coverage

Section 605 of the COBRA provisions provides that the election period during which a qualified beneficiary may elect continuation coverage must extend for at least sixty days, measured from the later of the date on which coverage otherwise would terminate or the date on which the notice of the right to elect continuation coverage is sent to the qualified beneficiary. The plan administrator's provision of the notice of right to elect continuation coverage, therefore, initiates the qualified beneficiary's right to elect and begins the running of the period of that right. The Department, accordingly, believes that the notice of right to elect continuation coverage must provide the qualified beneficiary with the information relevant to the exercise of the right. The following questions should be considered in light of this concern.

A. What information should be required to be included in the notice of the right to elect continuation coverage?

B. For example, should the notice be required to include:

1. A description of the continuation coverage that the qualified beneficiary is entitled to elect;

2. A description of the period over which such continuation coverage would be provided;

3. A description of the premiums that the qualified beneficiary would be required to pay, including the manner in which such premiums were calculated, the dates on which payment would be due, the address to which payment should be sent, and the consequences of nonpayment;

4. An explanation of the election process, including the period of time within which an election can be made, the consequences of electing or failing to elect continuation coverage, and the possibility of rescinding an election; or

5. An explanation of any rights that might arise to cause an extension of the maximum period of continuation coverage (such as with respect to any qualified beneficiary who is determined to be disabled within the first 60 days of continuation coverage) and the notice obligations imposed on any such qualified beneficiary?

C. Is there other information that should be required to be included in the notice of right to elect continuation coverage, such as the significance of electing continuation coverage for rights granted by HIPAA or the FMLA?

D. Should significant information relevant to the decision whether to elect continuation coverage be required to be provided in the notice, or should inclusion of the information in the summary plan description (SPD), with a reference in the notice to the relevant information in the SPD, be deemed adequate?

E. Should the Department provide a ''model'' notice of right to elect continuation coverage or ''model'' language on selected subjects for use in the notice?

IV. Social Security Disability Notice

A. What, if any, problems have covered employees, qualified beneficiaries, employers, or plan administrators encountered in obtaining the 11-month extension or in administering the provisions granting the right to the 11-month extension, particularly with respect to satisfying the notice requirements imposed by sections 602(2)(v) and 606(3)?

V. Other Issues

A. What are the practical and appropriate means (e.g., written notices, electronic media, and/or oral interviews) through which the COBRA notice requirements should be satisfied?

B. What kinds of procedures should or may plan administrators establish to permit qualified beneficiaries to establish their entitlement to extensions of the period of continuation coverage, such as through the occurrence of second qualifying events or as a result of disability determinations?

C. What administrative procedures have plan administrators adopted to provide additional notices or information not expressly mandated in the COBRA provisions, but necessary or useful in the orderly implementation of continuation coverage requirements, such as to explain changes in the coverage provided under the group health plan (including changes in the issuer or service provider), to make available open enrollment or election periods provided under the plan, to enforce due dates for continuation coverage premiums, or to implement the termination of continuation coverage and make available any conversion options provided under the plan?

All submitted comments will be made part of the record of the preceding referred to herein and will be available for public inspection.

Signed at Washington, DC, this 17th day of September, 1997.

Olena Berg,

Assistant Secretary for Pension and Welfare Benefits, U.S. Department of Labor.

[FR Doc. 97–25240 Filed 9–22–97; 8:45 am]

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Federal Register

Tuesday
September 23, 1997

Part V

Department of Defense
General Services Administration
National Aeronautics and Space Administration

48 CFR Parts 15, 31, and 52
Federal Acquisition Regulations; Pay-As-You-Go Pension Costs; Clause Flowdown-Commercial Items; and
Federal Acquisition Regulation; Taxes Associated With Divested Segments; Proposed Rules

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Parts 15, 31, and 52

[FAR Case 89–012]

RIN 9000–AC90

Federal Acquisition Regulation; Pay-As-You-Go Pension Costs

AGENCIES: Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Proposed rule.

SUMMARY: The Civilian Agency Acquisition Council and the Defense Acquisition Regulations Council are proposing to amend the Federal Acquisition Regulation (FAR) to provide consistency with the cost accounting standards for composition and measurement of pension cost and adjustment and allocation of pension cost. This regulatory action was not subject to Office of Management and Budget review under Executive Order 12866, dated September 30, 1993. This is not a major rule under 5 U.S.C. 804.

DATES: Comments should be submitted on or before November 24, 1997 to be considered in the formulation of a final rule.

ADDRESSES: Interested parties should submit written comments to: General Services Administration, FAR Secretariat (MVRS), 1800 F Street, NW, Room 4035, Washington, DC 20405.

E-mail comments submitted over Internet should be addressed to: farcase.89–012@gsa.gov.

Please cite FAR case 89–012 in all correspondence related to this case.

FOR FURTHER INFORMATION CONTACT: The FAR Secretariat, Room 4035, GS Building, Washington, DC 20405 (202) 501–4755 for information pertaining to status or publication schedules. For clarification of content, contact Mr. Jeremy Olson, Procurement Analyst, at (202) 501–3221. Please cite FAR case 89–012.

SUPPLEMENTARY INFORMATION:

A. Background

This rule proposes to amend FAR 31.001, Definitions; FAR 31.205–6, Compensation for personal services; and FAR 52.215–27, Termination of Defined Benefit Pension Plans, to provide consistency with 48 CFR 9904.412, Cost Accounting Standard for composition and measurement of pension cost (CAS 412), and 48 CFR 9904.413, Adjustment and allocation of pension cost (CAS 413). The interim rule, which was published in the **Federal Register** at 54 FR 13022, March 29, 1989 was necessary because the United States Court of Appeals had ruled that FAR 31.205–6(j)(5) was inconsistent with CAS 412, and that the controlling regulation was CAS 412.

Since the 1989 interim FAR rule was published, the Office of Federal Procurement Policy, Cost Accounting Standards Board, made substantial changes to CAS 412 and 413 relating to accounting for pension costs under negotiated Government contracts. These changes were published in the **Federal Register** as a proposed rule with request for comment at 58 FR 58999, November 5, 1993. Public comments were received and considered in the development of the final CAS rule published in the **Federal Register** at 60 FR 16534, March 30, 1995. The changes in the final CAS rule addressed pension cost recognition for qualified pension plans subject to the tax-deductibility limits of the Federal Tax Code, problems associated with pension plans that are not qualified plans under the Federal Tax Code, and problems associated with overfunded pension plans.

This proposed rule would: (1) Revise the definitions at FAR 31.001 to conform with the CAS Board's definitions; (2) delete references to ''unfunded pension plans'' since CAS 412 and CAS 413 no longer refer to unfunded pension plans; (3) add new language to FAR 31.205–6(j) to address transfer of assets to another account within the same fund, to address the allowability of costs for nonqualified pension plans using the pay-as-you-go cost method, and to address both CAS requirements and all other situations not covered by CAS; (4) add new language at FAR 31.205–6(j)(6), which was previously reserved, to refer to CAS 412 and CAS 413 for treatment of pension plans using the pay-as-you-go cost method; (5) provide other editorial changes to make FAR 31.001 and 31.205–6 consistent with the language of CAS 412 and CAS 413; and (6) revise the clause at FAR 52.215–27, Termination of Defined Benefit Pension Plans, to conform the clause with the proposed FAR Part 31 changes.

Eighteen comments were received in response to the interim FAR rule. All comments were considered in the development of this proposed rule.

B. Regulatory Flexibility Act

This proposed rule is not expected to have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.*, because most contracts awarded to small entities use simplified acquisition procedures or are awarded on a competitive, fixed-price basis, and do not require application of the cost principle contained in this rule. An Initial Regulatory Flexibility Analysis has, therefore, not been performed. Comments from small entities concerning the affected FAR subpart will be considered in accordance with 5 U.S.C. 610 of the Act. Such comments must be submitted separately and should cite 5 U.S.C. 601, *et seq.* (FAR case 89–012), in correspondence.

C. Paperwork Reduction Act

The Paperwork Reduction Act does not apply because the proposed changes to the FAR do not impose recordkeeping or information collection requirements, or collections of information from offerors, contractors, or members of the public which require the approval of the Office of Management and Budget under 44 U.S.C. 3501, *et seq.*

List of Subjects in 48 CFR Parts 15, 31 and 52

Government procurement.

Dated: September 17, 1997.

Edward C. Loeb,

Director, Federal Acquisition Policy Division.

Therefore, it is proposed that 48 CFR Parts 15, 31 and 52 be amended as set forth below:

1. The authority citation for 48 CFR Parts 15, 31 and 52 continues to read as follows:

Authority: 40 U.S.C. 486(c); 10 U.S.C. chapter 137; and 42 U.S.C. 2473(c).

PART 15—CONTRACTING BY NEGOTIATION

15.804–8 [Amended]

1a. Section 15.804–8 is amended in paragraph (e) by revising ''Termination of Defined Benefit Pension Plans'' to read ''Pension Adjustments and Asset Reversions''.

PART 31—CONTRACT COST PRINCIPLES AND PROCEDURES

2. Section 31.001 is amended by removing the definitions ''Actuarial liability'' and ''Unfunded pension plan''; by adding, in alphabetical order, the definitions ''Actuarial accrued liability'', ''Nonqualified pension plan'', and ''Qualified pension plan''; by

revising the definitions of ''Accrued benefit cost method'', ''Actuarial assumption'', ''Actuarial cost method'', ''Actuarial valuation'', ''Funded pension cost'', ''Normal cost'', ''Pension plan'', ''Projected benefit cost method'', and revising the definition heading ''Termination gain or loss'' to read ''Temination of employment gain or loss'' as follows:

31.001 Definitions.

Accrued benefit cost method means an actuarial cost method under which units of benefits are assigned to each cost accounting period and are valued as they accrue; *i.e.,* based on the services performed by each employee in the period involved. The measure of normal cost under this method for each cost accounting period is the present value of the units of benefit deemed to be credited to employees for service in that period. The measure of the actuarial accrued liability at a plan's inception date is the present value of the units of benefit credited to employees for service prior to that date. (This method is also known as the Unit Credit cost method without salary projection.

* * * * *

Actuarial accrued liability means pension cost attributable, under the actuarial cost method in use, to years prior to the current period considered by a particular actuarial valuation. As of such date, the actuarial accrued liability represents the excess of the present value of future benefits and administrative expenses over the present value of future normal costs for all plan participants and beneficiaries. The excess of the actuarial accrued liability over the actuarial value of the assets of a pension plan is the unfunded actuarial liability. The excess of the actuarial value of the assets of a pension plan over the actuarial accrued liability is an actuarial surplus and is treated as a negative unfunded actuarial liability.

Actuarial assumption means an estimate of future conditions affecting pension cost; *e.g.,* mortality rate, employee turnover, compensation levels, earnings on pension plan assets, and changes in values of pension plan assets.

Actuarial cost method means a technique which uses actuarial assumptions to measure the present value of future pension benefits and pension plan administrative expenses, and which assigns the cost of such benefits and expenses to cost accounting periods. The actuarial cost method includes the asset valuation method used to determine the actuarial value of the assets of a pension plan.

* * * * *

Actuarial valuation means the determination, as of a specified date, of the normal cost, actuarial accrued liability, actuarial value of the assets of a pension liability, actuarial value of the assets of a pension plan, and other relevant values for the pension plan.

* * * * *

Funded pension cost means the portion of pension cost for a current or prior cost accounting period that has been paid to a funding agency.

* * * * *

Nonqualified pension plan means any pension plan other than a qualified pension plan as defined in this part.

Normal cost means the annual cost attributable, under the actuarial cost method in use, to current and future years as of a particular valuation date excluding any payment in respect of an unfunded actuarial liability.

* * * * *

Pension plan means a deferred compensation plan established and maintained by one or more employers to provide systematically for the payment of benefits to plan participants after their retirements, provided that the benefits are paid for life or are payable for life at the option of the employees. Additional benefits such as permanent and total disability and death payments, and survivorship payments to beneficiaries of deceased employees may be an integral part of a pension plan.

* * * * *

Projected benefit cost method means either

(1) Any of the several actuarial cost methods which distribute the estimated total cost of all of the employees' prospective benefits over a period of years, usually their working careers, or

(2) A modification of the accrued benefit cost method that considers projected compensation levels.

* * * * *

Qualified pension plan means a pension plan comprising a definite written program communicated to and for the exclusive benefit of employees which meets the criteria deemed essential by the Internal Revenue Service as set forth in the Internal Revenue Code for preferential tax treatment regarding contributions, investments, and distributions. Any other plan is a nonqualified pension plan.

* * * * *

3. Section 31.205–6 is amended by revising paragraphs (j)1) through (j)(6) to read as follows:

31.205–6 Compensation for personal services.

* * * * *

(j) *Pension costs.* (1) A pension plan is a deferred compensation plan as defined in 31.001. Additional benefits such as permanent and total disability and death payments and survivorship payments to beneficiaries of deceased employees may be treated as pension costs, provided the benefits are an integral part of the pension plan and meet all the criteria pertaining to pension costs.

(2) Pension plans are normally segregated into two types of plans: defined-benefit or defined-contribution pension plans. The cost of all defined-benefit pension plans shall be measured, allocated, and accounted for in compliance with the provisions of 48 CFR 9904.412, Cost accounting standard for composition and measurement of pension cost, and 48 CFR 9904.413, Adjustment and allocation of pension cost. The costs of all defined-contribution pension plans shall be measured, allocated and accounted for in accordance with the provisions of 48 CFR 9904.412. Pension costs are allowable subject to the referenced standards and the cost limitations and exclusions set forth in paragraph (j)(2)(i) and in paragraphs (j)(3) through (8) of this subsection.

(i) Except for nonqualified pension plans using the pay-as-you-go cost method to be allowable in the current year, pension costs must be funded by the time set for filing of the Federal income tax return or any extension thereof. Pension costs assigned to the current year, but not funded by the tax return time, shall not be allowable in any subsequent year. For nonqualified pension plans using the pay-as-you-go cost method, to be allowable in the current year, pension costs must be allocable in accordance with 48 CFR 9904.412–50(d)(3).

(ii) Pension payments must be reasonable in amount and be paid pursuant to (A) an agreement entered into in good faith between the contractor and employees before the work or services are performed and (B) the terms and conditions of the established plan. The cost of changes in pension plans which are discriminatory to the Government or are not intended to be applied consistently for all employees under similar circumstances in the future are not allowable.

(iii) Except as provided for early retirement benefits in paragraph (j)(7) of this subsection, one-time-only pension supplements not available to all participants of the basic plan are not allowable as pension costs unless the

supplemental benefits represent a separate pension plan and the benefits are payable for life at the option of the employee.

(iv) Increases in payments to previously retired plan participants covering cost-of-living adjustments are allowable if paid in accordance with a policy or practice consistently followed.

(3) *Defined-benefit pension plans.* This paragraph covers pension plans in which the benefits to be paid or the basis for determining such benefits are established in advance and the contributions are intended to provide the stated benefits. The cost limitations and exclusions pertaining to defined-benefit plans are as follows:

(i)(A) Except for nonqualified pension plans, pension costs (see 48 CFR 9904.412–40(a)(1)) assigned to the current accounting period but not funded during it, shall not be allowable in subsequent years (except that a payment made to a fund by the time set for filing the Federal income tax return or any extension thereof is considered to have been made during such taxable year).

(B) For nonqualified pension plans, except those using the pay-as-you-go cost method, allowable costs are limited to the amount allocable in accordance with 48 CFR 9904.412–50(d)(2).

(C) For nonqualified pension plans using the pay-as-you-go cost method, allowable costs are limited to the amounts allocable in accordance with 48 CFR 9904.412–50(d)(3).

(ii) Any amount funded before the time it becomes assignable is not allowable and shall be accounted for as set forth at 48 CFR 9904.412–50(a)(4), and shall be allowable in the future period to which it is assigned, to the extent it is allocable, reasonable, and not otherwise unallowable.

(iii) Increased pension costs caused by delay in funding beyond 30 days after each quarter of the year to which they are assignable are unallowable. If a composite rate is used for allocating pension costs between the segments of a company and if, because of differences in the timing of the funding by the segments, an inequity exists, allowable pension costs for each segment will be limited to that particular segments calculation of pension costs as provided for in 48 CFR 9904.413–50(c). Determination of unallowable costs shall be made in accordance with the actuarial cost method used in calculating pension costs.

(iv) Allowability of the cost of indemnifying the Pension Benefit Guaranty Corporation (PBGC) under Section 4062 or 4064 of the Employee's Retirement Income Security Act of 1974 (ERISA) arising from terminating an employee deferred compensation plan will be considered on a case-by-case basis; provided that if insurance was required by the PBGC under ERISA Section 4023, it was so obtained and the indemnification payment is not recoverable under the insurance. Consideration under the foregoing circumstances will be primarily for the purpose of appraising the extent to which the indemnification payment is allocable to Government work. If a beneficial or other equitable relationship exists, the Government will participate, despite the requirements of 31.205–19 (a)(3) and (b), in the indemnification payment to the extent of its fair share.

(v) Increased pension costs resulting from the withdrawal of assets from a pension fund and transfer to another employee benefit plan fund, or transfer of assets to another account within the same fund, are unallowable except to the extent authorized by an advance agreement. The advance agreement shall:

(A) State the amount of the Government's equitable share in the gross amount withdrawn or transferred; and

(B) Provide that the Government receive a credit equal to the amount of the Government's equitable share of the gross withdrawal or transfer.

(4) *Pension adjustments and asset reversions.* (i) For segment closings, pension plan terminations, or curtailment of benefits, whether or not the contract or subcontract is subject to Cost Accounting Standards (CAS), the adjustment amounts shall be the amounts measured, assigned, and allocated in accordance with 48 CFR 9904.413–50(c)(12). Notwithstanding the language in 48 CFR 9904.413–50(c)(12)(vi), which limits the numerator of the adjustment to CAS-covered contracts, for the purposes of the calculations under this paragraph, all contracts and subcontracts that are subject to subpart 31.2 or for which cost or pricing data were submitted shall be treated as if they were subject to 48 CFR 9904.413 and shall be included in the numerator of the adjustment.

(ii) For all other situations when assets revert to the contractor, or such assets are constructively received by it for any reason, the contractor shall, at the Governments option, make a refund or give a credit to the Government for its equitable share of the gross amount withdrawn. The Governments equitable share shall reflect the Governments participation in pension costs through those contracts for which cost or pricing data were submitted or which are subject to subpart 31.2. Excise taxes on pension plan asset reversions or withdrawals are unallowable under this paragraph (j)(4)(ii) in accordance with 31.205–41(b)(6).

(5) *Defined-contribution pension plans.* This paragraph covers those pension plans in which the contributions are established in advance and the level of benefits is determined by the contributions made. It also covers profit sharing, savings plans, and other such plans provided the plans fall within the definition of a pension plan in paragraph (j)(1) of this subsection.

(i) Allowable pension cost is limited to the net contribution required to be made for a cost accounting period after taking into account dividends and other credits, where applicable. However, any portion of pension cost computed for a cost accounting period that exceeds the amount required to be funded pursuant to a waiver granted under the provisions of ERISA will be allowable in those future accounting periods in which the funding of such excess amounts occurs (see 48 CFR 9904.412–50(c)(5)).

(ii) Any amount funded before the time it becomes assignable is not allowable and shall be accounted for as set forth at 48 CFR 9904.412–50(a)(4), and shall be allowable in the future period to which it is assigned, to the extent it is allocable, reasonable, and not otherwise unallowable.

(iii) The provisions of paragraph (j)(3)(iv) of this subsection apply to defined-contribution plans.

(6) *Pension plans using the pay-as-you-go cost method.* The cost of pension plans using the pay-as-you-go cost method shall be measured, allocated, and accounted for in accordance with 48 CFR 9904.412 and 9904.413. Pension costs for a pension plan using the pay-as-you-go cost method shall be allowable to the extent they are allocable, reasonable, and not otherwise unallowable.

* * * * *

PART 52—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

4. Section 52.215–27 is revised to read as follows:

52.215–27 Pension Adjustments and Asset Reversions.

As prescribed in 15.804–8(e), insert the following clause:

Pension Adjustments and Asset Reversions (Date)

(a) The Contractor shall promptly notify the Contracting Officer in writing when it determines that it will terminate a defined-benefit pension plan or otherwise recapture such pension fund assets.

(b) For segment closings, pension plan terminations, or curtailment of benefits, whether or not this contract or the applicable subcontract is subject to Cost Accounting Standards (CAS), the adjustment amounts shall be the amounts measured, assigned, and allocated in accordance with 48 CFR 9904.413–50(c)(12). Notwithstanding the language in 48 CFR 9904.413–50(c)(12)(vi), which limits the numerator of the adjustment to CAS-covered contracts, for the purposes of the calculations under this paragraph, all contracts and subcontracts that are subject to Subpart 31.2 or for which cost or pricing data were submitted shall be treated as if they were subject to 48 CFR 9904.413 and shall be included in the numerator of the adjustment.

(c) For all other situations when assets revert to the Contractor, or such assets are constructively received by it for any reason, the Contractor shall, at the Government's option, make a refund or give a credit to the Government for its equitable share of the gross amount withdrawn. The Government's equitable share shall reflect the Government's participation in pension costs through those contracts for which cost or pricing data were submitted or which are subject to Subpart 31.2 of the Federal Acquisition Regulation (FAR).

(d) The Contractor shall include the substance of this clause in all subcontracts under this contract which meet the applicability requirements of FAR 15.804–8(e).

(End of clause)

[FR Doc. 97–25244 Filed 9–22–97; 8:45 am]

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DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Part 52

[FAR Case 96–023]

RIN 9000–AH69

Federal Acquisition Regulation; Clause Flowdown-Commercial Items

AGENCIES: Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Proposed rule.

SUMMARY: The Civilian Agency Acquisition Council and the Defense Acquisition Regulations Council are proposing to amend the Federal Acquisition Regulation (FAR) to clarify requirements for the inclusion of FAR provisions and clauses in subcontracts for commercial items and commercial components. This regulatory action was not subject to Office of Management and Budget review under Executive Order 12866, dated September 30, 1993. This is not a major rule under 5 U.S.C. 804.

DATES: Comments should be submitted on or before November 24, 1997 to be considered in the formulation of a final rule.

ADDRESSES: Interested parties should submit written comments to: General Services Administration, FAR Secretariat (MVRS), 1800 F Street, NW, Room 4035, Washington, DC 20405.

E-mail comments submitted over Internet should be addressed to: farcase.96–023@gsa.gov.

Please cite FAR case 96–023 in all correspondence related to this case.

FOR FURTHER INFORMATION CONTACT: The FAR Secretariat, Room 4035, GS Building, Washington, DC 20405 (202) 501–4755 for information pertaining to status or publication schedules. For clarification of content, contact Ms. Linda Klein, Procurement Analyst, at (202) 501–3775. Please cite FAR case 96–023.

SUPPLEMENTARY INFORMATION:

A. Background

This rule proposes amendments to the clause at FAR 52.244–6, Subcontracts for Commercial Items and Commercial Components, to clarify that contractors are required to include, in subcontracts at any tier for commercial items or commercial components, the FAR clauses and provisions listed in the clause at FAR 52.244–6 and such other clauses and provisions as may be required by addenda, to the extent they are applicable or necessary to establish the reasonableness of prices under FAR Part 15.

B. Regulatory Flexibility Act

This proposed rule is not expected to have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.*, because the rule only clarifies existing requirements regarding the inclusion of FAR provisions and clauses in subcontracts for commercial items and commercial components. An Initial Regulatory Flexibility Analysis has, therefore, not been performed. Comments from small entities concerning the affected FAR subpart will be considered in accordance with 5 U.S.C. 610 of the Act. Such comments must be submitted separately and should cite 5 U.S.C. 601, *et seq.* (FAR case 96–023), in correspondence.

C. Paperwork Reduction Act

The Paperwork Reduction Act does not apply because the proposed changes to the FAR do not impose recordkeeping or information collection requirements, or collections of information from offerors, contractors, or members of the public which require the approval of the Office of Management and Budget under 44 U.S.C. 3501, *et seq.*

List of Subjects in 48 CFR Part 52

Government procurement.

Dated: September 18, 1997.

Edward C. Loeb,

Director, Federal Acquisition Policy Division.

Therefore, it is proposed that 48 CFR Part 52 be amended as set forth below:

PART 52—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

1. The authority citation for 48 CFR Part 52 continues to read as follows:

Authority: 40 U.S.C. 486(c); 10 U.S.C. chapter 137; and 42 U.S.C. 2473(c).

2. Section 52.244–6 is amended by revising the clause date and paragraph (c) introductory text to read as follows:

52.244–6 Subcontracts for Commercial items and Commercial Components.

* * * * *

Subcontracts for Commercial Items and Commercial Components (Date)

* * * * *

(c) Notwithstanding any other clause of this contract, the Contractor is not required to include any provision or clause, other than those listed below to the extent they are applicable (and other clauses as may be required by addenda to this paragraph to establish the reasonableness of prices under FAR Part 15) in a subcontract at any tier for commercial items or commercial components:

* * * * *

[FR Doc. 97–25242 Filed 9–22–97; 8:45 am]

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DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Part 31

[FAR Case 97–010]

RIN 9000–AH71

Federal Acquisition Regulation; Taxes Associated With Divested Segments

AGENCIES: Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Proposed rule.

SUMMARY: The Civilian Agency Acquisition Council and the Defense Acquisition Regulations Council are proposing to amend the Federal Acquisition Regulation (FAR) to add increased taxes resulting from a contractors sale of a segment to the list of unallowable costs in the cost principle. This regulatory action was not subject to Office of Management and Budget review under Executive Order 12866, dated September 30, 1993. This is not a major rule under 5 U.S.C. 804.

DATES: Comments should be submitted on or before November 24, 1997 to be considered in the formulation of a final rule.

ADDRESSES: Interested parties should submit written comments to: General Services Administration, FAR Secretariat (MVRS), 1800 F Street, NW, Room 4035, Washington, DC 20405.

E-mail comments submitted over Internet should be addressed to: farcase.97–010@gsa.gov.

Please cite FAR case 97–010 in all correspondence related to this case.

FOR FURTHER INFORMATION CONTACT: The FAR Secretariat, Room 4035, GS Building, Washington, DC 20405 (202) 501–4755 for information pertaining to status or publication schedules. For clarification of content, contact Ms. Linda Nelson at (202) 501–1900. Please cite FAR case 97–010.

SUPPLEMENTARY INFORMATION:

A. Background

When a contractor discontinues operations through the sale or other transfer of ownership of a segment, the contractor may be assessed state and local taxes on the gain resulting from that sale or transfer. Since the Government does not share in the gain resulting from the segment sale or transfer, the Government should not share in any tax increases resulting from the segment sale or transfer. This proposed rule adds increased taxes resulting from a contractor's sale or other transfer of ownership of a segment to the list of unallowable costs at FAR 31.205–41(b).

B. Regulatory Flexibility Act

This proposed rule is not expected to have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.*, because most contracts awarded to small entities use simplified acquisition procedures or are awarded on a competitive, fixed-price basis, and do not require application of the cost principle contained in this rule. An Initial Regulatory Flexibility Analysis has, therefore, not been performed. Comments from small entities concerning the affected FAR part will be considered in accordance with 5 U.S.C. 610 of the Act. Such comments must be submitted separately and should cite 5 U.S.C. 601, *et seq.* (FAR case 97–010), in correspondence.

C. Paperwork Reduction Act

The Paperwork Reduction Act does not apply because the proposed changes to the FAR do not impose recordkeeping or information collection requirements, or collections of information from offerors, contractors, or members of the public which require the approval of the Office of Management and Budget under 44 U.S.C. 3501, *et seq.*

List of Subjects in 48 CFR Part 31

Government procurement.

Dated: September 17, 1997.

Edward C. Loeb,

Director, Federal Acquisition Policy Division.

Therefore, it is proposed that 48 CFR Part 31 be amended as set forth below:

PART 31—CONTRACT COST PRINCIPLES AND PROCEDURES

1. The authority citation for 48 CFR Part 31 continues to read as follows:

Authority: 40 U.S.C. 486(c); 10 U.S.C. chapter 137; and 42 U.S.C. 2473(c).

2. Section 31.205–41 is amended by adding paragraph (b)(8) to read as follows:

31.205–41 Taxes.

* * * * *

(b) * * *

(8) Net increase in taxes incurred by a seller or transferor resulting from a sale or other transfer of ownership of a segment (*e.g.*, taxes on the gain on disposition of a segment). For purposes of this subpart, ''net'' is defined as the difference between the actual taxes paid and the taxes that would have been paid had the sales or other transfer of ownership not occurred. When the amount of taxes that would have been paid had the sale or other transfer of ownership not occurred is less than zero, the amount that would have been paid shall be deemed to be zero.

* * * * *

[FR Doc. 97–25243 Filed 9–22–97; 8:45 am]

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The items in this list were editorially compiled as an aid to Federal Register users. Inclusion or exclusion from this list has no legal significance.

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- Foreign pesticide producing establishments; submission of registration applications and annual reports; change of address; published 9-23-97

Superfund program:
- National oil and hazardous substances contingency plans—
  - National priorities list update; published 9-23-97

MERIT SYSTEMS PROTECTION BOARD

Organization, functions, and authority delegations:
- Headquarters organization changes, etc.; published 9-23-97

SOCIAL SECURITY ADMINISTRATION

Social security benefits and supplemental security income:
- Federal old age, survivors and disability insurance and aged, blind, and disabled—
  - Disability claims; testing elimination of final step in administrative review process; published 9-23-97

TREASURY DEPARTMENT

Customs Service

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- Archaeological and ethnological material from—
  - Mali; published 9-23-97

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Commodity Credit Corporation

Loan and purchase programs:
- Price support levels—
  - Peanuts; comments due by 9-30-97; published 8-18-97

AGRICULTURE DEPARTMENT

Farm Service Agency

Federal claims collection; administrative offset; comments due by 9-30-97; published 8-1-97

Program regulations:
- Disaster set-aside program; second installment provisions; comments due by 9-30-97; published 8-1-97

AGRICULTURE DEPARTMENT

Rural Business-Cooperative Service

Federal claims collection; administrative offset; comments due by 9-30-97; published 8-1-97

Program regulations:
- Disaster set-aside program; second installment provisions; comments due by 9-30-97; published 8-1-97

AGRICULTURE DEPARTMENT

Rural Housing Service

Federal claims collection; administrative offset; comments due by 9-30-97; published 8-1-97

Program regulations:
- Disaster set-aside program; second installment provisions; comments due by 9-30-97; published 8-1-97

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Electric loans:
- Electric engineering, architectural services, and design policies and procedures; comments due by 10-3-97; published 8-4-97

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Program regulations:
- Disaster set-aside program; second installment provisions; comments due by 9-30-97; published 8-1-97

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National Oceanic and Atmospheric Administration

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- Umpqua River cutthroat trout; critical habitat designation; comments due by 9-29-97; published 7-30-97

Fishery conservation and management:
- Alaska; fisheries of Exclusive Economic Zone—
  - Bering Sea and Aleutian Islands groundfish; comments due by 9-29-97; published 8-15-97
  - Bering Sea and Aleutian Islands groundfish; comments due by 9-29-97; published 8-13-97
  - Gulf of Alaska groundfish; comments due by 9-29-97; published 7-29-97
- Alaska; fisheries of Exclusive Economic zone—
  - Gulf of Alaska groundfish; comments due by 10-2-97; published 8-18-97

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- Architect-engineer selection process; comments due by 9-29-97; published 7-29-97

Privacy act; implementation; comments due by 9-30-97; published 8-1-97

ENERGY DEPARTMENT

Energy Efficiency and Renewable Energy Office

Consumer products; energy conservation program:
- Fluorescent lamp ballasts; potential impact of possible energy efficiency levels; report availability and comment request; comments due by 10-2-97; published 8-25-97

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Air pollution control; new motor vehicles and engines:
- National low emission vehicle program; voluntary standards; State commitments; comments due by 9-29-97; published 9-23-97

Air programs:
- Outer Continental Shelf regulations—
  - California; consistency update; comments due by 9-29-97; published 8-28-97

Air programs: approval and promulgation; State plans for designated facilities and pollutants:
- Louisiana; comments due by 9-29-97; published 8-29-97

Air programs; approval and promulgation; State plans for designated facilities and pollutants:
- Louisiana; comments due by 9-29-97; published 8-29-97

Air quality implementation plans; approval and promulgation; various States:
- Maryland; comments due by 10-2-97; published 9-2-97
- Rhode Island; comments due by 10-2-97; published 9-2-97

Air quality planning purposes; designation of areas:
- Arizona; comments due by 10-2-97; published 9-2-97
- California; comments due by 10-2-97; published 9-2-97
- Texas; comments due by 10-2-97; published 9-2-97

Clean Air Act:
- State operating permits programs—
  - California; comments due by 10-3-97; published 9-3-97

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- Buprofezin; comments due by 9-29-97; published 7-30-97
- Fludioxonil; comments due by 9-30-97; published 8-1-97

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- Lead-based paint activities in public buildings, commercial buildings, and steel structures; requirements; meeting; comments due by 10-3-97; published 8-22-97
- Testing requirements—
  - Biphenyl, etc.; comments due by 9-30-97; published 7-15-97

FEDERAL COMMUNICATIONS COMMISSION

Common carrier services:
- Telecommunications Act of 1996; implementation—
  - Unbundled shared transport facilities use in conjunction with unbundled switching; local competition provisions; comments due by 10-2-97; published 8-28-97

Radio services, special:
- Private land mobile services—
  - 800 and 900 MHz bands; operation and licensing; comments due by 10-3-97; published 9-3-97

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- Texas; comments due by 9-29-97; published 8-13-97