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Briefing on How To Use the Federal Register
For information on the briefing in St. Louis, MO, see announcement on the inside cover of this issue.

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THE FEDERAL REGISTER
WHAT IT IS AND HOW TO USE IT

FOR: Any person who uses the Federal Register and Code of Federal Regulations.

WHO: The Office of the Federal Register.

WHAT: Free public briefings (approximately 3 hours) to present:

1. The regulatory process, with a focus on the Federal Register system and the public's role in the development of regulations.
2. The relationship between the Federal Register and Code of Federal Regulations.
3. The important elements of typical Federal Register documents.
4. An introduction to the finding aids of the FR/CFR system.

WHY: To provide the public with access to information necessary to research Federal agency regulations which directly affect them. There will be no discussion of specific agency regulations.

ST. LOUIS, MO

WHEN: April 23; at 9:00 a.m.
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Contents

Federal Register

Vol. 57, No. 73

Wednesday, April 15, 1992

Separate Parts In This Issue

Reader Aids
Additional information, including a list of public laws, telephone numbers, and finding aids, appears in the Reader Aids section at the end of this issue.

CFR PARTS AFFECTED IN THIS ISSUE

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

Federal Register
Vol. 57, No. 73
Wednesday, April 15, 1992

Presidential Documents

Title 3—

The President

Proclamation 6420 of April 13, 1992

National Recycling Day, 1992

By the President of the United States of America

A Proclamation

Throughout the United States concerned Americans are actively involved in recycling solid waste as a way to help protect our environment and to conserve our natural resources. Consumers are choosing to buy products made with recycled materials, and more and more people are recycling materials that were once discarded; business owners are using recycled materials to produce high quality goods; and government officials are working to encourage further efforts of this kind.

Recycling is fast becoming a key part of our Nation's integrated waste management program. In response to public interest—and in an effort to address rising disposal costs and shrinking landfill capacity—more and more communities now collect recyclables at curbside. There are now more than 2,700 curbside recycling programs in communities across the United States. Beyond this, there exist thousands of other sites where citizens can drop off recyclables. Traditional "paper drives" and other voluntary recycling activities continue in many communities, and countless Americans "recycle" in their own backyards by composting yard trimmings.

Businesses both large and small have also responded to the challenge of recycling. Historically, this country has benefitted from the unsung efforts of waste haulers and scrap dealers who have taken our discarded paper, metals, and other commodities and used them to create jobs and economic opportunity. Recently, however, other businesses have stepped forward to apply American ingenuity in collecting all kinds of recyclable commodities and processing and remanufacturing them to produce new, high quality goods.

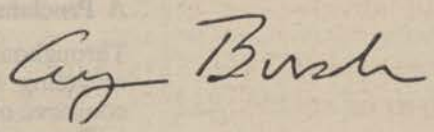
While we have made significant and commendable progress, all sectors of society must continue to work together to promote recycling. Public and private research efforts to develop more cost-effective and efficient recycling technologies are very important. In particular, we must explore new initiatives to encourage the use of recovered materials as feedstock for the manufacture of marketable products. Only when recovered materials are returned to the marketplace and purchased by consumers is recycling complete.

Today, every American can help to promote recycling by participating in curbside collection and other recycling programs and by purchasing recycled products whenever practical. On this occasion, let us reaffirm our commitment to reducing the amount of pollution that we generate overall and to recycling those materials that can be recovered for beneficial use.

The Congress, by Senate Joint Resolution 246, has designated April 15, 1992, as "National Recycling Day" and has authorized and requested the President to issue a proclamation in observance of this day.

NOW, THEREFORE, I, GEORGE BUSH, President of the United States of America, do hereby proclaim April 15, 1992, as National Recycling Day. I urge all Americans to observe this day with appropriate programs and activities that underscore and renew our commitment to recycling and other forms of environmental stewardship throughout the year. I specifically urge the Federal Government to attend to my direction of Executive Order 12780 regarding recycling and procurement in order to carry out its due share of continually improving the environment of the United States.

IN WITNESS WHEREOF, I have hereunto set my hand this thirteenth day of April, in the year of our Lord nineteen hundred and ninety-two, and of the Independence of the United States of America the two hundred and sixteenth.



[FR Doc. 92-8902
Filed 4-13-92; 4:08 pm]
Billing code 3195-01-M

Rules and Regulations

Federal Register
Vol. 57, No. 73
Wednesday, April 15, 1992

DEPARTMENT OF AGRICULTURE

Farmers Home Administration

7 CFR Parts 1924 and 1980

Amendments of Farmer Programs Insured and Guaranteed Loan Making Regulations

AGENCY: Farmers Home Administration, USDA.

ACTION: Interim rule with request for comments.

SUMMARY: The Farmers Home Administration (FmHA) amends its Farmer Programs insured and guaranteed loan making regulations to implement an amendment made to section 331E of the Consolidated Farm and Rural Development Act (CONACT) by section 501(d) of the "Food, Agriculture, Conservation, and Trade Act Amendments of 1991" (Pub. L. 102–237), to allow an applicant for the purposes of averaging past production/yields to develop a normal average production/yield for use in developing a projected plan of operation, to exclude the crop year with the lowest actual or County average yield, if the applicant was affected by a disaster during at least 2 of the 5 crop years immediately preceding the year of application.

DATES: Interim rule effective April 15, 1992. Written comments must be submitted on or before May 15, 1992.

ADDRESSES: Submit written comments, in duplicate, to the Office of the Chief, Regulations Analysis and Control Branch, Farmers Home Administration, USDA, room 6348, South Agriculture Building, 14th Street and Independence Avenue SW., Washington, DC 20250. All written comments made pursuant to this notice will be available for inspection during regular working hours at the above address.

FOR FURTHER INFORMATION CONTACT: David R. Smith, Senior Loan Officer, Farmer Programs Loan Making Division, Farmers Home Administration, USDA, South Building, 14th and Independence Avenue SW., Washington, DC 20250, telephone (202) 720–1645.

SUPPLEMENTARY INFORMATION:

Classification

This action has been reviewed under USDA procedures established in Departmental Regulation 1512–1, which implements Executive Order 12291, and has been determined to be nonmajor because it will not result in an annual effect on the economy of $100 million or more.

Intergovernmental Consultation

1. For the reasons set forth in the final rule related to notice 7 CFR part 3015, subpart V (48 FR 29115, June 24, 1983) and FmHA Instruction 1940–J, "Intergovernmental Review of Farmers Home Administration Programs and Activities" (December 23, 1983), Farm Operating Loans and Farm Ownership Loans are excluded with the exception of nonfarm enterprise activity from the scope of Executive Order 12372 which requires intergovernmental consultation with State and local officials.

2. The Soil and Water Loan Program is subject to the provisions of Executive Order 12372 and FmHA Instruction 1940–J.

Programs Affected

These changes affect the following FmHA programs as listed in the Catalog of Federal Domestic Assistance:

10.406—Farm Operating Loans
10.407—Farm Ownership Loans
10.418—Soil and Water Loans
10.404—Emergency Loans

Environmental Impact Statement

This document has been reviewed in accordance with 7 CFR part 1940, subpart G, "Environmental Program." It is the determination of FmHA that this action does not constitute a major Federal action significantly affecting the quality of the human environment, and in accordance with the National Environmental Policy Act of 1969, Public Law 91–190, an Environmental Impact Statement is not required.

Discussion of Interim Rule

It is the policy of this Department, that rules relating to public property, loans, grants, benefits, or contracts shall be published for comment notwithstanding the exemption of 5 U.S.C. 553 with respect to such rules. However, FmHA is making this action effective immediately upon publication in the **Federal Register** without prior public comment because section 501(d)(3)(A) of the "Food, Agriculture, Conservation, and Trade Act Amendments of 1991, "Public Law 102–237, mandates the Secretary of Agriculture to issue interim regulations without prior public notice and comment, to implement the subject change beginning in crop year 1992. Section 501(d)(3)(B) also requires that public notice and comments are provided before final regulations are issued, and this interim rule complies with that mandate.

The changes incorporated in this interim rule ease the requirements for obtaining assistance under the Farmer Programs loan programs. By implementing these regulations immediately, assistance can be provided to many farmers and ranchers who, without this regulation change, could not otherwise have developed a feasible plan of operation because of reduced production/yields as a result of disasters they suffered. Solicited comments will be considered carefully and taken into account before publication of a final rule.

The Agency has reformatted § 1924.57(d)(1) of subpart B of part 1924 for clarity and readability and corrected a procedural reference.

Discussion of Background

Farm loans made to FmHA applicants are governed mainly by the CONACT (7 U.S.C. 1921 *et seq.*). FmHA has historically based applicants' projected plans of operation on actual historical yield/production data from the applicant/borrower's reliable records. The historical average yield/production has been based on an average of the 5 years' yield/production immediately preceding the planned year. During the past several crop years, many States have experienced consecutive declared or designated disasters with a resultant lower commodity yield production average in many situations. This has created a problem in developing feasible plans of operation based on actual historical yield data. As a result of this problem, Congress enacted Section 331E of the CONACT in 1985 allowing

applicants to use County or State average yields in place of actual yields in calculating their historical average yield, when the applicant's yield(s) has been affected by natural disasters. This Act provided some relief to those farmers experiencing a reduced yield average as the result of one or more natural disasters during the 5 years preceding the planning year. In a continued effort to assist farmers who have been experiencing distressed operating and financial conditions as the result of consecutive natural disasters, Congress enacted the "Food, Agriculture, Conservation, and Trade Act Amendment of 1991." Section 501 (d) of said Act amended section 331E of the CONACT to allow farmers to exclude the crop year with the lowest yield in arriving at a historical average yield, to be used in developing a projected plan of operation, providing their yields have been affected by natural disaster(s) or major disasters or emergencies during at least 2 of the 5 years immediately preceding the planned year.

The Agency amends subpart B of part 1924 and subpart B of part 1980 to incorporate the recent amendment to section 331E relative to excluding the crop year with the lowest yield in calculating the historical average yield used in developing a projected plan of operation.

List of Subjects

7 CFR Part 1924

Agriculture, Construction management, Construction and repair, Energy conservation, Housing, Loan programs—Agriculture, Loan programs—Housing and community development, Low and moderate income housing.

7 CFR Part 1980

Agriculture, Loan programs—Agriculture.

Therefore, chapter XVIII, title 7, Code of Federal Regulations is amended as follows:

PART 1924—CONSTRUCTION AND REPAIR

1. The authority citation for part 1924 is revised to read as follows:

Authority: 7 U.S.C. 1989; 42 U.S.C. 1480; 5 U.S.C. 301; 7 CFR 2.23; 7 CFR 2.70.

Subpart B—Management Advice to Individual Borrowers and Applicants

2. Section 1924.57 is amended by revising paragraph (d)(1) to read as follows:

§ 1924.57 Planning.

* * * * *

(d) * * *

(1) Plans will be documented in sufficient detail to adequately reflect the overall condition of the operation, including the borrower's current financial condition. The borrower's projected income and expenses must be based on the borrower's proven record of production and financial management.

(i) For existing farmers, actual production and financial history for the 5 years immediately preceding the year of application is required.

(ii) For beginning farmers and those with less than a 5-year operating history, the applicant's available production history taken from the applicant's reliable records will be used.

(iii) The County Supervisor will document the source used to complete the 5-year average. To compute the 5-year average for such applicants, the County Supervisor will utilize available records in the order of priority as follows:

(A) Agriculture Stabilization and Conservation Service (ASCS) records, for that particular farm;

(B) County averages;

(C) State averages;

(D) Extension Service (ES) data; or

(E) Other reliable sources of data to develop the projections.

(iv) When an accurate projection cannot be made because the applicant's production history has been affected by a disaster(s) declared by the President or designated by the Secretary of Agriculture, and for those farmers who would have had a qualifying loss, as defined in § 1945.154 (a)(31) of Subpart D of Part 1945 of this chapter, but were not located in a designated/declared disaster area, the following applies:

(A) County average yields will be used for the disaster year(s). If the applicant's disaster year(s) yields are less than the County average yields, County average yields will be used for that year(s). If County average yields are not available, State average yields will be used.

(B) To calculate a historical average yield to be used in developing a projected plan of operation, the applicant may exclude the crop year with the lowest actual or County average yield, providing the applicant's yields were affected by disasters during at least 2 of the past 5 years immediately preceding the planned year.

* * * * *

PART 1980—GENERAL

3. The authority citation for part 1980 continues to read as follows:

Authority: 7 U.S.C. 1989; 42 U.S.C. 1480; 5 U.S.C. 301; 7 CFR 2.23 and 2.70.

Subpart B—Farmer Program Loans

4. Section 1980.113 is amended by revising paragraph (d)(8)(ii)(D) to read as follows:

§ 1980.113 Receiving and processing applications.

* * * * *

(d) * * *

(8) * * *

(ii) * * *

(D) When an accurate projection cannot be made because the applicant's production history has been affected by a disaster declared by the President or designated by the Secretary of Agriculture, the following applies:

(*1*) County average yields will be used for the disaster year(s). If the applicant's disaster year(s) yields are less than the County average yields, County average yields will be used for that year(s). If County average yields are not available, State average yields will be used.

(*2*) To calculate a historical average yield to be used in developing a projected plan of operation, the applicant may exclude the crop year with the lowest actual or County average yield, providing the applicant's yields were affected by disasters during at least 2 of the past 5 years immediately proceding the planned year.

* * * * *

Dated: February 5, 1992.

La Verne Ausman,

Administrator, Farmers Home Administration.

[FR Doc. 92-8648 Filed 4-14-92; 8:45 am]

BILLING CODE 3410-07-M

FEDERAL RESERVE SYSTEM

12 CFR Parts 211, 225, 263, 265

[Docket No. R-0754]

Regulation K—International Banking Operations and Regulation Y—Bank Holding Companies and Change in Bank Control

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Interim rule with request for comments.

SUMMARY: This interim rule implements the Foreign Bank Supervision Enhancement Act of 1991 (FBSEA or

Act), Subtitle A of Title II of the Federal Deposit Insurance Corporation Improvement Act of 1991, which made changes to the authority of the Board of Governors of the Federal Reserve System (Board) under the International Banking Act of 1978 (IBA). Regulation K is amended to reflect the Board's new authority in the supervision and regulation of foreign banks seeking to do business in the United States. Regulation Y is amended to require that foreign banking organizations acquiring more than 5 percent of the shares of a U.S. bank or bank holding company file an application with the Board under the Bank Holding Company Act (BHC Act). These amendments are intended to implement the provisions of the FBSEA that enhance the Board's authority over the establishment of U.S. offices by foreign banks and other aspects of the supervision of the U.S. operations of foreign banks.

DATES: *Effective Date.* This interim rule is effective April 15, 1992. *Comment Date.* Comments are requested and must be submitted by June 15, 1992.

ADDRESSES: Comments, which should refer to Docket No. R-0754, may be mailed to the Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue, NW., Washington, DC 20551, to the attention of Mr. William W. Wiles, Secretary. Comments addressed to the attention of Mr. Wiles may be delivered to the Board's mailroom between 8:45 a.m. and 5:15 p.m., and to the security control room outside of those hours. Both the mailroom and the security control room are accessible from the courtyard entrance on 20th Street between Constitution Avenue and C Street, NW. Comments may be inspected in room B-1122 between 9 a.m. and 5 p.m., except as provided in § 261.8 of the Board's Rules Regarding the Availability of Information, 12 CFR 261.8.

FOR FURTHER INFORMATION CONTACT: Kathleen M. O'Day, Assistant General Counsel (202/452-3786), Ann E. Misback, Senior Attorney (202/452-3788), Gregory A. Baer, Attorney (202/452-3236), or Margaret E. Miniter, Attorney (202/452-3900), Legal Division; Michael G. Martinson, Assistant Director (202/452-3640), Betsy Cross, Manager (202/452-2574), Division of Banking Supervision and Regulation, Board of Governors of the Federal Reserve System. For the hearing impaired *only*, Telecommunication Device for the Deaf (TDD), Dorothea Thompson (202/452-3544), Board of Governors of the Federal Reserve System, 20th and C Streets, NW., Washington, DC 20551.

SUPPLEMENTARY INFORMATION: The FBSEA grants to the Board new powers in the supervision and regulation of foreign banks operating or seeking to operate in the United States. The Board is amending its Regulation K to conform it to the new authority provided under the FBSEA. The amendments are effective immediately. The Board is seeking comment on these amendments and will consider further revisions as appropriate on the basis of the comments received.

The Board finds that it is necessary to issue its rule on an interim basis subject to public comment in order to conform its regulations to the applicable statutes and to ensure that applications by foreign banks to establish offices in the United States will not be delayed pending the end of a notice and comment period. There was no opportunity for the Board to publish proposed regulations for comment prior to the effective date of the FBSEA, as the Act was effective upon enactment. Accordingly, the Board, for good cause, finds that the notice and public comment procedure normally required is impractical and contrary to the public interest under 5 U.S.C. 553(b)(B). The Board further finds that, for the same reasons, there is good cause under 5 U.S.C. 553(d)(3) to make the interim rule effective immediately, without regard for the 30-day period provided for in 5 U.S.C. 553(d).

The enactment of the IBA in 1978 subjected the operations of foreign banks in this country to federal regulation for some purposes. Since that time, the presence of foreign banks in the United States has expanded significantly. As of December 31, 1991, there were 304 foreign banks with operations in the United States with aggregate banking assets of $866 billion. Branches and agencies of foreign banks alone had aggregate assets of approximately $716 billion, or 20 percent of total banking assets in this country, as of year end 1991. Approximately 94 percent of the total assets of foreign bank branches and agencies were in 532 state-licensed branches and agencies, while 6 percent were in 84 federally licensed branches and agencies.

Foreign banks have made significant contributions to the banking environment in the United States and have been an important source of credit for American business. Over the last three years, however, the Board has conducted investigations and taken enforcement actions with respect to unlawful activities at the U.S. offices of several foreign banks. In 1990, as a result of one investigation, the Board forwarded recommendations to the Congress to subject a foreign bank's branches and agencies in this country to various provisions of the criminal code governing bank fraud and other bank crimes. Those recommendations were acted upon by the Congress in the Crime Control Act of 1990.

In 1991 the Board conducted a further review of the statutes, regulations and supervisory policies governing the operations of foreign banks in the United States, and concluded that legislation was needed to strengthen the system of federal regulation and supervision of foreign bank operations in this country. In response to a request for legislative recommendations from the Congress, the Board sent a legislative proposal to the Chairmen of the Senate and House Banking Committees of the United States Congress on May 9, 1991. The Congress enacted substantial portions of this proposal on December 19, 1991 as the FBSEA.

In enacting the FBSEA, Congress sought to provide federal regulators with clear standards to govern the establishment of U.S. offices by foreign banks and with enhanced tools for supervising their ongoing operations in the United States. The Board's interim rule amends Regulation K to reflect these and other changes made by the FBSEA. The Board has revised Regulation K to establish procedures for the exercise of the Board's responsibilities relating to the approval, examination and termination of foreign bank operations in the United States. It has also revised Regulation K to implement provisions of the FBSEA that allow for disclosure of certain information to foreign supervisors and establish limits on loans to a single borrower by state branches and agencies. In addition, the Board is amending Regulation Y to reflect that foreign banking organizations acquiring an interest of greater than 5 percent of the voting shares of a U.S. bank or bank holding company must file an application with the Board under the BHC Act.

Establishment of Foreign Bank Offices

Board Approval

Regulation K is amended to implement the statutory requirement that a foreign bank obtain the prior approval of the Board before it establishes a branch, agency, representative office, or commercial lending company subsidiary (collectively, "office") in the United States. The regulation provides that changing the status of an office in a way

that makes a material difference in the activities of that office—for example, from an agency to a branch—or the relocation of an office from one state to another constitutes the establishment of an office for which prior Board approval is required. In certain circumstances, the regulation also requires Board approval, although not necessarily *prior* Board approval, when a foreign bank or parent company of a foreign bank acquires ownership or control of a commercial lending company through acquisition or merger, or when a foreign bank assumes the operations of a branch, agency, or representative office through certain mergers or acquisitions.

The Board's authority to approve new foreign bank offices parallels the continuing authority of the Office of the Comptroller of the Currency (Comptroller) to license new federal branches and agencies of foreign banks and the authority of state banking departments or authorities to license new state branches and agencies. The Board's approval authority does not supplant the authority of the Comptroller and the state regulatory authorities to license new foreign bank offices in accordance with whatever terms or conditions those authorities might establish.

Definitions

The regulation adopts a new set of definitions applicable to the provisions implementing the FBSEA. It also makes complementary amendments to definitions previously contained in Subparts A and B of Regulation K. With respect to the definition of representative office, the regulation describes the kinds of functions—representational and administrative—permitted for representative offices. It has been amended to specify that certain activities would not be permitted for such offices.

Under the FBSEA, Board approval is required before a foreign bank may establish any office in the United States or acquire control of a commercial lending company. "Establish" is defined as opening and engaging in business at a new office. It is also defined to include the assumption by a foreign bank through merger, or the acquisition of the operations, of an office that is open and conducting business in the United States, where the institution that will operate the U.S. office ceases operation as a separate entity or otherwise changes in corporate form following the merger or acquisition. Finally, the definition of "establish" further includes upgrading the status of an office or relocating an office from one state to another. The definition does not refer to a change involving a commercial lending company because approval by the licensing or chartering authority, as well as by the Board, would be required where a change in the corporate form of a subsidiary is involved.

Branch and Agency Functions

It has come to the Board's attention that certain offices or subsidiaries of foreign banks in the United States that are not regulated as a branch or agency by any banking authority in this country are nevertheless performing functions that are appropriate only to banks, branches, or agencies licensed by U.S. bank regulatory authorities. These functions go beyond soliciting business on behalf of the foreign bank to include entering into contracts with customers for the account of the foreign bank parent, with the resulting transaction often being booked at one of the offshore, shell branches of the parent bank. To the extent that employees of these offices or subsidiaries in the United States—or employees of the foreign bank operating from U.S. offices or subsidiaries or other locations—are contracting on behalf of the foreign bank to lend money or to take deposits in this country, these activities in the United States appear to fall within the definition of "agency" or "branch" in the IBA. Such activities are only permissible if the foreign bank first obtains a license from the appropriate state or federal authority to operate a branch or agency. This approach would not preclude a foreign bank with an authorized U.S. branch or agency from also using employees located in the United States to perform activities on behalf of an offshore shell branch or agency.

Procedures for Applications

A foreign bank seeking to establish an office must file an application with the Board and give notice of its application to the public. The Board's publication requirement parallels that currently employed by the Comptroller for applications by a foreign bank to establish a federal branch or federal agency. For applications to establish a federal branch or federal agency, compliance with the publication procedures of the Comptroller will satisfy the Board's requirement.

The regulation provides for public comment within 30 days of the publication of the notice and for Board action generally within 60 days of acceptance of the application. The Board may request any information in addition to that supplied in the application when the Board believes that additional information is necessary for its decision, and may extend the 60-day period for decision if it determines that an extension would serve the public interest and so notifies the applicant. These rules are similar to those for bank holding company applications.

Special procedures for obtaining after-the-fact approval by the Board of applications to establish offices are provided to address the establishment of U.S. offices through certain mergers or acquisitions of foreign banks. Such establishment occurs when there is a change in the corporate form of the foreign bank operating the branch, agency, representative office, or commercial lending company in this country, such as through a merger of that foreign bank into another foreign bank or, in certain circumstances, the acquisition of the assets or operations of the foreign bank by another foreign bank. In order to allow the transaction to be accomplished without delay, the Board may permit consummation to occur before an application has been filed with or acted upon by the Board. The regulation sets forth the criteria on which the Board may base such a decision. The Board's after-the-fact approval procedures apply only if the new bank resulting from a merger or the bank being acquired does not control or own more than 5 percent of the voting shares of a U.S. bank. In all cases, the Board reserves the right to deny the application, and an applicant must agree to abide by the Board's decision, including by, if necessary, terminating the activities of any U.S. office as required by the Board.

In contrast, no application is required where a foreign bank with a U.S. office is acquired by a foreign bank or foreign company if the acquired foreign bank continues to operate in the same corporate form as prior to the acquisition, and the acquired foreign bank does not control or own more than 5 percent of the shares of a U.S. bank. In such circumstance, there would be no change in the corporate form of the foreign bank that operates the U.S. office, and for that reason no application would be required. The regulation does require a written notice within 10 days of the change in ownership or control of the foreign bank with the U.S. office in order for the Board to be able to monitor whether other regulatory requirements—such as the qualifying foreign banking organization standard—are being met by the new consolidated organization.

The Board wishes to make clear that under no circumstances is an application to the Board required for a merger or acquisition of two or more foreign banks that occurs wholly outside the United States where the foreign

banks have no U.S. offices and do not control a U.S. bank.

The Board's regulation takes account of the fact that the Board will be acting on applications for foreign bank offices for which approval must also be obtained from the Comptroller or the relevant state banking authority. For that reason, the Board envisions close cooperation between itself and these agencies. The Board will notify the Comptroller or the relevant state banking authority when an application is received and will consult with that agency throughout the application process. In acting on an application, the Board will rely to the extent possible on information already supplied by the applicant or otherwise available to the Comptroller or the relevant state banking authority.

The Board will also consult with the Comptroller, the Federal Deposit Insurance Corporation (FDIC) and the state supervisors in an effort to develop a uniform standard form for applications by foreign banks to establish branches, agencies, representative offices, and commercial lending companies. Until a form is issued, an applicant should submit to the appropriate Reserve Bank a copy of its application to either the state banking authority or the Comptroller, and should contact the responsible Reserve Bank to determine what additional information should be provided.

Standards for Approval of Applications to Establish a Branch, Agency, or Commercial Lending Company Subsidiary

Regulation K is revised to implement the statutory requirements for approval of foreign bank applications and additional requirements imposed by the Board pursuant to its statutory authority. The Board may condition approval of an application as it deems necessary.

Comprehensive supervision or regulation of a foreign bank on a consolidated basis by home country authorities is one of the mandatory requirements for the establishment of an office in the United States. The Board's regulation provides a standard for assessing consolidated supervision or regulation: whether a foreign bank is supervised or regulated in such a manner that its home country supervisor receives sufficient information on the worldwide operations of the foreign bank, including the relationship of the bank to affiliated companies, to be able to assess its overall financial condition and compliance with law. In making that determination, the Board will assess, among other factors, the extent to which the home country supervisor:

1. Ensures that the foreign bank has adequate procedures for monitoring and controlling its worldwide operations;
2. Obtains information on the condition of the foreign bank and its subsidiaries or offices, whether through examination, audit reports, or otherwise;
3. Obtains information on the dealings and relationship between the foreign bank and its affiliates;
4. Receives financial reports that permit analysis of the consolidated, worldwide condition of the foreign bank;
5. Evaluates prudential standards on a worldwide basis.

The Board recognizes that the legal systems for supervision and regulation vary from country to country, and that comprehensive supervision or regulation on a consolidated basis can be achieved in different ways. The regulation includes both the general standard the Board will apply in making its determination and the primary elements it will consider in applying this standard. At the same time, the regulation gives the Board flexibility in making case-by-case determinations without imposing the U.S. regulatory system on foreign banks outside the United States.

The proposed factors focus on the ability of the home country supervisor to obtain information on, and supervise, the foreign bank's operations and overall condition, but they do not mandate that the information be obtained in a particular form or through particular methods. The Board will obtain information on these factors by requiring the foreign bank to submit in its application a description of the supervision to which it is subject, or any changes in such supervision since the last relevant Board determination on consolidated supervision in the foreign bank's home country. The Board will also seek to gather information from outside sources, including the home country authorities.

It is possible that different types of institutions from the same country may be supervised in a different manner. Thus, a decision in a particular case relating to a home country's supervision may not always be determinative for other applicants from that country. There will also be applications from banks in one country that are owned by banks in another country. In such a case, both the applicant bank and any parent foreign bank must be subject to consolidated home country supervision, necessitating determinations for more than one country.

The discretionary standards for approval are adopted from the statute and further clarified by the regulation. The financial and managerial standards imposed by the regulation reflect those required of domestic banks under the Board's Regulation Y. In addition, the standard for managerial resources includes consideration of management's experience and capacity to engage in international banking and any record of a foreign bank or its management with respect to compliance with laws and regulations. Where the foreign bank is already present in the United States, the standard requires consideration of a foreign bank's fulfillment of any commitments to, and any conditions imposed by, the Board in connection with prior applications. The Board will also examine whether the foreign bank's home country supervisor and the supervisor of any foreign bank parent share information about the bank with the Board and other supervisors.

One of the discretionary standards established by the FBSEA for applications to establish a branch, agency, or commercial lending company is whether the foreign bank has provided the Board with adequate assurances that it will make available to the Board information on the operations of the bank and its affiliates necessary to determine compliance with U.S. law. Although this standard is discretionary for such applications, the FBSEA also amended the BHC Act to make these assurances a mandatory requirement for the acquisition of a U.S. bank by a company, including a foreign bank or other foreign company.

In making such assurances on disclosure of information to the Board, the applicant is required to describe applicable secrecy laws, and how those laws would restrict the provision of information to the Board. If the restrictions are significant enough to impede materially the monitoring of the foreign bank's operations, the standard on disclosure of information would allow the Board to deny the application. There could, however, be instances in which such restrictions would not impede the review of a foreign bank's operations. In such circumstances, if the Board has no reason to believe that the affiliates are engaged in violations of law, the application could still be approved subject to the imposition of a condition that activities of the foreign bank's U.S. office or subsidiary must be terminated if the information restrictions subsequently interfere with the Board's ability to determine the safety and soundness of the U.S. operations of the foreign bank or the foreign bank's compliance with U.S. laws and regulations.

Abbreviated Procedures

The Comptroller currently may apply abbreviated procedures for applications to establish an additional federal branch or federal agency within a state in which a foreign bank already maintains a federal branch or federal agency. The Board is considering, and is seeking comment on, whether to establish similar procedures after it has gained experience in reviewing applications from foreign banks under the new regulations.

The Board may also consider more streamlined procedures or delegation of authority to the Reserve Banks for the approval of certain applications for new offices after the Board has developed experience in approving such applications sufficient to provide a basis for identifying the appropriate circumstances for more limited procedures.

Representative Offices

In acting on applications by foreign banks to establish representative offices, the Board will take into account to the extent it deems appropriate the standards for approval of applications to establish branches, agencies, and commercial lending company subsidiaries. In so doing, the Board will consider the nature and extent of the proposed activities of the representative office in the United States.

Applications under the Bank Holding Company Act

Section 207 of the FBSEA eliminated a provision in section 8 of the IBA that exempted foreign banks and companies controlling foreign banks from certain of the requirements of section 3 of the BHC Act if the foreign bank operated in the United States only through branches, agencies, or commercial lending companies. As a result, a foreign bank or a company that controls a foreign bank that maintains a branch or agency in the United States or controls a commercial lending company in the United States is now subject to all of the provisions of the BHC Act as if the foreign bank or company were a bank holding company under the BHC Act. The Board has adopted a conforming amendment to Regulation Y that specifies that in general a foreign banking organization with a branch, agency, or commercial lending company subsidiary in the United States is subject to the application requirements of section 3 of the BHC Act for the acquisition of a direct or indirect interest in a U.S. bank or U.S. bank holding company. The conforming amendment also provides that an application is not required under section 3 for the acquisition of more than 5 percent of the shares of a foreign banking organization that does not control a bank in the United States.

Termination of an Office of a Foreign Bank in the United States

Grounds for Termination of Offices

Regulation K is revised to include the statutory standards for termination by the Board of the operations in the United States of a representative office or state branch, state agency, or commercial lending company of a foreign bank. Before terminating any state branch or state agency, the Board will request and consider the views of the relevant state supervisor. The regulation also reflects the statutory requirement that the Board recommend to the Comptroller that a federal branch or federal agency be terminated if the termination would be warranted under the same standards applicable to a state branch or agency.

Hearing

Under the FBSEA, a termination order generally will be issued only after notice and an opportunity for a hearing. The Board may act without providing for a hearing if it determines that doing so is necessary in order to protect the public interest. When such action is necessary, the Board may take other actions designed to give the foreign bank notice and an opportunity to present its views.

Voluntary Termination

The Board's regulation requires notice of the voluntary termination of an office by a foreign bank 30 days in advance of that termination. Such a procedure is necessary for the Board to monitor a foreign bank's presence in the United States. This notice requirement is in addition to, and does not satisfy, any other requirement by federal or state authorities relating to a voluntary liquidation or branch closing.

Examinations of Offices and Affiliates of Foreign Banks

Under sections 7(c) and 10(c) of the IBA, the Board is granted authority to examine any branch, agency, or representative office of a foreign bank, any commercial lending company or bank controlled by one or more foreign banks, and any other office or affiliate of a foreign bank that conducts business in the United States. Moreover, the Board is authorized to coordinate examinations of the U.S. offices and U.S. affiliates of a foreign bank with the other federal and state banking regulators and to conduct its own examinations of such offices. The Board has delegated the authority to coordinate such examinations to its Director of the Division of Banking Supervision and Regulation.

Regulation K is revised to implement the statutory requirement that each branch and agency of a foreign bank be examined on site at least once in every twelve-month period, beginning on the date on which the most recent examination ended, by one of the federal or state banking agencies. This interim rule also revises Regulation K to implement the statutory standard that representative offices shall be examined in the manner and with the frequency determined by the Board. The Board is also exercising its discretion to add commercial lending companies to the list of offices to be examined in every twelve-month period.

Disclosure of Information to Foreign Supervisors

Under section 15(a) of the IBA, the Board is authorized to disclose supervisory information to a foreign supervisor if such disclosure is appropriate and would not prejudice the interests of the United States. Before disclosing any information, the Board is required to obtain, to the extent necessary, the agreement of the foreign supervisor to maintain the confidentiality of the information to the extent possible under applicable law. The Board delegates to the General Counsel the authority to determine whether disclosure is appropriate in a particular case and to negotiate any confidentiality agreement. The General Counsel will consult with the other federal banking agencies as appropriate in deciding whether to disclose supervisory information.

Limitation on Loans to One Borrower

The FBSEA amends section 7 of the IBA to provide that a state branch or state agency must comply with the same limitations with respect to loans made to a single borrower as are applicable to a federal branch or federal agency under the IBA. Under the IBA, a federal branch or agency is subject to the limit on loans to single borrowers found in the National Bank Act. Under that Act, the federal branches and agencies of the same foreign bank must aggregate all their loans to the same borrower to determine compliance with this limit. The capital against which the loans are measured is the consolidated capital of the foreign bank.

The regulation implements the new requirement in the FBSEA by requiring a foreign bank with a state branch or agency to aggregate all loans made to

the same borrower by all of its branches and agencies in the United States—regardless of whether they have federal or state licenses—for purposes of determining compliance with the statutory limit. The intent of the provision is to put the operations of the foreign bank in the United States on a comparable footing with domestic banks for lending purposes.

Activities of State Branches and Agencies

Section 7(h)(1) of the IBA, as enacted by the FBSEA, provides that a state branch or state agency may not engage in any type of activity not permissible for a federal branch unless the Board has determined that such activity is consistent with sound banking practices. In the case of insured branches, the FDIC must also determine that the activity poses no significant risk to the deposit insurance fund. The Board proposes to address this provision at a later time, after consulting the FDIC.

Deposit Insurance Requirement for Retail Deposit-Taking

There is an unresolved issue concerning the scope of section 6(c) of the IBA, specifically whether a foreign bank must establish an insured bank subsidiary if it maintains any deposits with balances under $100,000, or whether a foreign bank need only establish an insured bank subsidiary if it accepts or maintains deposits with balances under $100,000 that are domestic retail deposits requiring deposit insurance pursuant to sections 6(a) and (b) of the IBA and the regulations adopted by the FDIC and the Comptroller. On December 19, 1991, the Board and the Comptroller provided guidance to foreign banks that, until the agencies issued clarifying rules or interpretations, the foreign banks would not be considered to be in violation of section 6(c) if they limited their deposit-taking activities in branches and agencies to those permitted by regulations of the FDIC and the Comptroller in effect on December 19, 1991. The Board is continuing to review section 6(c) and the intent of the Congress with respect to this provision, and has therefore reserved this part of the regulation for future promulgation.

Rules of Practice for Hearings

Under amendments to the IBA made by the FBSEA, the Board must, unless expeditious action is required, hold hearings before terminating the activities of a state branch, state agency, subsidiary, or representative office of a foreign bank. Accordingly, the Board has revised its hearing rules to make them applicable in such cases.

Penalties for Violation of the IBA

Section 208 of the FBSEA added a new section 16 to the IBA that provides for civil money penalties for violation of the IBA. That provision, like the rest of the FBSEA, is currently effective. The Board is working with the other federal banking agencies to determine whether it is necessary to adopt conforming regulations, and that effort will be the subject of a separate notice and opportunity for comment.

Initial Regulatory Flexibility Analysis

The Regulatory Flexibility Act (5 U.S.C. 601-612) requires an initial regulatory flexibility analysis with any notice of proposed rulemaking. Two of the requirements of an initial regulatory flexibility analysis—a description of the reasons why the action by the agency is being considered and a statement of the objectives of, and the legal basis for, the proposed rule—are contained in the supplementary information above. The Board's interim rule requires no additional reporting or recordkeeping requirements other than as are necessary to implement the statute; nor are there relevant federal rules that duplicate, overlap, or conflict with the proposed rule, other than as required by law.

Another requirement of the initial regulatory flexibility analysis is a description of and, where feasible, an estimate of the number of small entities to which the proposed rule shall apply. The interim rule will apply to all foreign offices, regardless of size. The rule should not have a significant economic impact on small branches, agencies, representative offices, and commercial lending companies, but rather will improve the supervision and regulation of all such offices.

Paperwork Reduction

The Board, acting pursuant to authority delegated to it by the Director of the Office of Management and Budget under 44 U.S.C. 3507(e), has approved the collection of information called for by sections 211.25 and 211.27 of the Board's Rules and sections 7 and 10 of the IBA.

List of Subjects

12 CFR Part 211

Exports, Federal Reserve System, Foreign banking, Holding companies, Investments, Reporting and recordkeeping requirements.

12 CFR Part 225

Administrative practice and procedure, Banks, banking, Federal Reserve System, Holding companies, Reporting and recordkeeping requirements, Securities.

12 CFR Part 263

Administrative practice and procedure, Federal Reserve System.

12 CFR Part 265

Authority delegations (Government agencies), Federal Reserve System.

For the reasons outlined above, the Board of Governors is amending 12 CFR parts 211, 225, 263 and 265 to read as set forth below:

PART 211—INTERNATIONAL BANKING OPERATIONS

1. The authority citation for 12 CFR part 211 continues to read as follows:

Authority: Federal Reserve Act (12 U.S.C. 221 *et seq.*); Bank Holding Company Act of 1956, as amended (12 U.S.C. 1841 *et seq.*); the International Banking Act of 1978 (Pub. L. 95-369; 92 Stat. 607; 12 U.S.C. 3101 *et seq.*); the Bank Export Services Act (Title II, Pub. L. 97-290, 96 Stat. 1235); the International Lending Supervision Act (Title IX, Pub. L. 98-181, 97 Stat. 1153, 12 U.S.C. 3901 *et seq.*); and the Export Trading Company Act Amendments of 1988 (Title III, Pub. L. 100-418, 102 Stat 1384 (1988)).

2. Section 211.2 is amended by revising paragraph (t) to read as follows:

§211.2 Definitions.

* * * * *

(t) *Representative office* means an office that:

(1) Engages solely in representational and administrative functions, such as soliciting new business or acting as liaison between the organization's head office and customers in the United States; and

(2) Does not have authority to make any business decision for the account of the organization it represents, including contracting for any deposit or deposit-like liability on behalf of the organization.

* * * * *

3. Section 211.21 is amended by removing the word "and" where it appears in paragraph (b)(1), by removing the period at the end of paragraph (b)(2) and adding a semi-colon in its place, and by adding new paragraphs (b)(3) through (b)(8) to read as follows:

§211.21 Authority, purpose, and scope.

* * * * *

(b) * * *

(3) Board approval of the acquisition or establishment of an office of a foreign

bank in the United States under §§ 7(d) and 10(a) of the IBA (12 U.S.C. 3105(c), 3107(a));

(4) The termination by the Board of a foreign bank's representative office, state branch, state agency, or commercial lending company subsidiary in the United States under sections 7(e) and 10(b) of the IBA (12 U.S.C. 3105(d), 3107(b));

(5) The examination of any office or affiliate of a foreign bank in the United States under sections 7(c) and 10(c) of the IBA (12 U.S.C. 3105(b), 3107(c));

(6) The disclosure of supervisory information to a foreign supervisor under section 15 of the IBA (12 U.S.C. 3109);

(7) The limitations on loans to one borrower by state branches and state agencies of a foreign bank under section 7(h) of the IBA (12 U.S.C. 3105(g)); and

(8) The deposit insurance requirement for retail deposit taking by a foreign bank under section 6 of the IBA (12 U.S.C. 3104).

4. Sections 211.22 and 211.23 are redesignated as §§ 211.23 and 211.24, respectively.

5. Newly designated § 211.23 is amended by removing paragraph (a) and redesignating paragraphs (b) through (e) as paragraphs (a) through (d), respectively.

6. Newly redesignated § 211.24 is amended by removing paragraph (a) and redesignating paragraphs (b) through (i) as paragraphs (a) through (h), respectively.

7. A new § 211.22 is added to read as follows:

§211.22 Definitions.

The definitions of § 211.2 in subpart A of this part apply to this subpart except as a term is otherwise defined in this section:

(a) *Affiliate*, of a foreign bank or of a parent of a foreign bank, means any company that controls, is controlled by, or is under common control with, the foreign bank or the parent of the foreign bank.

(b) *Agency* means any office or any place of business of a foreign bank located in any state at which credit balances are maintained, checks are paid, or money is lent, but at which deposits may not be accepted from a citizen or resident of the United States. Obligations shall not be considered credit balances unless they:

(1) Are incidental to, or arise out of the exercise of, other lawful banking powers;

(2) Are to serve a specific purpose;

(3) Are not solicited from the general public;

(4) Are not used to pay routine operating expenses in the United States such as salaries, rent, or taxes;

(5) Are withdrawn within a reasonable period of time after the specific purpose for which they were placed has been accomplished; and

(6) Are drawn upon in a manner reasonable in relation to the size and nature of the account.

(c) *Banking subsidiary*, with respect to a specified foreign bank, means a bank that is a subsidiary as the terms *bank* and *subsidiary* are defined in section 2 of the BHC Act (12 U.S.C. 1841).

(d) *Branch* means any place of business of a foreign bank located in any state at which deposits are received.

(e) *Change the status* of an office means convert a representative office into a branch or an agency, or convert an agency into a branch.

(f) *Commercial lending company* means any organization, other than a bank or an organization operating under section 25 of the FRA (12 U.S.C. 601-604a), organized under the laws of any state, that maintains credit balances permissible for an agency and engages in the business of making commercial loans. *Commercial lending company* includes any company chartered under Article XII of the banking law of the State of New York.

(g) *Comptroller* means the Office of the Comptroller of the Currency.

(h) *Control* has the same meaning assigned to it in section 2 of the BHC Act (12 U.S.C. 1841), and the terms *controlled* and *controlling* shall be construed consistently with the term *control*.

(i) *Domestic branch* means any office or any place of business of a foreign bank located in any state that may accept domestic deposits and deposits that are incidental to or for the purpose of carrying out transactions in foreign countries.

(j) A foreign bank *engages directly in the business of banking outside of the United States* if the foreign bank engages directly in banking activities usual in connection with the business of banking in the countries where such foreign bank is organized or operating.

(k) To *establish* means to:

(1) Open and conduct business through an office;

(2) Assume, through merger, the operations of an office that is open and conducting business;

(3) Acquire an office through the acquisition of a subsidiary where such subsidiary would cease to operate in the same corporate form following the acquisition;

(4) Change the status of an office; or

(5) Relocate an office from one state to another.

(l) *Federal agency*, *federal branch*, *state agency* and *state branch* have the same meanings as in section 1 of the IBA (12 U.S.C. 3101).

(m) *Foreign bank* means an organization that is organized under the laws of a foreign country and that engages directly in the business of banking. The term *foreign bank* does not include central banks of foreign countries that are not engaged in a commercial banking business in the United States.

(n) *Foreign banking organization* means a foreign bank (as defined in section 1(b)(7) of the IBA (12 U.S.C. 3101(b)(7)) that operates a branch, agency or commercial lending company subsidiary in the United States or that controls a bank in the United States, and any company of which such foreign bank is a subsidiary.

(o) *Home country*, with respect to a foreign bank, means the country in which the foreign bank is chartered or incorporated.

(p) *Home country supervisor*, with respect to a foreign bank, means the governmental entity or entities in the foreign bank's home country with responsibility for the supervision and regulation of the foreign bank.

(q) *Licensing authority* means:

(1) With respect to an application to establish a state branch or state agency of a foreign bank, the relevant state supervisor;

(2) With respect to an application to establish a federal branch or federal agency, the Comptroller.

(r) *Office* or *office of a foreign bank* means any branch, agency, representative office, or commercial lending company subsidiary of a foreign bank in the United States.

(s) The *parent* of a foreign bank means any company of which the foreign bank is a subsidiary; the *immediate parent* of a foreign bank is the company of which the foreign bank is a direct subsidiary; and the *ultimate parent* of a foreign bank is the parent of the foreign bank that is not the subsidiary of any other company.

(t) *Relevant state supervisor* means the state entity that is authorized to supervise and regulate a state branch, state agency or commercial lending company.

(u) *Representative office* means an office that:

(1) Engages in representational and administrative functions, such as soliciting new business or acting as liaison between the foreign bank's head

office and customers in the United States; and

(2) Does not have authority to make any business decision for the account of the foreign bank it represents, including contracting for any deposit or deposit-like liability on behalf of the foreign bank.

(v) *State* means any state of the United States or the District of Columbia.

(w) *Subsidiary* means any organization 25 percent or more of whose voting shares is directly or indirectly owned, controlled or held with power to vote by a foreign banking organization, or any organization that is otherwise controlled or capable of being controlled by a foreign banking organization.

8. Sections 211.25 through 211.30 are added to read as follows:

§211.25 Approval of offices of foreign banks.

(a) *Board approval of offices of foreign banks*—(1) *Prior Board approval.*

(i) Except as otherwise provided in paragraph (a)(2) of this section, a foreign bank shall obtain the approval of the Board before it establishes a branch, agency, representative office or commercial lending company subsidiary in the United States.

(ii) Except as otherwise provided in paragraph (a)(2) of this section, a foreign bank shall obtain the Board's prior approval before it acquires ownership or control of:

(A) A commercial lending company, or

(B) A foreign bank that owns or controls a commercial lending company in the United States where the acquired foreign bank would cease to operate in the same corporate form following the acquisition.

(2) *After-the-fact Board approval.* Where a foreign bank proposes to establish an office in the United States through an acquisition of, or merger with, a foreign bank with an office in the United States, the Board may, in its discretion, allow the acquisition or merger to proceed before an application to establish an office has been filed or acted upon under this section where:

(i) The foreign bank or banks will not own or control more than five percent of any class of the voting securities of, or control, a U.S. bank;

(ii) Prior to consummation of the acquisition or merger, each of the relevant foreign banks commits in writing to comply with the procedures for an application under this section within a reasonable period of time or has already filed an application; and

(iii) The Board is given reasonable advance notice of the proposed acquisition or merger, and each of the relevant foreign banks commits in writing to abide by the Board's decision on the application, including, if necessary, to terminate the activities of any U.S. office as required by the Board.

(3) *Notification of change in ownership or control.* A foreign bank with a U.S. office shall notify the Board in writing within 10 days of a change in its ownership or control where it is acquired or controlled by another foreign bank or company and the foreign bank with a U.S. office continues to operate in the same corporate form as prior to the change in ownership or control.

(4) *Transactions subject to approval under Regulation Y.* Subpart B of the Board's Regulation Y (12 CFR 225.11 through 225.14) governs the acquisition by a foreign bank or foreign banking organization of direct or indirect ownership or control of any voting securities of a bank or bank holding company in the United States if the acquisition results in the foreign bank or foreign banking organization's ownership or control of more than 5 percent of any class of voting securities of a U.S. bank or bank holding company, including through acquisition of a foreign banking organization that owns or controls more than 5 percent of any class of the voting securities of a U.S. bank or bank holding company.

(b) *Procedures for application*—(1) *Filing application.* An application for the Board's prior approval pursuant to this section shall be filed in the manner prescribed by the Board.

(2) *Publication requirement*—(i) *In general.* Except with respect to a proposed transaction where more extensive notice is required by statute or as otherwise provided in paragraphs (b)(2)(ii) and (b)(2)(iii) of this section, the applicant shall publish a notice in a newspaper of general circulation in the community in which the applicant proposes to engage in business. The notice shall state that an application is being filed as of the date of the notice and provide the name of the applicant, the subject matter of the application, and the date by which comments are due pursuant to paragraph (b)(3) of this section. The applicant shall furnish with its application to the Board a copy of the notice, the date of its publication, and the name and address of the newspaper in which it was published.

(ii) *Exception.* The Board may modify the publication requirement of paragraph (b)(2)(i) of this section in appropriate circumstances.

(iii) *Federal branch or federal agency.* In the case of an application to establish a federal branch or federal agency, compliance with the publication procedures of the Comptroller shall satisfy the publication requirement of this section. Comments regarding the application should be sent to the Board and the Comptroller.

(3) *Written comments.* Within 30 days after publication as required in this section, any person may submit to the Board written comments and data on an application. The Board may extend the 30-day comment period if the Board determines that additional relevant information is likely to be provided by interested persons or if other extenuating circumstances exist.

(4) *Action on application*—(i) *Time limits.* The Board shall act on an application from a foreign bank within 60 calendar days after the foreign bank has been notified that its application has been accepted, unless the Board determines that the public interest will be served by providing additional time to review the application and notifies the applicant that the 60-day period is being extended.

(ii) *Additional information.* The Board may request any information in addition to that supplied in the application when the Board believes that additional information is necessary for its decision.

(5) *Coordination with other regulators.* Upon receipt of an application by a foreign bank under this section, the Board shall promptly notify, consult with, and consider the views of the licensing authority.

(c) *Standards for approval*—(1) *Mandatory standards*—(i) *Applicable standards.* As specified in section 7(d) of the IBA (12 U.S.C. 3105(c)), the Board may not approve an application to establish a branch or an agency, or to acquire ownership or control of a commercial lending company, unless it determines that:

(A) The foreign bank and any parent foreign bank engage directly in the business of banking outside the United States and are subject to comprehensive supervision or regulation on a consolidated basis by the appropriate authorities in their home countries; and

(B) The foreign bank has furnished to the Board the information that the Board requires in order to assess the application adequately.

(ii) *Basis for determining comprehensive supervision or regulation on a consolidated basis.* In determining whether a foreign bank and any parent foreign bank is subject to comprehensive supervision or regulation on a consolidated basis, the Board will

determine whether the foreign bank is supervised or regulated in such a manner that its home country supervisor receives sufficient information on the worldwide operations of the foreign bank (including the relationship of the bank to any affiliate) to assess its overall financial condition and compliance with law and regulation. In making such a determination, the Board shall assess, among other factors, the extent to which the home country supervisor:

(A) Ensures that the foreign bank has adequate procedures for monitoring and controlling its activities worldwide;

(B) Obtains information on the condition of the foreign bank and its subsidiaries and offices outside the home country through regular reports of examination, audit reports, or otherwise;

(C) Obtains information on the dealings and relationship between the foreign bank and its affiliates, both foreign and domestic;

(D) Receives from the foreign bank financial reports that are consolidated on a worldwide basis, or comparable information that permits analysis of the foreign bank's financial condition on a worldwide, consolidated basis;

(E) Evaluates prudential standards, such as capital adequacy and risk asset exposure, on a worldwide basis.

(2) *Discretionary standards.* In acting on any application under this subpart, the Board may take into account:

(i) Whether the appropriate authorities in the home country of the foreign bank have consented to the proposed establishment of a branch, agency or commercial lending company subsidiary;

(ii) The financial resources of the foreign bank (including the foreign bank's capital position, projected capital position, profitability, level of indebtedness, and future prospects) and the condition of any U.S. office of the foreign bank;

(iii) The managerial resources of the foreign bank, including the competence, experience, and integrity of the officers, directors, and principal shareholders; management's experience and capacity to engage in international banking; and the record of the foreign bank and its management of complying with laws and regulations, and of fulfilling any commitments to, and any conditions imposed by, the Board in connection with any prior application;

(iv) Whether the foreign bank's home country supervisor and the home country supervisor of any parent of the foreign bank share material information regarding the operations of the foreign bank with other supervisory authorities;

(v) Whether the foreign bank has provided the Board with adequate assurances that information will be made available to the Board on the operations or activities of the foreign bank and any of its affiliates that the Board deems necessary to determine and enforce compliance with the IBA, the BHC Act, and other applicable federal banking statutes; these assurances shall include a statement from the foreign bank describing any laws that would restrict the bank or any of its parents from providing information to the Board; and

(vi) Whether the foreign bank and its U.S. affiliates are in compliance with applicable U.S. law, and whether the applicant has established adequate controls and procedures in each of its offices to ensure continuing compliance with U.S. law, including controls directed to detection of money laundering and other unsafe or unsound banking practices.

(3) *Additional factor.* In acting on an application, the Board may consider the needs of the community and the history of operation of the foreign bank and its relative size in its home country, provided, however, that the size of the foreign bank shall not be the sole factor in determining whether an office of a foreign bank should be approved.

(4) *Establishment of conditions.* Consistent with the mandatory standards for approval, the Board may impose such conditions on its approval as it deems necessary, including a condition requiring future termination of any activities based on an inability of the foreign bank to provide information on the activities of itself or its affiliates necessary for the Board to determine and enforce compliance with U.S. banking laws.

(d) *Representative offices.*—(1) *Standard for approval.* As specified in section 10(a) of the IBA (12 U.S.C. 3107(a)), in acting on the application of a foreign bank to establish a representative office, the Board shall take into account to the extent it deems appropriate the standards for approval set out in paragraph (c) of this section.

(2) *Additional requirements.* The Board may impose any additional requirements that it determines to be necessary to carry out the purposes of the IBA.

(e) *Preservation of existing authority.* Nothing in this subpart shall be construed to relieve any foreign bank or foreign banking organization from any otherwise applicable requirement of federal or state law, including any applicable licensing requirement.

§211.26 Termination of an office of a foreign bank.

(a) *Grounds for termination.* As specified in section 7(e) and 10(b) of the IBA (12 U.S.C. 3105(d), 3107(b)), the Board may order a foreign bank to terminate the activities of its representative office, state branch, state agency, or commercial lending company subsidiary if the Board finds that:

(1) The foreign bank is not subject to comprehensive supervision or regulation on a consolidated basis by the appropriate authorities in its home country in accordance with § 211.25(c)(1)(ii); or

(2)(i) There is reasonable cause to believe that the foreign bank or any of its affiliates has committed a violation of law or engaged in an unsafe or unsound banking practice in the United States; and

(ii) As a result of such violation or practice, the continued operation of the foreign bank's representative office, state branch, state agency, or commercial lending company subsidiary would not be consistent with the public interest or with the purposes of the IBA, the BHC Act, or the Federal Deposit Insurance Act (FDIA) (12 U.S.C. 1811 *et seq.*).

(b) *Factor.* In making its findings under this section, the Board may take into account the needs of the community as well as the history of operation of the foreign bank and its relative size in its home country, provided, however, that the size of the foreign bank shall not be the sole determining factor in a decision to terminate an office.

(c) *Consultation with relevant state supervisor.* Before issuing an order terminating the activities of a state branch, state agency, or commercial lending company subsidiary under this section, the Board shall request and consider the views of the relevant state supervisor.

(d) *Termination procedures.*—(1) *Notice and hearing.* Except as otherwise provided in paragraph (d)(3) of this section, an order issued under this section shall be issued only after notice to the relevant state supervisor and the foreign bank and an opportunity for a hearing.

(2) *Procedures for hearing.* Hearings under this section shall be conducted pursuant to the Board's Rules of Practice for Hearings (12 CFR part 263).

(3) *Expedited procedure.* The Board may act without providing an opportunity for a hearing if it determines that expeditious action is necessary in order to protect the public interest. When the Board finds that it is necessary to act without providing an

opportunity for a hearing, the Board may, solely in its discretion, provide the foreign bank that is the subject of the termination order with notice of the intended termination order, grant the foreign bank an opportunity to present a written submission opposing issuance of the order, or take any other action designed to provide the foreign bank with notice and an opportunity to present its views concerning the order.

(e) *Termination of federal branch or federal agency.* The Board may transmit to the Comptroller a recommendation that the license of a federal branch or federal agency be terminated if the Board has reasonable cause to believe that the foreign bank or any affiliate of the foreign bank has engaged in conduct for which the activities of a state branch or state agency may be terminated pursuant to this section.

(f) *Voluntary termination.* A foreign bank shall notify the Board at least 30 days prior to terminating the activities of any office. Notice pursuant to this paragraph is in addition to, and does not satisfy, any other federal or state requirements relating to the termination of an office or the requirement for prior notice of the closing of a branch pursuant to section 39 of the FDIA (12 U.S.C. 1831p).

§211.27 Examination of offices and affiliates of foreign banks.

(a) *Conduct of examinations.* The Board may examine any branch, agency, or representative office of a foreign bank, any commercial lending company or bank controlled by one or more foreign banks or one or more foreign companies that control a foreign bank, and any other office or affiliate of a foreign bank conducting business in any state.

(b) *Coordination of examinations.* To the extent possible, the Board shall coordinate its examinations of the U.S. offices and U.S. affiliates of a foreign bank with the appropriate supervisory authorities, including simultaneous examinations of such U.S. offices and U.S. affiliates of a foreign bank.

(c) *Annual on-site examinations.* Each branch, agency, or commercial lending company subsidiary of a foreign bank shall be examined at least once during each 12-month period (beginning on the date the most recent examination of the office ended) by the Board or an appropriate supervisory authority.

(d) *Examination of representative offices.* Representative offices shall be examined in the manner and with the frequency determined by the Board.

(e) *Definition.* For purposes of this section, *appropriate supervisory authorities* means the Federal Deposit Insurance Corporation, if an office or affiliate of a foreign bank accepts or maintains insured deposits; the Comptroller, if an office or affiliate of a foreign bank is licensed by the Comptroller; and the relevant state supervisor, if the office or affiliate of a foreign bank is state-licensed.

§211.28 Disclosure of supervisory information to foreign supervisors.

(a) *Disclosure by Board.* The Board may disclose information obtained in the course of exercising its supervisory or examination authority to a foreign bank regulatory or supervisory authority if the Board determines that disclosure is appropriate for bank supervisory or regulatory purposes and will not prejudice the interests of the United States.

(b) *Confidentiality requirement.* Before making any disclosure of information pursuant to paragraph (a) of this section, the Board shall obtain, to the extent necessary, the agreement of the foreign bank regulatory or supervisory authority to maintain the confidentiality of such information to the extent possible under applicable law.

§211.29 Limitation on loans to one borrower.

The total loans and extensions of credit by all the state branches and state agencies of a foreign bank outstanding to a single borrower at one time shall be aggregated with the total loans and extensions of credit by all federal branches and federal agencies of the same foreign bank outstanding to such borrower at the same time and shall be subject to the limitations and other provisions of section 5200 of the Revised Statutes (12 U.S.C. 84), and the regulations promulgated thereunder, in the same manner that extensions of credit by a federal branch or federal agency are subject to section 4(b) of the IBA (12 U.S.C. 3102(b)).

§211.30 Deposit insurance requirement for retail deposit taking by foreign banks.—[Reserved]

PART 225—BANK HOLDING COMPANIES AND CHANGE IN BANK CONTROL

1. The authority citation for 12 CFR part 225 continues to read as follows:

Authority: 12 U.S.C. 1817(j)(13), 1818, 1831i, 1843(c)(8), 1844(b), 1972(l), 3106, 3108, 3907, 3909, 3310, and 3331-3351.

2. Section 225.11 is amended by adding a new paragraph (f) to read as follows:

§225.11 Transactions requiring Board approval.

* * * * *

(f) *Transactions by a foreign banking organization.* Any transaction described in paragraphs (a) through (e) of this section by a foreign banking organization that involves the acquisition of an interest in a U.S. bank or bank holding company for which application would be required if the foreign banking organization were a bank holding company.

3. Section 225.12 is amended by adding a new paragraph (f) to read as follows:

§225.12 Transactions not requiring Board approval.

* * * * *

(f) *Acquisition of a foreign banking organization.* The acquisition of a foreign banking organization where the foreign banking organization does not directly or indirectly own or control a bank in the United States, unless the acquisition is also by a foreign banking organization and otherwise subject to § 225.11(f) of this subpart.

PART 263—RULES OF PRACTICE FOR HEARINGS

1. The authority citation for 12 CFR part 263 is revised to read as follows:

Authority: 5 U.S.C. 504; 12 U.S.C. 248, 324, 504, 505, 1817(j), 1818, 1828(c), 1847(b), 1847(d), 1884(b), 1972(2)(F), 3105, 3107, 3108, 3907, 3909; 15 U.S.C. 21, 78o-4, 78o-5, and 78u-2.

2. Section 263.50 is amended by removing the word "and" at the end of paragraph (b)(7), removing the period at the end of paragraph (b)(8) and adding in its place a semi-colon, and by adding paragraphs (b)(9) and (b)(10) to read as follows:

§263.50 Purpose and scope.

* * * * *

(b)* * *

(9) Termination of the activities of a state branch, state agency, or commercial lending company subsidiary of a foreign bank in the United States, pursuant to section 7(e) of the IBA (12 U.S.C. 3105(d)); and

(10) Termination of the activities of a representative office of a foreign bank in the United States, pursuant to section 10(b) of the IBA (12 U.S.C. 3107(b)).

3. Section 263.51 is amended by removing the period at the end of paragraph (b) and adding in its place a semi-colon and by adding the following new paragraph (c) to read as follows:

§263.51 Definitions.

* * * * *

(c) *Institution* has the same meaning as that assigned to it in § 263.4, and shall also include any foreign bank with a representative office in the United States.

PART 265—RULES REGARDING DELEGATION OF AUTHORITY

1. The authority citation for 12 CFR part 265 is revised to read as follows:

Authority: Section 11 (i) and (k) of the Federal Reserve Act, (12 U.S.C. 248(i) and (k)); and sections 7(c) and 15 of the International Banking Act of 1978 (12 U.S.C. 3015(c), 3109).

2. Section 265.6 is amended by adding paragraph (b)(2) to read as follows:

§265.6 Functions delegated to General Counsel.

* * * * *

(b)* * *

(2) *Disclosure to foreign authorities.* To make the determinations required for disclosure of information to a foreign bank regulatory or supervisory authority, and to obtain, to the extent necessary, the agreement of such authority to maintain the confidentiality of such information to the extent possible under applicable law (12 CFR 211.28).

* * * * *

3. Section 265.7 is amended by adding paragraph (d)(8) to read as follows:

§265.7 Functions delegated to Director of Division of Banking Supervision and Regulation.

* * * * *

(d)* * *

(8) *Conduct and coordination of examinations.* To authorize the conduct of examinations of the U.S. offices and affiliates of foreign banks under section 7(c) and 10(c) of the IBA (12 U.S.C. 3105(b), 3107(c)), and where appropriate to coordinate those examinations with examinations of the Office of the Comptroller of the Currency, the Federal Deposit Insurance Corporation, and the relevant state supervisors.

* * * * *

Board of Governors of the Federal Reserve System, April 9, 1992.

William W. Wiles,

Secretary of the Board.

[FR Doc. 92-8661 Filed 4-14-92 8:45 am]

BILLING CODE 6210-01-F

12 CFR Part 225

[Docket No. R-0755]

Regulation Y—Review Criteria for Bank Holding Company Applications

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Interim rule with request for comments.

SUMMARY: The Board is publishing for comment an amendment to its Regulation Y, which governs bank holding companies and foreign banking organizations with operations in the United States, to implement certain regulatory improvements contained in the Federal Deposit Insurance Corporation Improvement Act of 1991. The proposed amendment specifies additional factors that the Federal Reserve System must consider in acting on applications submitted under the Bank Holding Company Act to acquire a bank. The intended effect of the amendment is to conform the Board's Regulations to the statutory changes.

DATES: *Effective Date.* This interim rule is effective April 15, 1992. *Comment Date.* Comments should be received on or before June 15, 1992.

ADDRESSES: Comments, which should refer to Docket No. R-0755, may be mailed to the Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue, NW., Washington, DC 20551, to the attention of Mr. William W. Wiles, Secretary. Comments addressed to the attention of Mr. Wiles may be delivered to the Board's mail room between 8:45 a.m. and 5:15 p.m., and to the security control room outside of those hours. Both the mail room and the security control room are accessible from the courtyard entrance on 20th Street between Constitution Avenue and C Street, NW. Comments may be inspected in room B-1122 between 9 a.m. and 5 p.m., except as provided in § 261.8 of the Board's Rules Regarding the Availability of Information, 12 CFR 261.8.

FOR FURTHER INFORMATION CONTACT: Scott G. Alvarez, Associate General Counsel (202-452-3583), or Brian E.J. Lam, Attorney (202-452-2067), Legal Division; or Sidney M. Sussan, Assistant Director (202-452-2638), Division of Banking Supervision and Regulation. For the hearing impaired *only*, Telecommunications Device for the Deaf, Dorothea Thompson (202-452-3544).

SUPPLEMENTARY INFORMATION: The Board is implementing an interim rule and requesting public comment on revisions to its Regulation Y concerning the factors the Board must consider in reviewing and acting on applications by bank holding companies to acquire banks under section 3 of the Bank Holding Company Act. The changes are required by amendments made to the Bank Holding Company Act ("BHC Act") by the Federal Deposit Insurance Corporation Improvement Act of 1991 ("FDICI Act"), and conform the criteria set forth in the Board's regulations for evaluating such bank applications to the statutory requirements set forth in these amendments. Sections 202(d) and 210 of the FDICI Act, Pub. L. 102-242, 105 Stat. 2237, 2290, 2298.

The amendments enacted by the FDICI Act require the Board to disapprove any application under section 3 of the BHC Act if:

(A) The company fails to provide the Board with adequate assurances that the company will make available to the Board such information on the operations or activities of the company, and any affiliate of the company, as the Board determines to be appropriate to determine and enforce compliance with this Act; or

(B) In the case of an application involving a foreign bank, the foreign bank is not subject to comprehensive supervision or regulation on a consolidated basis by the appropriate authorities in the bank's home country. Section 202(d) of the FDICI Act, Pub. L. 102-242, 105 Stat. 2237, 2290.

These amendments also provide that the Board's consideration of the managerial resources of a company or bank "shall include consideration of the competence, experience, and integrity of the officers, directors, and principal shareholders of the company or bank." Section 210 of the FDICI Act, Pub. L. 102-242, 105 Stat. 2237, 2298.

To implement these statutory provisions, the Board proposes to amend the list of factors contained in Regulation Y that the Board considers in reviewing bank acquisition proposals.

List of Subjects in 12 CFR Part 225

Administrative practice and procedure, Banks, banking, Federal Reserve System, Holding companies, Reporting and recordkeeping requirements, Securities.

For the reasons set forth in the preamble, and pursuant to the Board's authority under section 5(b) of the Bank Holding Company Act of 1956, 12 U.S.C. 1844(b), the Board is amending 12 CFR part 225 to read as follows:

PART 225—BANK HOLDING COMPANIES AND CHANGE IN BANK CONTROL

1. The authority for part 225 continues to read as follows:

Authority: 12 U.S.C. 1817(j)(13), 1818i, 1831(i), 1843(c)(8), 1844(b), 3106, 3108, 3907, 3909, 3310, and 3331-3351.

2. Section 225.13 is amended by revising the introductory text to paragraph (a) and paragraph (b)(2), and by adding paragraphs (b)(4) and (b)(5), to read as follows:

§ 225.13 Factors considered in acting on bank applications.

(a) *Prohibited anticompetitive transactions.* As specified in section 3(c) of the BHC Act, the Board may not approve any application under this subpart if:

* * * * *

(b) * * *

(2) *Managerial Resources.* The competence, experience, and integrity of the officers, directors, and principal shareholders of the applicant, and of the banks and bank holding companies concerned; their record of compliance with laws and regulations; and the record of the applicant and its affiliates of fulfilling any commitments to, and any conditions imposed by, the Board in connection with prior applications.

* * * * *

(4) *Availability of appropriate information.* Whether the applicant has provided the Board with adequate assurances that it will make available such information on its operations or activities, and the operations or activities of any affiliate of the applicant, that the Board deems appropriate to determine and enforce compliance with the BHC Act and other applicable federal banking statutes, and any regulations thereunder.

(5) *Comprehensive supervision of foreign banks.* Whether, in the case of an application involving a foreign bank, the foreign bank is subject to comprehensive supervision or regulation on a consolidated basis by the appropriate authorities in its home country, as provided in § 211.25(c)(1) of the Board's Regulation K (12 CFR 211.25(c)(1)).

* * * * *

By order of the Board of Governors of the Federal Reserve System, April 9, 1992.

William W. Wiles,

Secretary of the Board.

[FR Doc. 92-8660 Filed 4-14-92; 8:45 am]

BILLING CODE 6210-01-F

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Parts 21 and 25

[Docket No. NM-67; Special Conditions No. 25-ANM-55]

Special Conditions: DeHavilland DHC-7-102 and 103 Airplanes; High Intensity Radiated Fields (HIRF)

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final special conditions; request for comments.

SUMMARY: These special conditions are issued for certain DeHavilland DHC-7-102 and 103 airplanes modified by Field Aviation Co., Inc. These airplanes are equipped with high-technology digital avionics systems that perform critical functions. The applicable regulations do not contain adequate or appropriate safety standards for the protection of these systems from the effects of high-intensity radiated fields (HIRF). These special conditions provide the additional safety standards that the Administrator considers necessary to ensure that the critical functions performed by these systems are maintained when the airplane is exposed to HIRF.

DATES: The effective date of these special conditions is April 1, 1992.

Comments must be received on or before June 1, 1992.

ADDRESSES: Comments may be mailed in duplicate to: Federal Aviation Administration, Office of the Assistant Chief Counsel, Attn: Rules Docket (ANM-7), Docket No. NM-67, 1601 Lind Avenue SW., Renton, Washington, 98055-4056; or delivered in duplicate to the Office of the Assistant Chief Counsel at the above address. Comments must be marked Docket No. NM-67. Comments may be inspected in the Rules Docket weekdays, except Federal holidays, between 7:30 a.m. and 4 p.m.

FOR FURTHER INFORMATION CONTACT: Gary Lium, FAA, Standardization Branch, ANM-113, Transport Standards Staff, Transport Airplane Directorate, Aircraft Certification Service, 1601 Lind Avenue SW., Renton, Washington 98055-4056; telephone (206) 227-1112.

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA has determined that good cause exists for making these special conditions effective upon issuance; however, interested persons are invited to submit such written data, views, or arguments as they may desire. Communications should identify the regulatory docket and special conditions number and be submitted in duplicate to the address specified above. All communications received on or before the closing date for comments will be considered by the Administrator. These special conditions may be changed in light of the comments received. All comments submitted will be available in the Rules Docket for examination by interested persons, both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerning this rulemaking will be filed in the docket. Persons wishing the FAA to acknowledge receipt of their comments submitted in response to this request must submit with those comments a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket No. NM-67." The postcard will be date stamped, and returned to the commenter.

Background

On December 9, 1991, Transport Canada applied to the FAA New York Aircraft Certification Office for a supplemental type certificate (STC) on behalf of Field Aviation Co., Inc. to modify certain DHC-7-102 and-103 airplanes. The DHC-7-102 and-103 are minimum two-crew, four-engine airplanes, each with a maximum takeoff weight of up to 44,000 lbs. The proposed modification incorporates the installation of an Electronic Flight Instrument System (EFIS) and additional navigation and avionic systems. The equipment originally installed in these airplanes presented the required information in the form of analog displays. The information presented is flight critical. The EFIS as a digital system is vulnerable to high-intensity radiated fields external to the airplane.

Supplemental Type Certification Basis

Under the provisions of § 21.101, Field Aviation Co., Inc. must show that the modified DHC-7-102 and-103 airplanes continue to meet the applicable provisions of the regulations incorporated by reference in Type Certificate A20EA, or the applicable regulations in effect on the date of application for the change. The regulations incorporated by reference in the type certificate are commonly referred to as the "original type certification basis."

The regulations incorporated by reference in Type Certificate No. A20EA are as follows: Part 25 of the FAR, as amended by Amendments 25-1 through

25–31; Part 36 of the FAR, as amended by Amendments 36–1 through 36–5; Special Federal Aviation Regulation (SFAR) 27, as amended by Amendments 27–1 and 27–2; and Special Conditions No. 25–53–EA–10 dated May 7, 1973. In addition, compliance has been established with the optional requirements of § 25.1419 (Ice Protection) and § 25.801 (Ditching).

If the Administrator finds that the applicable airworthiness regulations (i.e., Part 25 as amended) do not contain adequate or appropriate safety standards for the modified DHC–7–102 and –103 airplanes because of a novel or unusual design feature, special conditions are prescribed under the provisions of § 21.16 to establish a level of safety equivalent to that established by the regulations.

Special conditions, as appropriate, are issued in accordance with § 11.49 of the FAR after public notice, as required by §§ 11.28 and 11.29(b), and become part of the type certification basis in accordance with § 21.101(b)(2).

Discussion

There is no specific regulation that addresses protection requirements for electrical and electronic systems from high-intensity radiated fields (HIRF). Increased power levels from ground based radio transmitters and the growing use of sensitive electrical and electronic systems to command and control airplanes have made it necessary to provide adequate protection.

To ensure that a level of safety is achieved equivalent to that intended by the regulations incorporated by reference, these special conditions require that new technology electrical and electronic systems, such as the EFIS, be designed and installed to preclude component damage and interruption of function due to HIRF.

High-Intensity Radiated Fields (HIRF)

With the trend toward increased power levels from ground-based transmitters, plus the advent of space and satellite communication, coupled with electronic command and control of the airplane, the immunity of critical digital avionics systems, such as the EFIS, to HIRF must be established.

It is not possible to precisely define the HIRF to which the airplane will be exposed in service. There is also uncertainty concerning the effectiveness of airframe shielding for HIRF. Furthermore, coupling to cockpit installed equipment through the cockpit window apertures is undefined. Based on surveys and analysis of existing HIRF emitters, an adequate level of protection exists when compliance with the HIRF protection special condition is shown with either paragraphs 1 or 2 below:

1. A minimum threat of 100 volts per meter peak electric field strength from 10 KHz to 18 GHz.

a. The threat must be applied to the system elements and their associated wiring harnesses without the benefit of airframe shielding.

b. Demonstration of this level of protection is established through system tests and analysis.

2. A threat external to the airframe of the following field strengths for the frequency ranges indicated.

Frequency	Peak (V/M)	Average (V/M)
10–500 KHz	60	60
500–2000 KHz	80	80
2–30 MHz	200	200
30–100 MHz	33	33
100–200 MHz	150	33
200–400 MHz	56	33
400–1000 MHz	4,020	935
1–2 GHz	7,850	1,750
2–4 GHz	6,000	1,150
4–6 GHz	6,800	310
6–8 GHz	3,600	666
8–12 GHz	5,100	1,270
12–18 GHz	3,500	551
18–40 GHz	2,400	750

The envelope given in paragraph 2 above is a revision to the envelope used in previously issued special conditions in other certification projects. It is based on new data and SAE AE4R subcommittee recommendations. This revised envelope includes data from Western Europe and the U.S.

Conclusion

This action affects only certain unusual or novel design features on one model of airplane. It is not a rule of general applicability and affects only the applicant who applied to the FAA for approval of these features on the airplane.

The substance of the special conditions for this airplane has been subjected to the notice and comment procedure in several prior instances and has been derived without substantive change from those previously issued. It is unlikely that prior public comment would result in a significant change from the substance contained herein. For this reason, and because a delay would significantly affect the certification of the airplane, which is imminent, the FAA has determined that prior public notice and comment are unnecessary and impracticable, and good cause exists for adopting these special conditions immediately. Therefore, these special conditions are being made effective upon issuance. The FAA is requesting comments to allow interested persons to submit views that may not have not been submitted in response to the prior opportunities for comment described above.

List of Subjects in 14 CFR Parts 21 and 25

Air Transportation, Aircraft, Aviation, Safety.

The authority citation for these special conditions is as follows:

Authority: 49 U.S.C. 1344, 1348(c), 1352, 1354(a), 1355, 1421 through 1431, 1502, 1651(b)(2), 42 U.S.C. 1857f–10, 4321 et seq.; E.O. 11514; and 49 U.S.C. 106(g).

The Final Special Conditions

Accordingly, pursuant to the authority delegated to me by the Administrator, the following special conditions are issued as part of the supplemental type certification basis for the modified DeHavilland Canada DHC–7–102 and 103 airplanes:

1. *Protection from Unwanted Effects of High-Intensity Radiated Fields (HIRF).* Each electrical and electronic system that performs critical functions must be designed and installed to ensure that the operation and operational capability of these systems to perform critical functions are not adversely affected when the airplane is exposed to high-intensity radiated fields external to the airplane.

2. The following definition applies with respect to this special condition:

Critical Function. Function whose failure would contribute to or cause a failure condition that would prevent the continued safe flight and landing of the airplane.

Issued in Renton, Washington, on April 1, 1992.

Leroy A. Keith,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 92–8675 Filed 4–14–92; 8:45 am]

BILLING CODE 4910–13–M

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14 CFR Part 39

[Docket No. 91–CE–86–AD; Amendment 39–8218; AD 92–08–07]

Airworthiness Directives; Beech 33, 35, and 36 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment supersedes Airworthiness Directive (AD) 91–14–13, which currently requires initial and repetitive inspections of the wing front spar carry-through frame structure for cracks on certain Beech 33, 35, and 36 series airplanes, and repair or

reinforcement if found cracked. The Federal Aviation Administration (FAA) has determined that the available service history justifies the requirement for the initial inspection, but that the repetitive inspection requirement should be based on the results of the fleet-wide initial inspection. Therefore, this action will retain the initial inspection required by AD 91–14–13, and will require a report to the FAA on the results of the one-time inspection to determine whether additional rulemaking is necessary. The actions specified by this AD are intended to prevent structural damage to the wing that could progress to the point of failure.

DATES: Effective May 18, 1992.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of May 18, 1992.

ADDRESSES: Service information that is applicable to this AD may be obtained from the Beech Aircraft Corporation, P.O. Box 85, Wichita, Kansas 67201–0085. This information may also be examined at the FAA, Central Region, Office of the Assistant Chief Counsel, room 1558, 601 E. 12th Street, Kansas City, Missouri 64106; or at the Office of the Federal Register, 1100 L Street, NW., room 8401, Washington DC.

FOR FURTHER INFORMATION CONTACT: Mr. Larry Engler, Aerospace Engineer, Wichita Aircraft Certification Office, 1801 Airport Road, room 100, Mid-Continent Airport, Wichita, Kansas 67209; Telephone (316) 946–4122; Facsimile (316) 946–4407.

SUPPLEMENTARY INFORMATION: A proposal to amend part 39 of the Federal Aviation Regulations to include an AD that is applicable to certain Beech 33, 35, and 36 series airplanes was published in the Federal Register on January 3, 1992 (57 FR 237). The action proposed to supersede AD 91–14–13, Amendment 39–7054, with a new AD that would (1) Retain the inital inspection of the wing front spar carry-through web structure for cracks and the repair or reinforcement of structures found cracked that is currently required by AD 91–14–13; and (2) require a reporting requirement of this initial requirement to help the FAA determine whether additional rulemaking should be initiated. The inspection and possible repair/reinforcement actions would be done in accordance with Beech Service Bulletin No. 2360, dated November 1990. The repetitive inspections that are currently required by AD 91–14–13 would no longer be required.

Interested persons have been afforded an opportunity to participate in the making of this amendment. No comments were received on the proposed rule or the FAA's determination of the cost to the public. After careful review, the FAA has determined that air safety and the public interest require the adoption of the rule as proposed except for minor rewrites that provide clarification of the criteria for the possible repair required by the initial inspection. The FAA has determined that these minor rewrites will not change the meaning of the AD nor add any additional burden upon the public than was already proposed.

The FAA estimates that 11,000 airplanes in the U.S. registry will be affected by this AD, that it will take approximately 8 workhours per airplane to accomplish the required action, and that the average labor rate is approximately $55 an hour. Based on these figures, the total cost impact of the AD on U.S. operators is estimated to be $4,840,000. The above cost analysis is the same as AD 91–14–13, which will be superseded by this AD. There would be additional cost impact on U.S. operators by this proposed action than that which is currently required by AD 91–14–13.

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

For the reasons discussed above, I certify that this action: (1) Is not a "major rule" under Executive Order 12291; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the final evaluation prepared for this action is contained in the Rules Docket. A copy of it may be obtained by contracting the Rules Docket at the location provided under the caption **"ADDRESSESS".**

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

Authority: 49 U.S.C. 1354(a), 1421 and 1423; 49 U.S.C. 106(g); and 14 CFR 11.89.

§ 39.13 [Amended]

2. Section 39.13, is amended by removing AD 91–14–13, Amendment 39–7054 (56 FR 31324, July 10, 1991), and adding the following new AD:

92–08–07 Beech: Amendment 39–8218; Docket No. 91–CE–86–AD. Supersedes AD 91–14–13, Amendment 39–7054.

Applicability: Applies to the following Models and serial numbered airplanes, certificated in any category.

Models	Serial Numbers
35–33, 35–A33, 35–B33, 35–C33, E33, F33, and G33.	CD–1 through CD–1304.
35–C33A, E33A, and F33A	CE–1 through CE–1192.
E33C and F33C	CJ–1 through CJ–179.
H35, J35, K35, M35, N35, P35, S35, V35, V35A, and V35B.	D–4866 through D–10403.
36 and A36	E–1 through E–2397.
A36TC and B36TC	EA–1 through EA–471.

Compliance: Required as indicated after the effective date of this AD, unless already accomplished.

To prevent structural damage to the wing that could progress to the point of failure, accomplish the following:

(a) Upon the accumulation of 1,500 hours time-in-service (TIS), or within the next 100 hours TIS, whichever occurs later, unless already accomplished (AD 91–14–13, Amendment 7054), inspect the wing front spar carry-through frame (web) structure for cracks in accordance with the instructions in Beech Service Bulletin (SB) No. 2360, dated November 1990.

(b) If cracks are found in the bend radius and not in the web face in the areas of the huckbolt fasteners as a result of the inspection required in paragraph (a) of this AD, accomplish the following accordance with instructions in Beech SB No. 2360:

(1) For cracks up to 2.25 inches, accomplish one of the following as applicable:

(i) If not more than one crack on either side of the wing forward spar carry-through frame structure bend radius is found, prior to further flight, stop drill each crack at the crack ends. Within the next 200 hours TIS and thereafter at intervals not to exceed 200 hours TIS, reinspect each crack for progression and repair accordingly. These repetitive inspections may be discontinued upon the installation of the applicable P/N 36–4004 Kit.

(ii) If more than one crack is found on either side of the wing forward spar carry-

through frame structure bend radius, prior to further flight, install the applicable Beech P/N 36–4004 Kit.

(2) For cracks between 2.25 and 4.0 inches, accomplish one of the following as applicable:

(i) If not more than one crack on either side of the wing forward spar carry-through frame structure bend radius is found, prior to further flight, stop drill each crack at the crack ends, and within the next 100 hours TIS, install the applicable Beech P/N 36–4004 Kit.

(ii) If more than one crack is found on either side of the wing forward spar carry-through frame structure bend radius, prior to further flight, install the applicable P/N 36–4004 Kit.

(3) For cracks exceeding 4.0 inches, prior to further flight, install the applicable Beech P/N 36–4004 Kit.

(c) If cracks are found in the web face in the area of the heckbolt fasteners but not in the bend radius as a result of the inspections required in paragraph (a) of this AD, accomplish the following in accordance with the instructions in Beech SB No. 2360, but do not stop drill the cracks because it is possible to damage the structure behind the web face:

(1) For cracks less than 1.0 inch in length, accomplish one of the following as applicable:

(i) If not more than one crack on either side of the wing forward spar carry-through frame structure web face is found, within the next 200 hours TIS and thereafter at intervals not to exceed 200 hours TIS, reinspect each crack for progression and repair accordingly. These repetitive inspections may be discontinued upon the installation of the applicable P/N 36–4004 Kit.

(ii) If more than one crack is found on either side of the wing forward spar carry-through frame structure web face, prior to further flight, install the applicable Beech P/N 36–4004 Kit.

(2) For cracks more than 1.0 inch in length, accomplish one of the following as applicable:

(i) If not more than one crack on either side of the wing forward spar carry-through frame structure web area is found, within the next 25 hours TIS, install the applicable Beech P/N 36–4004 Kit.

(ii) If more than one crack is found on either side of the wing forward spar carry-through frame structure bend radius, prior to further light, install the applicable Beech P/N 36–4004 Kit.

(3) If a crack passes through two fasteners but is less than 0.5 inches beyond fastener, accomplish one of the following as applicable:

(i) If not more than one crack on either side of the wing forward spar carry-through frame structure web area is found, within the next 25 hours TIS, install the applicable Beech P/N 36–4004 Kit.

(ii) If more than one crack is found on either side of the wing forward spar carry-through frame structure bend radius, prior to further flight, install the applicable Beech P/N 36–4004 Kit.

(4) If a crack passes through two fasteners but is more than 0.5 inches beyond either fastener, prior to further flight, install the applicable Beech P/N 36–4004 Kit.

(d) If cracks are found in both the web face in the area of the huckbolt fasteners and the bend radius as a result of the inspections required in paragraph (a) of this AD, accomplish the following in accordance with the instructions in Beech SB No. 2360:

(1) If only one crack is found on either side of the airplane, repair each crack in accordance with the criteria and instructions in paragraphs (b)(1) through (b)(3) or (c)(1) through (c)(4) of this AD, as applicable.

(2) If more than one crack is found on either side of the airplane, accomplish one of the following as applicable:

(i) For any crack that is 1.0 inch or more in length, prior to further flight, install the applicable Beech P/N 36–4004 Kit.

(ii) For any crack under 1.0 inch in length, within the next 200 hours TIS and thereafter at intervals not to exceed 200 hours TIS, reinspect each crack for progression and repair accordingly. These repetitive inspections may be discontinued upon the installation of the applicable P/N 36–4004 Kit.

(e) If a fuselage skin crack is found around the opening for the lower forward carry-through fitting, prior to further flight, obtain repair instructions from the manufacturer through the Wichita Aircraft Certification Office at the address specified in paragraph (g) of this AD.

(f) Send the results of each inspection in writing to the Manager, Wichita Aircraft Certification Office, FAA, 1801 Airport Road, room 100, Wichita, Kansas 67209, within 10 days after the inspection or 15 days after the effective date of this AD, whichever occurs later. State whether cracks, were found, the location and length of any cracks, and the total hours TIS of the component at the time the crack was discovered. The form presented as Figure 1 of this AD may be used. (Reporting approved by the Office of Management and Budget under OMB No. 2120–0056).

Figure I

Reporting Form

Date of inspection:
Airplane serial number:
Total airplanes hours time-in-service:
Were cracks found as a result of the inspection?
If so, provide the following information:

1. Crack locations (Refer to Beech Service Bulletin No. 2360).
2. Length of cracks (Refer to applicable paragraph in Beech Service Bulletin No. 2360).
3. Was a Beech kit installed?

(g) Special flight permits may be issued in accordance with FAR 21.197 and 21.199 to operate airplanes to a location where the requirements of this AD can be accomplished.

(h) An alternative method of compliance or adjustment of the initial or repetitive compliance times that provides an equivalent level of safety may be approved by the Manager, Wichita Aircraft Certification Office, FAA, 1801 Airport Road, room 100, Wichita, Kansas 67209. The request should be forwarded through an appropriate FAA Maintenance Inspector, who may add comments and send it to the Manager, Wichita Aircraft Certification Office.

Note: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Wichita Aircraft Certification Office.

(i) The inspection and possible repair/reinforcement required by this AD shall be done in accordance with Beech Service Bulletin SB No. 2360, dated November 1990. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the Beech Aircraft Corporation, P.O. Box 85, Wichita, Kansas 67201–0085. Copies may be inspected at the FAA, Central Region, Office of the Assistant Chief Counsel, room 1558, 601 E. 12th Street, Kansas City, Missouri, or at the Office of the Federal Register, 1100 L Street, NW., room 8401, Washington, DC.

(j) This amendment (39–8218) supersedes AD 91–14–13, Amendment 39–7054.

(k) This amendment (39–8218) becomes effective on May 18, 1992.

Issued in Kansas City, Missouri, on March 25, 1992.

Richard F. Yotter,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 92–8603 Filed 4–14–92; 8:45 am]

BILLING CODE 4910–13–M

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14 CFR Part 39

[Docket No. 91–CE–71–AD; Amendment 39–8215; AD 92–08–04]

Airworthiness Directives; Piper Aircraft Corporation PA34 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment supersedes Airworthiness Directive (AD) 90–17–04, which currently requires the replacement of the rudder torque tube fitting and attaching hardware on Piper PA34 series airplanes. Parts are currently not available to accomplish the modification required by AD 90–17–04. This action will allow continued operation of the affected airplanes until parts become available provided repetitive inspections are performed. The actions specified by this AD are intended to prevent failure of the torque tube fitting and possible loss of rudder control while also preventing inadvertent grounding of the affected airplanes.

DATES: Effective May 15, 1992.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of May 15, 1992.

ADDRESSES: Service information that is applicable to this AD may be obtained from the Piper Aircraft Corporation, Customer Services, 2926 Piper Drive, Vero Beach, Florida 32960. This information may also be examined at the Federal Aviation Administration (FAA), Central Region, Office of the Assistant Chief Counsel, room 1558, 601 E. 12th Street, Kansas City, Missouri 64106; or at the Office of the Federal Register, 1100 L Street NW., room 8401, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Mr. David Cundy, Aerospace Engineer, FAA, Atlanta Aircraft Certification Office, 1669 Phoenix Parkway, Suite 210C, Atlanta, Georgia 30349; Telephone (404) 991–2910; Facsimile (404) 991–3606.

SUPPLEMENTARY INFORMATION: A proposal to amend part 39 of the Federal Aviation Regulations to include an AD that is applicable to certain Piper PA34 series airplanes was published in the Federal Register on November 27, 1991 (56 FR 60076). The action proposed to supersede AD 90–17–04 with a new AD that would: (1) Retain the one-time inspection of the steel rudder torque tube fittings and the replacement of any aluminum rudder torque tube fitting with one made of steel in accordance with Piper Service Bulletin No. 899, dated February 10, 1989; or (2) would authorize continued operation of the airplane if parts are not available provided that (1) The airplane operator has ordered the parts from the manufacturer; (b) the airplane operator performs repetitive inspections (at intervals not to exceed 50 hours time-in-service) of the aluminum rudder torque tube fitting; and (c) cracked or corroded aluminum rudder torque tube fittings are replaced.

Interested persons have been afforded an opportunity to participate in the making of this amendment. No comments were received on the proposed rule or the FAA's determination of the cost to the public. After careful review, the FAA has determined that air safety and the public interest require the adoption of the rule as proposed except for minor editorial corrections. The FAA has determined that these minor corrections will not change the meaning of the AD nor add any additional burden upon the public than was already proposed.

The FAA estimates that 2,500 airplanes in the U.S. registry will be affected by this AD, that it will take approximately 4 hours per airplane to accomplish the required action, and that the average labor rate is approximately $55 an hour. Parts cost approximately $150 per airplane. Based on these figures, the total cost impact of the AD on U.S. operators is estimated to be $925,000. The above cost analysis is the same as AD 90–17–04, which will be superseded by this AD. This action will provide an alternative method that will avoid the impact associated with removing the affected airplanes from service if replacement parts are not immediately available.

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

For the reasons discussed above, I certify that this action (1) Is not a "major rule" under Executive Order 12291; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the final evaluation prepared for this action is contained in the Rules Docket. A copy of if may be obtained by contacting the Rules Docket at the location provided under the caption **"ADDRESSES"**.

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

Authority: 49 U.S.C. 1354(a), 1421 and 1423; 49 U.S.C. 106(g); and 14 CFR 11.89.

§ 39.13 [Amended]

2. Section 39.13 is amended by removing AD 90–17–04, Amendment 39–6674 (55 FR 3238, August 9, 1990), and adding the following new AD:

92–08–04 Piper Aircraft Corporation: Amendment 39–8215; Docket No. 91–CE–71–AD. Supersedes AD 90–17–04, Amendment 39–6674.

Applicability: Model PA34–200 airplanes (serial numbers (S/N) 34–7250001 through 34–7450220), Model PA34–200T airplanes (S/N 34–7570001 through 34–8170092), and Model PA34–220T airplanes (S/N 34–8133001 through 34–8533012), certificated in any category.

Compliance: Required as indicated, unless already accomplished.

To prevent failure of the torque tube fitting and possible loss of rudder control, accomplish the following:

(a) Within the next 50 hours time-in-service (TIS) after September 14, 1990 (the effective date of AD 90–17–04, Amendment 39–6674), inspect to determine whether the rudder torque tube fitting is steel or aluminum.

(1) If steel, inspect for proper attachment, and check the bolt torque in accordance with the criteria and instructions in Piper Service Bulletin (SB) No. 899, dated February 10, 1989. If fitting is improperly attached and bolt torque is incorrect, prior to further flight, properly attach fitting and torque to proper criteria as specified in and in accordance with the instructions in Piper SB No. 899, dated February 10, 1989.

(2) If aluminum, prior to further flight, replace with steel fitting in accordance with the instructions in Piper SB No. 899, dated February 10, 1989.

(b) If the steel fitting required by paragraph (a)(2) do this AD has been ordered but is not available, prior to further flight, accomplish the following:

(1) Visually inspect the aluminum fitting for corrosion. If any evidence of corrosion is found, remove and treat the corroded area in accordance with AC 43–13.1A.

(2) Dye penetrant inspect the aluminum fitting for cracks. If found cracked, replace with an aluminum fitting found to be free from cracks and corrosion.

(3) Visually inspect the aluminum fitting for proper attachment, cracks, and corrosion at intervals not to exceed 50 hours TIS.

(i) If fitting is found improperly attached or hardware is found loose, properly attach fitting in accordance with the instructions in Piper SB No. 899, dated February 10, 1989.

(ii) If any evidence of corrosion is found, remove and treat the corroded area in accordance with AC 43–13.1A.

(iii) If found cracked, replace with aluminum fitting found to be free from cracks and corrosion in accordance with the installation instructions in Piper SB No. 899, dated February 10, 1989.

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

(d) An alternative method of compliance or adjustment of the initial or repetitive compliance times that provides an equivalent level of safety may be approved by the Manager, Atlanta Aircraft Certification Office, 1669 Phoenix Parkway, Suite 210C, Atlanta, Georgia 30349. The request should be forwarded through an appropriate FAA Maintenance Inspector, who may add comments and then send it to the Manager, Atlanta Aircraft Certification Office.

Note: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be

obtained from the Atlanta Aircraft Certification Office.

(e) The checks and installations required by this AD shall be done in accordance with Piper Service Bulletin No. 899, dated February 10, 1989. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the Piper Aircraft Corporation, Customer Services, 2926 Piper Drive, Vero Beach, Florida 32960. Copies may be inspected at the FAA, Central Region, Office of the Assistant Chief Counsel, room 1558, 601 E. 12th Street, Kansas City, Missouri, or at the Office of the Federal Register, 1100 L Street, NW., room 8401, Washington, DC.

(f) This amendment (39–8215) supersedes AD 90–17–04, Amendment 39–6674.

(g) This amendment (39–8215 becomes effective on May 15, 1992.

Issued in Kansas City, Missouri, on March 24, 1992.

Richard F. Yotter,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 92–8606 Filed 4–14–92; 8:45 am]

BILLING CODE 4910–13–M

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14 CFR Part 39

[Docket No. 92–NM–61–AD; Amendment 39–8220; AD 92–08–09]

Airworthiness Directives; Airbus Industrie Model A320 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule; request for comments.

SUMMARY: This amendment adopts a new airworthiness directive (AD) that is applicable to certain Airbus Industrie Model A320 series airplanes. This action requires replacement of the hoses connecting the pitot probes to the air data modules (ADM) with shorter hoses. This amendment is prompted by a recent report of a discrepancy that was noted, during flight, between the captain's and the first officer's airspeed indicators. The actions specified in this AD are intended to prevent unsafe airspeeds.

DATES: Effective April 30, 1992.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of April 30, 1992.

Comments for inclusion in the Rules Docket must be received on or before June 15, 1992.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–103, Attention: Rules Docket No. 92–NM–61–AD, 1601 Lind Avenue SW., Renton, Washington 98055–4056.

The service information referenced in this AD may be obtained from Airbus Industrie, Airbus Support Division, Avenue Didier Daurat, 31700 Blagnac, France. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, Washington; or at the Office of the Federal Register, 1100 L Street NW., room 8401, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Mr. Greg Holt, Aerospace Engineer, Standardization Branch, ANM–113, FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, Washington, 98055–4056; telephone (206) 227–2140; fax (206) 227–1320.

SUPPLEMENTARY INFORMATION: The Direction Générale de l'Aviation Civile (DGAC), which is the airworthiness authority for France, recently notified the FAA that an unsafe condition may exist on certain Airbus Industrie Model A320 series airplanes. The DGAC advises that an operator of these airplanes recently reported that a discrepancy of approximately 15 knots between the captain's and the first officer's airspeed indicators was noted during flight. Investigation revealed that the hoses connecting the captain's and first officer's pitot probes with the air data modules (ADM) on these airplanes appear excessively long. Consequently, a low point could occur in the hose, causing water to accumulate between the pitot tubes and ADM. This could affect the pressure monitoring of the ADM, and could lead to inaccurate airspeed indications. This condition, if not corrected, could result in unsafe airspeeds.

Airbus Industrie has issued Service Bulletin A320–34–1024, Revision 3, dated December 13, 1991, that describes procedures for replacement of the hoses connecting the pitot probes to the ADM with shorter hoses. The DGAC classified this service bulletin as mandatory and issued French Airworthiness Directive 91–227–021(B)R1 in order to assure the continued airworthiness of these airplanes in France.

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

Since an unsafe condition has been identified that is likely to exist or develop on other airplanes of the same type design registered in the United States, this AD is being issued to prevent unsafe airspeeds. This AD requires replacement of the hoses connecting the pitot probes to the ADM with shorter hoses. The actions are required to be accomplished in accordance with the service bulletin described previously.

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

Comments Invited

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

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

Commenters wishing 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 92–NM–61–AD." The

postcard will be date stamped and returned to the commenter.

The regulations adopted herein will 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 final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

The FAA has determined that this regulation is an emergency regulation and that it is not considered to be major under Executive Order 12291. It is impracticable for the agency to follow the procedures of Order 12291 with respect to this rule since the rule must be issued immediately to correct an unsafe condition in aircraft. It has been determined further that this action involves an emergency regulation under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979). If it is determined that this emergency regulation otherwise would be significant under DOT Regulatory Policies and Procedures, a final regulatory evaluation will be prepared and placed in the Rules Docket. A copy of it, if filed, may be obtained from the Rules Docket at the location provided under the caption "ADDRESSES."

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

Authority: 49 U.S.C. 1354(a), 1421 and 1423; 49 U.S.C. 106(g); and 14 CFR 11.89.

39.13 [Amended]

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

92-08-09. Airbus Industrie: Amendment 39-8220. Docket 92-NM-61-AD.

Applicability: Model A320 series airplanes; manufacturer's serial numbers 002 through 122, 124 through 179, 183 through 194, 196 through 288, 230 through 245, and 247 through 255; on which the modification specified in Airbus Industrie Service Bulletin A320-34-1024, Revision 3, dated December 13, 1991, has not been accomplished; certificated in any category.

Compliance: Required as indicated, unless accomplished previously.

To prevent unsafe airspeeds, accomplish the following:

(a) Within 30 days after the effective date of this AD, replace the hoses connecting the pitot probes to the air data modules with shorter hoses, in accordance with Airbus Industrie Service Bulletin A320-34-1024, Revision 3, dated December 13, 1991.

(b) An alternative method of compliance or adjustment of the compliance time, which provides an acceptable level of safety, may be used when approved by the Manager, Standardization Branch, ANM-113, FAA, Transport Airplane Directorate. The request shall be forwarded through an FAA Principal Maintenance Inspector, who may concur or comment and then send it to the Manager, Standardization Branch, ANM-113.

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

(d) The replacement shall be done in accordance with Airbus Industrie Service Bulletin A320-34-1024, Revision 3, dated December 13, 1991. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C 552(a) and 1 CFR Part 51. Copies may be obtained from Airbus Industrie, Airbus Support Division, Avenue Didier Daurat, 31700 Blagnac, France. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, Washington; or at the Office of the Federal Register, 1100 L Street NW., room 8401, Washington, DC.

(e) This amendment becomes effective on April 30, 1992.

Issued in Renton, Washington, on March 30, 1992.

Darrell M. Pederson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 92-8721 Filed 4-14-92; 8:45 am]

BILLING CODE 4910-13-M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Part 271

[Docket No. RM91-8-000 Order No. 539]

Qualifying Certain Tight Formation Gas for Tax Credit

Issued April 9, 1992

AGENCY: Federal Energy Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Federal Energy Regulatory Commission (Commission) is issuing a final rule amending its current tight formation regulations by applying the existing maximum allowable production rate of 2,557 Mcf of gas per day for depths from 14,500 feet to 15,000 feet to all depths greater than 15,000 feet. The Final Rule also clarifies the permeability standard contained in the Commission's tight formation regulations by determining that the Commission will continue its existing practice of using only the arithmetic averaging method in reviewing permeability data contained in tight formation recommendations.

EFFECTIVE DATE: May 15, 1992.

FOR FURTHER INFORMATION CONTACT: Sandra Elliott, Office of the General Counsel, Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426. (202) 208-0694.

SUPPLEMENTARY INFORMATION: In addition to publishing the full text of this document in the **Federal Register**, the Commission also provides all interested persons an opportunity to inpsect or copy the contents of this document during normal business hours in room 3308, 941 North Capitol Street NE., Washington, DC.

The Commission Issuance Posting System (CIPS), an electronic bulletin board service, provides access to the texts of formal documents issued by the Commission. CIPS is available at no charge to the user and may be accessed using a personal computer with a modem by dialing (202) 208-1397. To access CIPS, set your communications software to use 300, 1200 or 2400 baud, full duplex, no parity, 8 data bits, and 1 stop bit. The full text of this notice will be available on CIPS for 30 days from the date of issuance. The complete text on diskette in WordPerfect format may also be purchased from the Commission's copy contractor, La Dorn Systems Corporation, also located in room 3308, 941 North Capitol Street, NE., Washington, DC 20426.

Before Commissioners: Martin L. Allday, Chairman; Charles A. Trabandt, Elizabeth Anne Moler, Jerry J. Langdon and Branko Terzic.

I. Introduction

The Commission issued a Notice of Proposed Rulemaking (NOPR) in this proceeding on March 20, 1991,[1] proposing three minor amendments to the Commission's regulations to carry out Congress' intent in restoring the tax credit for gas produced from newly drilled tight formation wells. These amendments were proposed as a result

[1] 56 FR 13094 (Mar. 29, 1991), IV FERC Stats. & Regs. ¶32,479.

of the provisions of the Revenue Reconciliation Act of 1990,[2] extending the tax credit for nonconventional fuels under Section 29 of the Internal Revenue Code, and revising the terms of eligibility so that tight formation gas is eligible for the tax credit even though the price for such gas is no longer regulated. On February 6, 1992, the Commission also issued a Request for Additional Comments [3] in this proceeding, seeking comments concerning the proper averaging methodology for establishing the permeability of a tight formation.

Comments have been received and considered, and in view of those comments and further analysis, the Commission has concluded that the proposed amendment extending maximum allowable production rates to below 15,000 feet, should be adopted, with revisions, for the reasons discussed below. However, the proposed amendment requiring the exclusion of a tight formation subject to a prior infill drilling order unless the tax credit is needed to develop the formation, and the proposed amendment to permit qualification of formations that do not meet the permeability standard if the tax credit is needed to warrant production, are not appropriate, and will not be adopted. Additionally, the Commission has concluded that it will continue to use an arithmetic averaging method to determine the permeability of a tight formation.

II. Background

Section 107(b) of the Natural Gas Policy Act of 1978 (NGPA) authorizes the Commission, by rule or order, to prescribe a maximum lawful price for first sales of high-cost natural gas, which exceeds the otherwise applicable maximum lawful price, if the Commission determines that a "special price is necessary to provide reasonable incentives for the production of such high-cost natural gas." NGPA section 107(c) defines high-cost natural gas; paragraphs (1) through (4) of section 107(c) specifically identify four types of gas that shall be considered high-cost gas. In addition, paragraph (5) of NGPA section 107 permits the Commission to define as high-cost natural gas, gas that is "produced under such other conditions as the Commission determines to present extraordinary risks or costs."

In Order Nos. 99 and 99–A,[4] the Commission exercised its authority under NGPA sections 107 (b) and (c)(5) to define gas produced from tight formations as high-cost gas and to establish an incentive ceiling price for that gas. The Commission established certain general criteria which an area must meet in order to be designated as a tight formation. The Commission also set forth procedures for the designation of specific areas as tight formations. Under those procedures, "jurisdictional agencies" [5] would make recommendations that certain areas be designated as tight formations. Once the Commission received a recommendation, it would then approve or disapprove the recommendation pursuant to its general rulemaking authority under NGPA section 501, rather than using the specific procedures set forth in NGPA section 503 for Commission review of jurisdictional agency well category determinations. However, in *Williston Basin Interstate Pipeline Co. v. FERC*,[6] the U.S. Court of Appeals for the District of Columbia Circuit held that jurisdictional agency tight formation determinations must be reviewed only through the procedural scheme set forth in NGPA section 503, rather than under the commission's broad rulemaking power under NGPA section 501. However, the court's decision left undisturbed the general criteria promulgated in Order Nos. 99 and 99–A for determining whether a particular formation is a tight formation.

In Order No. 519,[7] issued February 12, 1990, the Commission terminated the incentive ceiling price for sales of tight formation natural gas produced from wells spudded or recompleted after May 12, 1990. However, in the Revenue Reconciliation Act of 1990, extending the tax credit for nonconventional fuels under section 29 of the Internal Revenue Code, Congress made tight formation gas eligible for the tax credit even though the price for such gas is no longer regulated. The Commission then issued the March 20 NOPR to amend its tight formation regulations to allow producers to take full advantage of the tax credit.

Section 271.703 of the Commission's regulations, as adopted by Order Nos. 99 and 99–A, provides that a formation must meet three guidelines to qualify as a tight formation: a permeability standard, a maximum production rate for gas, and an oil production limit. In the NOPR, the Commission proposed to amend § 271.703(c)(2)(i)(B) of its regulations [8] to establish maximum stabilized production rates for gas from formations with an average depth of more than 15,000 feet.[9] The price of gas produced from below 15,000 feet was deregulated on November 1, 1979, and was thus not subject to a price ceiling. Therefore, the Commission never established maximum production rates for formations below that depth, because there was no point in qualifying gas from such formations for an incentive price (*i.e.* a higher ceiling price) when such gas was not subject to any ceiling price whatsoever. However, now that the tax credit is available for tight formation gas that is not subject to a ceiling price, it is appropriate to amend the regulations so that tight formations from below 15,000 feet may qualify for the tax credit.

The proposed maximum stabilized production rates below 15,000 feet were based on the same formula used to establish maximum rates down to that depth. Based on that formula, the Commission proposed maximum allowable production levels down to a depth of 19,500 feet. The Commission then proposed that the maximum allowable production for depths of 19,500 feet apply to all depths greater than 19,500 feet. The maximum allowable rate proposed in the NOPR was for formations 19,500 feet and deeper, because very little gas is produced from below 20,000 feet, and the proposed maximum for 19,500 feet was believe to be adequate measure of tight formation production rates from any lower depths.

The Commission also proposed to amend § 271.703(c)(2)(ii). That section currently provides that a jurisdictional agency may designate as a tight formation a formation that does not meet the 0.1 millidarcy permeability standard (but meets the maximum allowable production rates for gas and oil), if the agency shows that the formation exhibits low permeability characteristics and the incentive price is needed to develop the formation. In the NOPR in this proceeding, the Commission proposed that formations that do not meet the permeability standard remain eligible for designation as tight formations based on a showing

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[2] Pub. L. 101–58, § 11501, 104 Stat. 1388–479 (1990).

[3] 58 FERC ¶61,126 (1992).

[4] Regulations Covering High-Cost Natural Gas Produced From Tight Formations, FERC Statutes and Regulations, Regulations Preambles 1977–1981 ¶30,183 (1980); reh'g denied, FERC Statutes and Regulations, Regulations Preambles 1977–1981 ¶30,198 (1980) (Order No. 99–A); aff'd, Pennzoil Co. v. FERC 671 F. 2d 119 (5th Cir. 1982).

[5] A jurisdictional agency is a State or Federal agency having regulatory jurisdiction with respect to the production of the gas. See 18 CFR 274.501.

[6] 816 F. 2d 777 (D.C. Cir. 1987).

[7] Limitation of Incentive Prices for High-Cost Gas to Commodity Values, 55 FR 6367 (Feb. 23, 1990), III FERC Stats. & Regs., ¶30,879.

[8] 18 CFR 271.703(c)(2)(i)(B).

[9] The average depth referred to means the average depth to the top of the formation.

either (1) the tax credit is needed to develop the formation or (2) that the incentive price was needed to develop wells spudded before May 13, 1990. (Under Order No. 519, such wells are still eligible for the incentive ceiling price). However, the Commission recognized that some formations with permeability in excess of 0.1 millidarcy, which may be designated as tight formations solely on the ground that the tax credit is needed to develop the formation, may include wells that were studded before May 13, 1990, and sought comment on whether gas from such wells should qualify for the incentive price as a result of a designation on the sole ground that the tax credit is necessary to warrant further development, when there has been no showing that the incentive ceiling price was necessary to provide reasonable incentives for production.

Additionally, the Commission proposed to amend § 271.703(c)(2)(i)(D), which currently requires a jurisdictional agency to exclude a formation, or portion of a formation, from designation as a tight formation, if the field that overlies the formation is subject to a prior infill drilling order by the jurisdictional agency, and the agency determines that the formation can be developed without the incentive price. If a producer has sought and received authority from the jurisdictional agency to drill additional wells in a producing field—at closer intervals than originally permitted—then presumably there are incentives for drilling the additional wells apart from the incentive prices for tight formation gas. The proposed amendment would have required a jurisdictional agency to continue to exclude a formation that is subject to a prior infill drilling order from designation as a tight formation, if the agency determines that the formation can be economically developed without the tax credit or, for wells, spudded before May 13, 1990, the incentive price.

Finally, on February 6, 1992, the Commission sought comments on whether the Commission should continue to use the arithmetic averaging method in analyzing permeability data when reviewing tight formation recommendations, or whether it should allow jurisdictional agencies to use geometric mean or median averaging methodologies. As discussed above, one of the guidelines for qualifying a formation as a tight formation under § 271.703(c)(2) is that "the estimated average *in situ* gas permeability, throughout the pay section is expected to be 0.1 millidarcy or less." The Commission has consistently used an arithmetic averaging method to determine whether estimated average *in situ* permeability meets the guideline established by the Commission. However, the Commission has never expressly stated a preferred averaging methodology for determining the average permeability. When a tight formation recommendation by a state agency included an estimate of *in situ* permeability based on median and/or geometric mean averaging methodologies, the Commission did not approve the recommendation unless the data fulfilled the arithmetic averaging standards as well.

The NOPR was published in the **Federal Register** on March 29, 1991. The deadline for filing comments on the NOPR was April 29, 1991. Comments from twenty parties were filed timely. Four comments were received after the deadline. The Request for Additional Comments was published in the **Federal Register** on February 13, 1992. The deadline for filing comments on the February 13 Request was March 4, 1992. Eighteen timely comments were filed. Wexpro Company, State of Colorado Oil and Gas Conservation Commission, State of New Mexico Energy, Minerals and Natural Resources Department, Railroad Commission of Texas, and Wyoming State Office, Bureau of Land Management filed late comments. A list of the commenters is shown in the Appendix to this order.

III. Discussion

Several of the commenters support the proposed amendments to the Commission's regulations without qualification.[10] Most of the other commenters generally support the proposals, but raise issues or objections concerning one or more aspects of them, or propose other related amendments.

A. Maximum Production Rates

TEX/CON Oil & Gas Company (TEX/CON) urges the Commission to permit jurisdictional agencies to designate a formation as a tight formation even though production from below 10,000 feet exceeds the standard "flow rate" test (maximum allowable stabilized production rates), if the tax credit is necessary to provide the drilling incentive.[11] In the alternative, TEX/CON recommends that the maximum allowable production rates be increased for production from below 12,000 feet to reflect the greater drilling costs per foot at such depths.

TEX/CON submits a table in lieu of the table proposed in the NOPR in which maximum allowable production rates are increased by a multiplier of 1.18 for each 500 foot increment of depth, from 10,000 feet to 15,000 feet, and a multiplier of 1.2 per 500 feet, from 15,000 feet to 19,000 feet.[12] TEX/CON asserts that drilling and completion costs have increased more than twenty percent over the last four years, while the price of gas has declined. Drilling in deep, over-pressured areas, such as in the Anadarko basin, has been most severely affected, according to TEX/CON, and without the tax credits as incentives, and higher allowable production rates for tight formations, exploration and drilling activity in those areas will decrease and may be prematurely abandoned.[13]

Arco Oil and Gas Company (ARCO) generally supports the amendments proposed in the NOPR, but states that the Commission is merely proposing conforming changes in its regulations, and not suggesting anything that will stimulate the development of tight formations as an adjunct to implementation of the National Energy Strategy. ARCO asserts that the Commission has been conservative in what it will permit to be eligible for a higher than market price, in view of its role of insuring that the greatest supply of gas reaches the consumer at the least possible price. However, in ARCO's view, the Commission should modify its conservative approach to the definition of tight formations in carrying out its role under the Internal Revenue Code. Accordingly, ARCO recommends that the maximum allowable production rates be increased by a multiplier of 1.7 or 1.8, instead of the existing formula, and that the permeability standard for tight formations should be increased from 0.1 millidarcy to 0.3 millidarcy.

Chevron U.S.A. Inc. also recommends that the production limitations be revised upward. Chevron states that when the maximum production rates were established in 1980, the incentive price for tight formation production was approximately $4.50 per MMBtu, while

[10] Mission Oil Corporation, Mid Louisiana Gas Company *et al.*, Shell Western E & P Inc., Amoco Corporation, State of Kansas, State of Wyoming, and Edge Petroleum Corporation.

[11] Anderman/Smith Operating Company also makes this proposal.

[12] TEX/CON asserts that the table proposed by the Commission uses a straight multiplier of 1.156 for each 500 foot increase in depth.

[13] Louisiana Land and Exploration Company, Sonat Exploration Company, and GHK Company support TEX/CON's proposal to increase the multiplier for maximum production rates for production from below 10,000 feet.

the projected average spot price for 1991 is $1.54 per MMBtu. The tax credit for tight formation gas is approximately $.52 per Mcf. Therefore, Chevron argues, if the tax credit is to act as an effective stimulant to the development of tight formation gas, the maximum production rates must be increased at all depths. Chevron also urges the Commission to recognize that drilling technologies, such as horizontal drilling, that have been developed since 1980, tend to produce significantly larger quantities of oil and gas when compared to production from conventionally drilled vertical wells, and are also more expensive. Accordingly, Chevron argues, jurisdictional agencies should be allowed to apply different oil and gas production standards to horizontally drilled wells in tight formations. Union Pacific Resources Company states that a well drilled horizontally into a tight formation will normally have a much higher production rate than a well drilled vertically into the same formation, and suggests that the maximum production rates should not apply to production from horizontally drilled wells. The Independent Petroleum Association of America makes a similar suggestion, and also proposes, in the alternative, that the use of horizontal drilling techniques be considered as a means of stimulating production so as not to cause a violation of the production rate standard.

The Commission will retain the existing maximum production rates in the table in § 271.703(c)(2)(i)(B) for depths from 0 to 15,000 feet and amend that table so that the existing maximum allowable production rate for depths from 14,500 to 15,000 feet [14] will also apply to all depths greater than 15,000 feet.[15] This will be done in view of the fact that the tax credit is now available for tight formation gas that is produced from below 15,000 feet even though it is not subject to a ceiling price. In Wyoming-16 (Docket No. RM79–76–189),[16] the Commission designated as tight formations the Muddy, Lakota, Morrison and Sundance Formations, which are entirely below 15,000 feet. The Commission determined that a jurisdictional agency may recommend areas for designation as a tight formation even if they are located at depths greater than 15,000 feet so long as the tight formation standards are met. The Commission concludes that its regulations should now be amended to reflect this policy. The maximum allowable rate for formations deeper than 14,500 feet, will be the existing maximum for 14,500 to 15,000 feet, which is considered to be an adequate measure of tight formation production rates from any lower depths.

The Commission agrees that the production rates from horizontally drilled wells normally exceed those from vertically drilled wells. The maximum allowable production rates were not set with horizontal drilling technology in mind, and it would be difficult to adjust the rates to account for the increased production rates and increased costs of horizontal drilling. Rather than attempt to develop some alternative table of maximum rates for horizontally drilled wells completed in tight formations, the Commission will permit jurisdictional agencies to determine how much consideration to give to production rates from horizontally drilled wells in areas with vertically and horizontally drilled wells. If there are no vertically drilled wells in the formation under consideration, the jurisdictional agencies should provide a detailed statement in their notices explaining why they believe the formation meets the Commission's guidelines.

The Commission will not adopt the proposals of TEX/CON, ARCO, and Chevron to adjust the existing maximum production levels upward. Nor will the Commission adopt ARCO's proposal to increase the permeability standard from 0.1 to 0.3 millidarcy. The Commission views its role as making conforming amendments to its regulations to make the tax credit available to producers from tight formations to carry out Congress' intent in restoring the tax credit for tight formation gas. Presumably, the Congress decided to extend the tax credit on the basis of some estimate of how much gas might qualify for the credit under the Commission's current definition of tight formations, and how it would cost the federal treasury. We believe that adoption of the various proposals to increase maximum production levels as well as to increase the permeability standard three-fold would go well beyond the intent of the Congress in restoring and extending the tax credit for tight formation gas.[17] Congress's intent appears to have been simply to ensure that the removal of price controls did not result in loss of the tax credit that would otherwise be available, not to make the tax credit available for substantial volumes of gas which never previously qualified.

B. Determining the Need for the Tax Credit

GHK Company and Apache Corporation oppose the proposal to amend the regulations to require jurisdictional agencies to exclude formations, or portions of formations, from designation as tight formations if they are subject to infill drilling orders and there are indications that the formations can be developed without the tax credit. They assert that jurisdictional agencies will only approve the drilling of infill wells if the existing well-spacing pattern is inadequate to recover the gas reserves, and that these decisions are made on the basis of geologic evidence. Accordingly, they argue that the existence of prior infill drilling orders bears no logical relationship on whether or not a formation should qualify as a tight formation. GHK and Apache argue that the existing regulations improperly require the exclusion of formations that would otherwise qualify as tight formations on the ground that the incentive price is not needed; this inequity should not be compounded, they argue, by also excluding tight formation gas from fields subject to prior infill drilling orders from eligibility for the tax credit.

The Independent Petroleum Association of America (IPAA) also argues that for purposes of designating formations as tight to qualify for the tax credit, the economics of the project, whether or not subject to infill drilling orders, should not be considered. The IPAA points out that section 29 of the Internal Revenue Code already provides that the tax credit will be phased out when oil prices are high enough to provide sufficient production incentives.[18] The IPAA argues that the legislative history of the statutory provisions at issue indicate Congress's intent that no other economic limitations were needed for tight formation gas.

[14] That maximum production level is 2.557 Mcf per day.

[15] While the existing table reflects a straight multiplier of approximately 1.156, the formula used to generate that table is shown in the Interim Rule Covering High-Cost Natural Gas Produced from Tight Formations, 45 FR 13414 (Feb. 28, 1980), FERC Stats. & Regs. [Regulations Preambles 1977–1981] ¶ 30,130 at p. 30,908.

[16] High-Cost Gas Produced from Tight Formations, 27 FERC ¶ 61,470 (1984).

[17] See *Interstate Natural Gas Association of America* v. *FERC*, 716 F.2d 1 (D.C. Cir. 1983), cert. denied, 104 S.Ct. 1616 (1984) (Commission's adoption of a Btu measurement convention (the "dry" rule), which permitted higher prices for gas, rejected, because the "wet" rule, which the Commission had always used in the past, was the only rule that Congress would have been familiar with when it enacted the ceiling prices of the NGPA).

[18] The price of natural gas is influenced by the price of crude oil; thus, as oil prices rise, gas prices will likely rise also.

Union Pacific Resources Company argues that the Commission is not permitted under the provisions of Section 29 of the Internal Revenue Code to consider whether infill drilling has been authorized in a tight formation and, if so, whether an incentive is needed to develop the formation. According to Union Pacific, the Commission and jurisdictional agencies are only permitted to determine "whether any gas is produced from * * * a tight formation," [19] and not to refuse to characterize a formation as tight on the ground that a tax credit is not needed. While the Commission was allowed under section 107(b) of the NGPA to prescribe incentive prices to the extent such prices were necessary to provide reasonable incentives for the production of high-cost gas, Union Pacific argues that Congress has determined that producers of tight formation gas are entitled to the tax credit, and did not authorize the Commission to make any assessment about the need for the tax credit as an incentive to drill.

Bataa Oil, Inc. argues that tight formations subject to an infill drilling order should not be excluded from eligibility for the tax credit. Bataa asserts that an infill well may have been drilled when gas prices were much higher, but there may have been no more wells in the tight formation because of the reduced prices. In some cases, initial infill wells may have been plugged and abandoned. Therefore, the incentive of the tax credit may be needed to justify drilling additional infill wells, even though it was not needed when the infill drilling order was issued.

The Railroad Commission of Texas states that infill drilling should no longer be a consideration in the designation of tight formations because the tax credit, unlike the incentive price, has no influence on market prices. According to the Railroad Commission, the tax credit can make a major difference in the economics of exploration and production decisions, but the infill drilling factor will unfairly penalize producers who were able to complete infill wells in a formation before it was designated as tight, and are denied the credit. Accordingly, the Railroad Commission argues that infill drilling should no longer be relevant in making tight formation determinations.[20]

The Commission will not adopt the proposed amendment to § 271.703(c)(2)(i)(D) that would have required exclusion of formations subject to infill drilling orders if the tax credit is not needed. The amendment proposed in the NOPR seemed to be necessary to conform to the similar amendment proposed for tight formations that do not meet the permeability test, but otherwise exhibit tight characteristics. However, the Commission has concluded that if formations otherwise qualify for designation as tight formations, they should not be denied that designation, and thus the tax credit for gas from such formations.

The current provisions of § 271.703(c)(2)(i)(D) require that the incentive price be denied to gas from a tight formation subject to a prior infill drilling order by excluding such a formation from designation as a tight formation, if there is information indicating that the formation can be developed without the incentive price. The other provisions of the tight formation regulations, provide, in effect, an irrebuttable presumption that the incentive price is needed for gas from any formation that meets the permeability and maximum production standards. However, the infill drilling authorization negates the irrebuttable nature of that presumption and requires denial of the incentive price (by means of denying tight formation designation) where there is evidence that the formation can or will be developed without the incentive price. The proposed amendment would have required denial of the tight formation designation when there is evidence that the formation can or will be developed without the tax credit.

The existing exception to the generally irrebuttable presumption was warranted because a producer's proposal to drill additional infill wells, before the underlying formation has qualified for an incentive price, strongly indicated that the field could be economically developed without an incentive price. These provisions are consistent with the Commission's rule under section 107(b) and (c)(5) of the NGPA, which is to determine whether gas produced under conditions of extraordinary risk or costs required a special price to provide reasonable incentives for its production. However, the Commission's role under section 29 of the Internal Revenue Code is to determine whether gas is produced from a tight formation in accordance with section 503 of the NGPA,[21] not to determine whether the tax credit is needed. Accordingly, the Commission will not amend § 271.703(c)(2)(i)(D) to require exclusion of formations from designation as tight formations on the ground that they can be developed without the tax credit. We will retain the requirement of that section that formations be excluded from such tight formation designation if there are indications that an incentive price is not needed. However, the incentive price is only available for gas from wells spudded (or recompleted) before May 13, 1990. Consequently, an indication that the incentive price is not needed to develop the formation is only relevant when a producer seeks to qualify gas for the incentive price, not for the tax credit. Therefore, jurisdictional agencies may determine that infill areas qualify as tight formations without a showing that the tax credit is needed to develop the reserves. However, unless the jurisdictional agency shows that the incentive price is necessary for development, wells spudded prior to May 13, 1990 will not be eligible for incentive prices.

C. Need for the Incentive Price to Qualify Formations with Permeabilities in Excess of the Guideline

The NOPR proposed to allow tight-formation designation of formations that do not meet the permeability test, but meet the other tight-formation guidelines, if there is a showing that eligibility for the tax credit or, parenthetically, the incentive price for wells spudded before May 13, 1990, is necessary to provide reasonable incentives for production. The Railroad Commission of Texas takes the position that the need for an incentive price for wells spudded before May 13, 1990, should not be a factor in making tight formation determinations. The Railroad Commission asserts that there are so few wells that would be affected by this factor, that the parenthetical language on incentive price is superfluous.

Enron Oil & Gas Company (Enron) also opposes the inclusion of the same parenthetical provision in the proposed amendment on designating formations that do not meet the permeability standard, and the identical provision in the proposed amendment concerning formations which have been authorized to be developed by infill drilling. However, Enron has a different reason for opposing these provisions. Enron believes that the inclusion of this alternative to consideration of a

[19] 26 U.S.C. 29(c)(2)(A) (1988).

[20] The Railroad Commission notes that Texas also provides a tax incentive for certain high-cost gas in the form of a temporary exemption from the state severance tax. The Railroad Commission says it will consider both the federal tax credit and the state tax exemption in making tight formation determinations for formations that do not meet the permeability standard.

[21] 26 U.S.C. 29(c)(2)(A) (1988).

producer's need for the tax credit creates a new opportunity for qualifying natural gas from a tight formation for an incentive regulated price, going beyond what Congress intended in extending the tax credit, and conflicting with the Commission's policy in Order No. 519, which eliminated the incentive price for tight formation gas, as well as the Congressional policy in the Natural Gas Wellhead Decontrol Act of 1989.

The Commission has determined not to adopt the amendment to § 271.703(c)(2)(ii) under which jurisdictional agencies would have been permitted to designate as tight formations a formation that does not meet the permeability standard, upon a finding that the tax credit is needed to warrant production. The Commission believes that adoption of this proposal could greatly expand the amount of gas that could be designated as tight formation gas. This would be contrary to Congress's intent, discussed above, which was to ensure that the removal of price controls did not result in loss of the tax credit that would otherwise be available. We believe Congress did not intend to make the tax credit available for substantial volumes of gas which never previously qualified as tight formation gas.

The proposed amendment to § 271.703(c)(2)(ii) could have the effect of allowing a large number of formations that do not meet the permeability guideline to qualify as tight formations simply by meeting the production guidelines for natural gas and crude oil, since in many cases the necessary finding concerning the tax credit could probably be made. Indeed, it is possible that most low producing formations would potentially qualify, whether they are tight formations or not. This was not the intent of the Commission when it issued Order No. 99 in which it set the standards for designating a tight formation.

In Order No. 99 the Commission stated that the objective of permeability standard is to identify and provide incentives for the development of tight formations, not to provide incentives to develop all formations with low prestimulation production rates. The Commission stated further that the problem presented by formations of extremely variable characteristics is not present in many tight formations and the estimates of average permeability may reasonably represent the permeability that will be encountered from one location to the next. Therefore, if formations that did not meet the permeability guideline were designated as tight solely on the basis that the tax credit is necessary to warrant production, more natural gas production would qualify as production from tight formation than was intended at the time the Commission instituted the tight formation designation or than Congress expected when allowed tight formation gas to qualify for the tax credit. This situation differs from where formations are subject to infill drilling orders, discussed above, in that the formations subject to infill drilling order must meet the tight formation guidelines. There are no special guidelines created for these formations such as the proposed amendment to allow qualification of formations that do not meet the permeability standard would create.

The Commission has decided, however, not to delete the current provision in § 271.703(c)(2)(ii) under which a formation not meeting the permeability standard can be designated as a tight formation upon a showing that the incentive price is necessary to provide reasonable incentives for production. This has the effect of permitting wells spudded before May 13, 1990 in formations that do not meet the permeability standard nevertheless to qualify for the ceiling price upon a finding that the price was needed to warrant production. This does not, however, create a new opportunity to qualify tight formation gas for the incentive price, as Enron argues, since it merely preserved eligibility for the incentive price under the existing regulations. In any event, the provision only affected a very few formations, if any, since most formations that could have qualified for the incentive price under the existing regulations, and for which there was any economic advantage in qualifying, have already been designated as tight formations.

In the NOPR, the Commission requested comments on whether gas from wells spudded before May 13, 1990, should become eligible for the incentive price where a formation that does not meet the permeability standard is subsequently designated as tight solely on the basis of a finding that the tax credit is necessary to warrant further development.[22] Bass Enterprises Production Company *et al.*[23] responded by stating that the availability of the tax credit should not result in the inadvertent qualification for incentive prices for gas that would not otherwise qualify. In light of our determination above not to adopt the proposal to permit designation of formations that do not meet the permeability standard as tight based on a finding that the tax credit is needed to warrant development, the issue whether such a designation should allow qualification for incentive prices has become moot.

D. Averaging Method for Determining the Permeability of a Tight Formation

In the Request for Additional Comments, the Commission sought comments concerning the proper averaging methodology for establishing the permeability for a tight formation. The Commission has consistently used an arithmetic averaging method to determine the average permeability of a formation but never expressly stated its preferred methodology for calculating that average. Numerous comments have been received. A number of the comments suggest that the Commission allow state agencies to select the best averaging method on a case by case basis.

The State of Kansas is in favor of switching to the use of a geometric mean in determining the permeability of a tight formation.[24] The State of Kansas also recommends: (a) When a formation is subject to the jurisdiction of more than one state agency, the later agency should be forced to use the same averaging method as was used by the first state agency to file for a tight formation designation involving that formation; (b) when two or more state agencies are filing to qualify different sections of a common gas reservoir as a "tight formation" at the same time, they would all have to use whichever averaging methodology was chosen; (c) a state jurisdictional agency should be allowed to rely on one method of averaging in one case and be able to rely on the alternate averaging method in other cases.[25]

Conoco Inc. contends that the method for calculating the average permeability for designation of tight formations should be determined based upon the type of formation involved. Conoco also

[22] Gas that may otherwise be eligible for the incentive price because it is produced from a designated tight formation may not receive that price unless it is sold under a contract that specifically provides for that price, or a specific fixed price within the incentive price ceiling. See 18 CFR 271.702(a)(1) (definition of "negotiated contract price").

[23] Referred to as "Undersigned Producers and Associations" and including CXY Energy Inc., Independent Oil & Gas Association of Pennsylvania, Independent Oil & Gas Association of West Virginia, Parker & Parsley Petroleum Company, and Texaco Inc—in addition to Bass Enterprises.

[24] Wexpro Company is also in favor of using the geometric mean averaging methodology.

[25] The New York State Department of Environmental Conservation and Hunt Oil Company also believe that the jurisdictional agency should have the authority to apply different methodologies in different cases.

recommends that discretion of whether to use the artthmetic average or geometric mean average should be left to the jurisdictional agency [26] with Commission oversight and that the same methodology be used where more than one jurisdictional agency is involved.

The Oklahoma Corporation Commission, Enron Oil & Gas Company, Bass Enterprises Production Co., Parker & Parsley Petroleum Company, and Samson Resources Company (jointly Bass), and the Apache Group [27] submit that the Commission should allow jurisdictional agencies to select the best averaging method on a case by case basis [28] and the Commission's review should be upon a "substantial evidence" basis only. Bass also submits that, if the Commission does mandate the use of a particular averaging methodology, it should designate the median methodology since only the median accurately reflects the central tendency—or the "average"—within a log normally distributed data group such as permeability data.

Chevron U.S.A. Inc. recommends requiring state agencies to approve a tight sand designation if it qualifies by using any of three identified averaging methodologies. However, it states that if the Commission decides to mandate the use of only one method, then it should require all jurisdictional agencies to use the geometric mean averaging method.

S. A. Holditch & Associates, Inc. submits that the median is the most appropriate measure of central tendency for average permeability because it does not require that the permeability be exactly normal or exactly lognormal.

Hunt Oil Company (Hunt) Shell Western E & P Inc., (Shell) and Enserch Exploration, Inc., (Enserch) argue that the Commission lacks authority under section 503 of the NGPA to impose an arithmetic averaging requirement. They argue that the Commission has previously stated in *Travis Peak* [29] that the methodology issue is "best left for determination in the first instance to the jurisdictional agency." Shell, Enserch and Bass state that in *Williston Basin* [30] the court found that in enacting section 503 of the NGPA, Congress expressly limited the Commission's role in "tight sands" determinations to that of an appellate body, therefore the Commission's review must be on a substantial evidence basis. Enserch also contends that if the Commission adopts the arithmetic averaging method that it may do so only prospectively and may not apply the test to applications already filed with the jurisdictional agencies. Enserch specifically argues that a change in policy to require arithmetic averaging now would deny the parties in *Travis Peak*, which is pending on remand before the Texas Railroad Commission, due process of law.

The Albuquerque District Office, Bureau of Land Management (BLM) recommends that the current arithmetic averaging methodology be retained by all jurisdictional agencies in all cases.[31] BLM contends the variance between results calculated by geometric mean and arithmetic averaging is too great to accommodate the use of both interchangeably. It reports that adopting the geometric mean would have the same effect as increasing the .1 md criteria to 1.1 md and the amount of land qualifying for tight formation designation would increase greatly.

After reviewing the comments, the Commission has determined to continue its existing practice of using only the arithmetic averaging method in reviewing permeability data contained in tight formation recommendations. Section 2(b) of the Natural Gas Wellhead Decontrol Act of 1989 [32] provides for the complete decontrol of wellhead prices of first sales of natural gas as of January 1, 1993, by repealing Title I of the NGPA. Any prospective change in the Commission's interpretation of its tight formation regulations would, therefore, be effective only for a very short time. Since there is no compelling reason to change the Commission's method of reviewing permeability data, the Commission sees no point in doing so when the deregulation process is so near to completion. Moreover, if the Commission does not continue to use the arithmetic averaging method for reviewing permeability data on a nationwide basis, jurisdictional agencies' tight formation recommendations could vary from state-to-state and reservoir-by-reservoir with no uniformity. Finally, as discussed more fully above, Congress's intent in extending the tax credit for tight formation gas appears to have been simply to ensure that the removal of price controls did not result in loss of the tax credit that would otherwise be available, not to make the tax credit available for substantial volumes of gas which never qualified for the tax credit previously. There is evidence that the amount of land qualifying for tight formation designation would increase greatly if the geometric mean methodology was used to determine average permeability.[33] Therefore, the Commission will not change its current arithmetic averaging methodology; nor will the Commission adopt the geometric mean or median methodology or permit the state agencies to choose a methodology.

The commenters supporting the median or geometric mean assert that the distribution of permeabilities in nature is usually "lognormally" distributed, rather than normally distributed. This means that a relatively small portion of a formation may have significantly higher permeability than the remainder of the formation. As a result, a few wells in an area for which a tight formation designation is sought may have significantly higher flow rates than most other wells in the area. The commenters assert that the median or geometric mean is a much better indicator of the expected permeability or flow rate value of a well randomly drilled within the formation, since the arithmetic average gives greater weight to the few wells with high flow rates than the median or geometric mean methods and thus often causes the overall average to be higher.

The Commission agrees that permeabilities in tight formations are generally not normally distributed (*i.e.*, more wells exhibit low permeabilities than high permeability characteristics). This can cause the median and geometric mean to be significantly less than the arithmetic mean for the same

[26] Amoco Production Company also recommends that the choice of whether to use the geometric averaging or arithmetic averaging be left to the discretion of the jurisdictional agencies.

[27] The Apache Group includes Apache Corporation, Grace Petroleum Corporation, and Maxus Exploration Company.

[28] Charles Nesbitt, Oklahoma Secretary of Energy, and Mobil Natural Gas Inc. concur that the jurisidctional agency should be allowed to select the appropriate averaging methodology on a case by case basis.

[29] Texas Railroad Commission, Travis Peak Formation, 41 FERC ¶ 61,213 (1987).

[30] *Williston Basin Interstate Company* v. *Federal Energy Regulatory Commission*, 816 F.2d 777 (D.C. Cir., 1987).

[31] Texas Eastern Transmission Corporation, Southern California Gas Company, Wyoming State Office of the Bureau of Land Management, and State of Colorado Oil and Gas Conservation Commission also recommend that the jurisdictional agencies retain the arithmetic mean averaging method in all cases. Texas Eastern states indiscriminate granting of section 107 status is inconsistent with the will of Congress to provide tax incentives to spur increases in production that would not otherwise occur.

[32] Pub. L. No. 101-60; 103 Stat. 157 (1989).

[33] See BLM Comments on Geometric vs Arithmetic Mean for Designating Tight Formation Areas at page 1 and the attached Comparison of Permeability Values Using Arithmetic Average and Geometric Mean.

data sample. The comments in support of the median or geometric mean are directed to the expected value of a single well to be randomly drilled in the formation. However, the Commission's concern is estimating an expected average permeability for the recommended formation, or portion thereof.

The Commission stated in Order No. 99 that portions of formations that do not meet the tight formation guidelines should not be included in jurisdictional agency recommendations (now determinations under section 503 of the NGPA). Since the permeability of a formation is not likely to be uniformly distributed throughout a recommended area and since the high permeability wells will usually exhibit permeability values that are significantly higher than the guidelines allow, the Commission believes that use of the arithmetic average insures that log-normally distributed data does not hide the presence of a portion of the recommended area which clearly does not meet the guidelines for tight formation designation (i.e., a "sweet spot"). Using the median or geometric mean does not offer the same safeguard against the inclusion of a "sweet spot."

Finally, the Commission rejects the contention by various commenters [34] that the Commission lacks authority under NGPA section 503 to require use of the averaging methodology. As discussed by Hunt, Shell, and Enserch, section 503(b) of the NGPA circumscribes the Commission's authority to review jurisdictional agency determinations concerning whether particular formations qualify as tight formations by limiting the Commission to considering whether there is "substantial evidence in the record upon which such determination is made." However, the Commission does have the authority under NGA sections 107(C)(5) and 501 to define by rule what constitutes high-cost gas. This includes the authority to establish generally applicable criteria which any formation must meet in order to be designated a tight formation, including the type of methodology that must be used in analyzing permeability data. Since the Commission can set the standard for determining what qualifies as a tight formation under section 501 of the NGPA, which no one disputes, it follows that the Commission can interpret that standard. Here the Commission is not adjudicating a particular case and determining whether the holding of a state agency that a particular formation is tight is supported by substantial evidence. Rather, the Commission is interpreting the generally applicable criteria for determining whether formations are tight as set forth in the Commission's regulations at § 271.703. This is a matter within the informed discretion of this Commission. It is not beyond the scope of the Commission's reviewing authority to interpret its own regulations.

In *Travis Peak*—cited by a number of parties—the Commission held "only that we have sufficient authority under section 503 of the NGPA to remand this matter to Texas for its further consideration based on the record before us." [35] We recognize that in *Travis Peak*, the Commission also stated,

> While it is true that the Commission has in the past used an arithmetic averaging method to determine permeability and flow rates we decline to rule, in light of *Williston Basin*, that jurisdictional agencies must follow an arithmetic averaging method. We believe that issue is best left for determination in the first instance by the jurisdictional agency, subject to Commission review under the procedures set forth in section 503. We will address the issue of methodology, if necessary, at such time as agency determinations come before the Commission in the future. [36]

However, in *Travis Peak*, the Commission was reviewing a determination by a jurisdictional agency that a particular formation qualified as a tight formation. Thus, the NGPA section 503 procedures for reviewing individual well category determinations applied in that case. Here, however, the Commission has, in a general rulemaking proceeding not involving any particular jurisdictional agency determination or tight formation, requested comment from all interested parties concerning the appropriate averaging methodology to determine permeability. Thus, the sole issue here is what generally applicable criteria should be used in determining whether any formation is tight. For the reasons discussed above, the Commission believes that it does have authority under NGPA section 501 to decide in a rulemaking proceeding issues concerning the generally applicable criteria which all formations must meet in order to be found by a jurisdictional agency to be tight. Indeed, in *Williston Basin*, the court's decision left undisturbed the *criteria* promulgated by Order No. 99 for determining what constitutes a "tight formation". The Commission has above discussed the reasons why, based on the record developed in this proceeding, it believes that the arithmetic averaging method is the only appropriate method for determining permeability.

The Commission does recognize, however, that the *Travis Peak* proceedings have been particularly lengthy and troublesome. Therefore, the Commission affirms here that it is not making a determination on the specific method to apply to determine the average permeability in the *Travis Peak* case in this proceeding, but will permit parties to raise the issue whether there are special circumstances in that case that warrant not applying the interpretation here adopted, after notice and comment, to that case. In remanding the Travis Peak tight formation recommendation to the Texas Railroad Commission, the Commission duly recognized the initial responsibility of the jurisdictional agency to examine permeability data in making tight formation designations. Thus, the Commission's actions are consistent with the court's decision in the appeal of the *Travis Peak* orders [37] which affirmed the remand of the Travis Peak recommendation.

E. Miscellaneous Issues

Petroleum Management Systems recommends that the regulations be revised to permit qualification of single wells with "tight" production characteristics in areas where other wells producing from the same formation are not "tight." The Commission will not adopt this proposal. The scheme of the regulations is to define and permit identification of tight formations, not "tight" wells completed in formations that are not tight. If a well is completed in a formation that is not a tight formation, the fact that its low rate of production may indicate a "tight" spot within the formation does not qualify the formation for designation as a tight formation under the existing regulations; and the Commission is not willing to redefine tight formation to the extent that would be necessitated by Petroleum Management's recommendation.

The Department of Environmental Resources, Commonwealth of Pennsylvania, objects to the proposal that wells drilled prior to May 13, 1990, be allowed to qualify for the tax credit. The Department argues that if a producer drilled a well knowing there was no tax incentive, there seems little

[34] These include Hunt, Shell, Enserch, and Apache.

[35] Travis Peak, 41 FERC at 61,580.

[36] Travis Peak, 41 FERC at 61,580.

[37] *Enserch Exploration, Inc., as Managing General Partner of EP Operating Company, v. FERC*, 887 F.2d 81 (5th Cir. 1989).

reason to provide it after the fact. The Commission's regulations address the qualification of formations as tight, not whether gas from a particular well qualifies for the tax credit. Questions about whether gas from a particular well qualifies for the tax credit are matters for the Internal Revenue Service.

F. Reviewing Determinations by Jurisdictional Agencies

The State of Oklahoma asserts that the tax credit has been extremely successful in stimulating the development and production of coalbed methane gas, which is entitled to an inflation-adjusted tax credit that is greater than the tax credit for tight formation gas. However, Oklahoma, which has no coalbed methane, states that its producers cannot effectively compete with the large quantities of coalbed methane gas from other states. Oklahoma recognizes that the only way it will be able to compete in this arena is to develop its potential for producing tight formation gas, which is also eligible for a tax credit. Accordingly, Oklahoma commends the Commission for the proposed amendments to facilitate more tight formation designations and requests the Commission to rely on the technical evaluations of its jurisdictional agency, the Oklahoma Corporation Commission, in making of these determinations.

The Commission has, and will continue to, rely on the technical expertise of the jurisdictional agencies. However, the Commission's statutory duties are to review the determinations for substantial evidence in the record. Therefore, the Commission will continue to review tight formation designations by jurisdictional agencies under the same standards it now uses.

G. Determinations after December 31, 1992

The IPAA notes that the Commission stated in Order No. 523 that it would continue to process well determination requests only until December 31, 1992,[38] and that the tax credit is now available to gas from wells spudded by that date in tight formations. However, because determination requests are not usually filed until after a well is drilled, the IPAA requests the Commission to extend the date it will process determination requests until at least December 31, 1993.

In Order No. 523, the Commission recognized its duty to continue processing requests for well category determinations, including tight formation designations, to allow producers to obtain tax credits, even if the determinations no longer affected the price of the gas. The Commission stated its intention to continue processing such requests until January 1, 1993, after which tax credits for newly spudded wells will no longer be available. The Senate Report on the 1989 Wellhead Decontrol Act,[39] which repeals section 503 of the NGPA, states in part, "The Committee intends the usual 'savings clause' interpretations, such as those in 1 U.S.C. 109, to be applied to this legislation. * * * The Committee intends that any incomplete section 503 procedures continue to be carried out by the state agencies and the FERC, so that the necessary determination can be made as to sales of gas delivered before contract expiration and decontrol." Similarly, the House Report on the 1989 Wellhead Decontrol Act states, "the gradual expiration of controls after enactment and before January 1, 1993, and their complete expiration on and after that date, will not affect civil or criminal proceedings pending at the time of decontrol, nor any action or proceeding based on pre-decontrol acts or conduct."[40] Therefore, Congress did not intend that repeal of NGPA Title I and section 503, would terminate the authority of the Commission to process tight formation applications filed with the jurisdictional agencies on or before December 31, 1992.

The Commission will continue to process notices of determination which are filed with the jurisdictional agencies by December 31, 1992, and received by the Commission by June 30, 1993.[41]

IV. Administrative Findings

A. Regulatory Flexibility Act Statement

The Regulatory Flexibility Act (RFA)[42] requires the Commission to describe the impact that a proposed rule would have on small entities or to certify that the rule will not have a significant economic impact on a substantial number of small entities.[43] The Commission is not required to make an analysis if a proposed or final rule will not have such an impact.[44]

In general, the economic impact of a final rule is not "significant" within the meaning of the RFA if the impact on small entities is expected to be beneficial.[45] The final rule will enable certain natural gas producers that may qualify as small entities to qualify for tax credits. The Commission believes this impact is beneficial and, therefore, certifies that the final rule will not have a significant economic impact on a substantial number of small entities.[46]

B. Environmental Review

The Commission is not preparing an environmental assessment or environmental impact statement in this proceeding because the amendments in the final rule do not substantially change the effect of the regulations being amended. The amendments provide procedures for carrying out the intent of Congress in reinstating the tax credit for gas produced from new wells in tight formations, but would have no significant effect on the human environment.[47]

C. Information Collection Statement

The Office of Management and Budget's (OMB) regulations require OMB to approve certain information collection requirements imposed by agency rule.[48] In order No. 523, *supra*, the Commission stated that it would continue to process applications for well category determinations through December 31, 1992, so that producers could qualify for tax credits. The final rule in the proceeding indicates that applications filed with the jurisdictional agencies by December 31, 1992, will be processed. However, the amendments to the Commission's regulations adopted in this final rule will not increase the regulatory burden on producers seeking to qualify tight formations so that gas produced from such formations will be eligible for the tax credit. The form used by producers seeking to qualify such

[38] Order Implementing the Natural Gas Wellhead Decontrol Act of 1989, 55 FR 17425 (Apr. 25, 1990), III FERC Stats. & Regs. ¶ 30,867 at p. 31,760 (1990).

[39] S. Rept. No. 39, 101st Cong., 1st Sess. (1989).

[40] H. Rept. No. 29, 101st Cong., 1st Sess. (1989).

[41] The Commission notes that complete applications may not be able to be filed by December 31, 1992, since a well completion report may not be available. In those cases, the jurisdictional agencies have the discretion to assign a filing date to an application that is substantially complete and specify a date when a complete application must be filed.

[42] 5 U.S.C. 601–12 (1988).

[43] The Act defines a "small entity" as a small business, a small not-for-profit enterprise, or a small government jurisdiction. 5 U.S.C. 601(b) (1988). A "small business" is defined by reference to section 3 of the Small Business Act as an enterprise "which is independently owned and operated and which is not dominant in its field of operation." 15 U.S.C. 6.32(a) (1988).

[44] 5 U.S.C. 605(b) (1988).

[45] *Mid-Tex Electric Cooperative, Inc.* v. *FERC*, 773 F.2d 327, 340–43 (D.C. Cir. 1985).

[46] 5 U.S.C. 605(n) (1988).

[47] Section 380.4(a)(2)(ii) of the Commission's regulations categorically exempt from environmental review Commission proposals for promulgation of rules that are clarifying, corrective, or procedural, or that do not substantially change the effect of the regulation being amended. *See also*, § 380.2(a) for the definition of "categorical exclusion."

formations (FERC–568) has already been reviewed by OMB and assigned Control No. 1902–0112. The Commission, however, is notifying OMB of its action in the final rule.

V. Effective Date

This final rule is effective May 15, 1991.

List of Subjects in 18 CFR Part 271

Natural gas, Price Controls.

In consideration of the foregoing, the Commission amends part 271, chapter I, Title 18, Code of Federal Regulations, as set forth below.

By the Commission.

Lois D. Cashell,

Secretary.

PART 271—CEILING PRICES

1. The authority citation for part 271 is revised to read as follows:

Authority: 15 U.S.C. 717–717w; 42 U.S.C. 7101–7352; E.O. 12009, 3 CFR 1978 Comp., p. 142; 15 U.S.C. 3301–3432.

2. In § 271.703, paragraph (c)(2)(i)(B) is revised to read as follows:

§ 271.703 Tight formations.

* * * * *

(c) * * *

(2) * * *

(i) * * *

(B) The stabilized production rate, against atmospheric pressure, of wells (other than horizontally drilled wells) completed in the formation, without stimulation, is not expected to exceed the production rate determined in accordance with the following table:

If the average depth to the top of the formation (in feet)		The maximum allowable production rate (in thousand cubic feet per day) may not exceed
Exceeds	But does not exceed	
0	1,000	44
1,000	1,500	51
1,500	2,000	59
2,000	2,500	68
2,500	3,000	79
3,000	3,500	91
3,500	4,000	105
4,000	4,500	122
4,500	5,000	141
5,000	5,500	163
5,500	6,000	188
6,000	6,500	217
6,500	7,000	251
7,000	7,500	290
7,500	8,000	336
8,000	8,500	388
8,500	9,000	449
9,000	9,500	519
9,500	10,000	600
10,000	10,500	693
10,500	11,000	802
11,000	11,500	927
11,500	12,000	1,071
12,000	12,500	1,238
12,500	13,000	1,432
13,000	13,500	1,655
13,500	14,000	1,913
14,000	14,500	2,212
14,500 +		2,557

* * * * *

This appendix will not be published in the Code of Federal Regulations.

Appendix

Intervenors in March 20 NOPR

1. TEX CON Oil and Gas Company
2. Petroleum Management Systems
3. Mission Oil Corporation
4. Dept. of Environmental Resources, Pennsylvania
5. Chevron U.S.A. Inc.
6. Mid Louisiana Gas Company, Wintershall Energy, and Associated Gas Resources, Inc
7. Union Pacific Resources Company
8. Shell Western E&P Inc.
9. Independent Petroleum Association of America
10. Amoco Corporation
11. Louisiana Land and Exploration Company
12. ARCO Oil and Gas Company
13. Anderman/Smith Operating Company
14. Enron Oil & Gas Company
15. Sonat Exploration Company
16. Bass Enterprises Production Company *et al.*
17. GHK Company
18. Apache Corporation
19. Bataa Oil, Inc.
20. State of Oklahoma
21. Railroad Commission of Texas
22. State of Kansas
23. State of Wyoming
24. Edge Petroleum Corporation

Intervenors Re: February 6 Request

1. Kansas Corporation Commission
2. Albuquerque District Office, BLM
3. Shell Western E&P Inc.
4. Hunt Oil Company
5. Dept. of Environmental Conservation, New York
6. Conoco Inc.
7. Oklahoma Corporation Commission
8. Chevron U.S.A. Inc.
9. Mobil Natural Gas Inc.
10. S.A. Holditch & Associates, Inc.
11. Oklahoma Secretary of Energy, Charles Nesbitt
12. Texas Eastern Transmission Corporation
13. Amoco Production Company
14. Southern California Gas Company
15. Enron Oil & Gas Company
16. The Apache Group
17. Enserch Exploration, Inc.
18. Bass Enterprises Production Co, Parker & Parsley Petroleum Company, and Samson Research Company
19. Wexpro Company
20. Oil and Gas Conservation Commission, Colorado
21. Wyoming State Office, BLM
22. Energy, Minerals and Natural Resources Department, New Mexico
23. Railroad Commission of Texas

[FR Doc. 92–8685 Filed 4–14–92; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF THE TREASURY

Customs Service

19 CFR Part 4

[T.D. 92–40]

Vessels in Foreign and Domestic Trades

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

ACTION: Final rule.

SUMMARY: This document amends the Customs Regulations to include Luxembourg in the lists of nations which permit vessels of the United States to transport certain articles specified in section 27, Merchant Marine Act of 1920, as amended, between their ports. This amendment will provide reciprocal privileges for vessels of Luxembourg registry.

Customs has been furnished with satisfactory evidence that Luxembourg places no restrictions on the transportation of certain specified articles by vessels of the U.S. between ports in that country.

EFFECTIVE DATES: The reciprocal privileges for vessels registered in Luxembourg became effective on January 1, 1991, the date when the Luxembourg shipping register became operative. This amendment is effective April 15, 1992.

FOR FURTHER INFORMATION CONTACT: Monika L. Rice, Carrier Rulings Branch (202–566–5706).

SUPPLEMENTARY INFORMATION:

Background

Section 27, Merchant Marine Act of 1920, as amended (46 U.S.C. App. 883), provides generally that no merchandise shall be transported by water, or by land and water, between points in the United States except in vessels built in and documented under the laws of the United States and owned by U.S. citizens. However, the 6th proviso of the Act, as amended, provides, upon a finding by the Secretary of the Treasury, pursuant to information obtained and furnished by the Secretary of State, that if a foreign nation does not restrict the

transportation of certain articles between its ports by vessels of the United States, reciprocal privileges will be accorded to vessels of the nation, and the prohibition against the transportation of those articles between points in the U.S. will not apply to its vessels.

In accordance with the Act, the Customs Service has listed in § 4.93(b)(1) of the Customs Regulations (19 CFR 4.93(b)(1)) those nations found to extend reciprocal privileges to vessels of the United States for the transportation of empty cargo vans, empty lift vans, and empty shipping tanks. Those nations found to grant reciprocal privileges to vessels of the United States for the transportation of equipment for use with cargo vans, lift vans, and shipping tanks; empty barges specifically designed for carriage aboard a vessel; empty instruments of international traffic; and certain stevedoring equipment and material, are listed in § 4.93(b)(2) of the Customs Regulations (19 CFR 4.93(b)(2)).

By letter dated May 29, 1991, from the Embassy of Luxembourg, the Department of State advised that Luxembourg places no restrictions on the transportation of the articles listed in the Act by vessels of the United States between ports in Luxembourg.

The authority to amend this section of the Customs Regulations has been delegated to the Chief, Regulations and Disclosure Law Branch.

Finding

On the basis of the information received from the Department of State, Luxembourg places no restrictions on the transportation of the articles specified in section 27 of the Merchant Marine Act of 1920, as amended (46 U.S.C. App. 883), by vessels of the United States. Therefore, appropriate reciprocal privileges are accorded to vessels of Luxembourg registry as of January 1, 1991.

Inapplicability of Public Notice and Delayed Effective Date Requirements

Because this amendment merely implements a statutory requirement and involves a matter in which the public is not particularly interested, pursuant to 5 U.S.C. 553(b)(3)(B), notice and public procedure thereon are unnecessary. Further, for the same reasons, good cause exists for dispensing with a delayed effective date under 5 U.S.C. 553(d)(1).

Inapplicability of the Regulatory Flexibility Act

This document is not subject to the provisions of the Regulatory Flexibility Act 5 U.S.C. 601 *et. seq.* That Act does not apply to any regulation such as this for which a notice of proposed rulemaking is not required by the Administrative Procedure Act (5 U.S.C. 551, *et. seq.*) or any other statute.

Executive Order 12291

This amendment does not meet the criteria for a major rule as defined in E.O. 12291. Accordingly, a regulatory impact analysis is not required.

Drafting Information

The principal author of this document was Joseph W. Clark, Regulations and Disclosure Law Branch, U.S. Customs Service; however, personnel from other offices of the Customs Service participated in its development.

List of Subjects in 19 CFR Part 4

Cargo vessels, Coastwise trade, Customs duties and inspection, Maritime carriers, Vessels.

Amendment to the Customs Regulations

To reflect the reciprocal privileges granted to vessels registered in Luxembourg, part 4, Customs Regulations (19 CFR part 4), is amended as follows:

PART 4—VESSELS IN FOREIGN AND DOMESTIC TRADES

1. The authority for part 4 continues to read in part as follows:

Authority 5 U.S.C. 301, 19 U.S.C. 66, 1624, 46 U.S.C. App. 3; * * *

* * * * *

Section 4.93 also issued under 19 U.S.C. 1322(a), 46 U.S.C. App. 883; * * *

§ 4.93 [Amended]

2. Sections 4.93(b) (1) and (2) are amended by adding "Luxembourg" alphabetically in the lists of countries under those paragraphs.

Dated: April 9, 1992.

Kathryn C. Peterson,

Chief, Regulations and Disclosure Law Branch.

[FR Doc. 92-8589 Filed 4-14-92; 8:45 am]

BILLING CODE 4820-02-M

Internal Revenue Service

26 CFR Part 1

[T.D. 8410]

RIN 1545-AM20

Allocation and Apportionment of Interest Expense

AGENCY: Internal Revenue Service, Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final Income Tax Regulations relating to the allocation and apportionment of interest expense for purposes of computing taxable income from sources within and without the United States. The final regulations require that, in certain circumstances, third party interest expense of an affiliated group of corporations be allocated directly to foreign source income. These final regulations implement section 864(e) of the Internal Revenue Code of 1986.

EFFECTIVE DATE: These regulations are effective for and apply to taxable years beginning after December 31, 1991. However, at the choice of the taxpayer, these regulations may be applied to taxable years beginning after December 31, 1987.

FOR FURTHER INFORMATION CONTACT: Judith Cavell of the Office of Associate Chief Counsel (International), within the Office of Chief Counsel, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington, DC 20224, Attention: CC:CORP:T:R (INTL-0952-86) (202-566-6442, not a toll-free call).

SUPPLEMENTARY INFORMATION:

Background

Proposed regulations which would have implemented section 864(e) of the Internal Revenue Code of 1986 were published in the **Federal Register** at 52 FR 34580 on September 11, 1987. Those proposed regulations were withdrawn and replaced by temporary regulations and a notice of proposed rulemaking by cross-reference to temporary regulations published on September 14, 1988, in the **Federal Register** at 53 FR 35525 and 53 FR 35467, respectively.

On March 12, 1991, the **Federal Register** published proposed regulation § 1.861-10(e) withdrawing and replacing the earlier regulation § 1.861-10(e) proposed by cross-reference, but not withdrawing and replacing the corresponding temporary regulation § 1.861-10T(e). Written comments responding to this latest notice were received, and a public hearing was held on June 21, 1991. The Treasury Department hereby issues final regulation § 1.861-10(e), which incorporates, where appropriate, comments concerning the proposed regulations.

Explanation of Provisions

A. Summary of Regulation

Section 1.861-10(e) provides generally that a U.S. affiliated group ("U.S. group") which has both excess loans to

related controlled foreign corporations ("excess related group indebtedness") and excess borrowing by the U.S. group from unrelated parties ("excess U.S. shareholder indebtedness") in the same taxable year must allocate directly to foreign source income an amount of interest expense equal to the amount of interest income received by the U.S. group with respect to excess related group indebtedness (or, if smaller, an amount of related group indebtedness equal to the amount of excess of U.S. shareholder indebtedness).

Section 1.861–10(e) employs a three-step process. In Step One, a U.S. group determines the amount of excess related group indebtedness (if any) for the current year by comparing its actual related group indebtedness for the year to the amount of allowable related group indebtedness for the year. The amount of allowable related group indebtedness is determined by multiplying the aggregate asset value of all related controlled foreign corporations (the "related CFC group") by the foreign base period ratio for the year. The foreign base period ratio for any taxable year is the average of the ratios of related group indebtedness to related CFC group assets for each of the five immediately preceding years.

In Step Two, the U.S. group determines the amount of excess of U.S. shareholder indebtedness (if any) for the current year by comparing its actual U.S. shareholder indebtedness for the year to the amount of allowable U.S. shareholder indebtedness for the year. The amount of allowable U.S. shareholder indebtedness is determined by multiplying the aggregate asset value of the U.S. group by the U.S. base period ratio for the year. The U.S. base period ratio for any taxable year is the average of the ratios of U.S. shareholder indebtedness to U.S. group assets for each of the five immediately preceding years.

In Step Three, the U.S. group compares the Step One amount of excess related group indebtedness and the Step Two amount of excess U.S. shareholder indebtedness. The amount of "allocable related group indebtedness" is the smaller of the two amounts. Interest expense, in an amount equal to the amount of interest income received by the U.S. group on allocable related group indebtedness, must be allocated directly to foreign source income of the U.S. group. This interest expense is allocated to separate limitation categories for purposes of section 904(d) in proportion to the amounts of related group indebtedness held by the U.S. group in each category. Several safe harbor rules and other special rules are provided. In addition, § 1.861–10(e)(9) provides rules for the application of § 1.861–10(e) by start-up companies and in the context of corporate acquisitions, dispositions and section 355 distributions.

B. Significant Comments and Revisions

Under § 1.861–10 (e)(2)(v)(A) and (e)(3)(v)(A), the foreign and U.S. base periods for any taxable year consist of the five immediately preceding taxable years. Under § 1.861–10 (e)(2)(v)(B) and (e)(3)(v)(B), U.S. group may choose, as its initial base years, the five years consisting of the 1982 taxable year through the 1986 taxable year. Under § 1.861–10 (e)(2)(v)(C) and (e)(3)(v)(C), a taxpayer that chooses to apply § 1.861–10(e) only with respect to taxable years beginning after December 31, 1991 and that does not choose the initial base years described in § 1.861–10 (e)(2)(v)(B) and (e)(3)(v)(B) may not include the taxable year immediately preceding the first effective taxable year within any base period. Section 1.861–10 (e)(2)(v)(D) and (e)(3)(v)(D) clarify that the same initial base years must be chosen for the foreign base period ratio and the U.S. base period ratio, and § 1.861–10 (e)(2)(iv) and (e)(3)(iv) have been revised to clarify that the 110 percent limitations imposed by those sections do not apply with respect to each of the five initial base years.

Several commenters suggested that the foreign and U.S. base period ratios be calculated on a "weighted average" basis. Under this method, the sum of the amounts of related group indebtedness or U.S. shareholder indebtedness for each of the five base years would be divided by the sum of the aggregate values of related CFC group assets or U.S. group assets, respectively, for each of the five base years. This method would effectively give greater weight to years in which asset values are relatively large. The suggested method might thus be viewed as beneficial for some taxpayers with growing domestic and foreign operations, since it would give greater weight to more recent years. However, it could also penalize some taxpayers whose domestic or foreign operations are decreasing in size by giving less weight to more recent years. The method of § 1.861–10 (e)(2)(iv) and (e)(3)(iv) gives equal weight to each base year and thus results in a more accurate approximation of the average level of each indebtedness-to-asset ratio during the base period.

Several commenters suggested that direct allocation of interest expense be required only when a taxpayer's actual amounts of related group indebtedness and U.S. shareholder indebtedness vary from its amounts of allowable related group indebtedness and allowable U.S. shareholder indebtedness, respectively, by a specified percentage (*e.g.*, by 10 percent). The commenters noted in particular that exchange rate fluctuation may cause uncontrollable fluctuations in either or both of the two indebtedness-to-asset ratios. This suggestion was not adopted. The comparison of current years amounts of related group and U.S. shareholder indebtedness to allowable amounts computed on the basis of average historical indebtedness-to-asset ratios (rather than absolute amounts for a prior year) is intended to accommodate year-to-year changes in the relevant indebtedness amounts for other than tax reasons. In addition, the translation rules provided in § 1.861–10(e)(8)(i) should prevent any fluctuation in either inidebtedness-to-asset ratio that is due solely to exchange rate fluctuations, and the provisions of § 1.861–10(e)(9) should accommodate fluctuations caused by significant corporate events.

Section 1.861–10(e)(2)(iv) provides that, for purposes of computing the foreign base period ratio for any taxable year, the ratio of related group indebtedness to related CFC group assets for any base year may not exceed 110 percent of the foreign base period ratio for that base year. Section 1.861–10(e)(3)(iv) provides a corresponding limitation with respect to the U.S. base period ratio. Several commenters stated that limitations of 110 percent place taxpayers with initially low foreign and U.S. base period ratios at a disadvantage, relative to taxpayers with initially high base period ratios. These commenters argued that a higher percentage limitation would reduce this disadvantage and better accommodate non-abusive transactions. This suggestion has not been adopted, because the Service believes that a 110 percent limitation provides sufficient flexibility for gradual adjustments in the foreign and U.S. base period ratios and that the rules of § 1.861–10 (e)(9) sufficiently accommodate significant corporate events. To reduce the potential for disadvantage of taxpayers with initially low base period ratios, § 1.861–10 (e)(2)(iv) and (e)(3)(iv) have been amended to provide that the 110 percent limitation does not apply with respect to any base period year for which the relevant indebtedness-to-asset ratio does not exceed 0.10.

A number of commenters suggested that, for purposes of computing the foreign base period ratio, the ratio of related group indebtedness to related

CFC group assets taken into account for any base year be no less than 90 percent of the foreign base period ratio for that base year. A corresponding limitation was suggested with respect to the U.S. base period ratio. The commenters argued that these additional limitations were necessary to counterbalance the restrictive effect of the 110 percent limitations imposed by § 1.861–10 (e)(2)(iv) and (e)(3)(iv). This suggestion was not adopted. The 110 percent limitations of § 1.861–10 (e)(2)(iv) and (e)(3)(iv) are necessary to prevent avoidance of § 1.861–10 (e). As anti-avoidance rules, they provide no rationale for the inclusion of reciprocal rules beneficial to the taxpayer. In addition, the Service believes that the suggested 90% limitation would have effectively preserved any relative advantage now enjoyed by taxpayers with initially high foreign and U.S. base period ratios.

Redundant "safe harbor" language of proposed § 1.861–10 (e)(2)(vii)(B) and (e)(3)(vii) has been eliminated. In response to taxpayer comments, a new safe harbor has been added to § 1.861–10(e)(3)(vii) under which a U.S. group is considered to have no excess U.S. shareholder indebtedness in any taxable year in which its ratio of U.S. shareholder indebtedness to U.S. group assets does not exceed 0.10. This new safe harbor is intended to relieve taxpayers who, by virtue of having historically low U.S. base period ratios, may trigger the application of § 1.861–10(e) with minimal fluctuations in U.S. group borrowing. A suggestion that a higher safe harbor ratio be provided in § 1.861–10 (e)(2)(vii)(B) was not adopted.

A number of commenters argued that the foreign base period ratio used in determining excess related group indebtedness under § 1.861–10 (e)(2)(i) for any taxable year should be no less than 0.10 (the safe harbor ratio provided in § 1.861–10 (e)(2)(vii)(B)). It was suggested that this rule would avoid disparate treatment of taxpayers with foreign base period ratios slightly lower than 0.10 and taxpayers with foreign base period ratios slightly higher than 0.10. This suggestion assumes incorrectly, however, that the safe harbor of § 1.861–10 (e)(2)(vii)(B) is intended to provide all taxpayers with an exemption from direct allocation for related group indebtedness in an amount equal to 10 percent of the value of related CFC group assets. In fact, the safe harbor rule is intended only to relieve taxpayers with relatively low levels of related group indebtedness from the computational burdens of § 1.861–10 (e). The Service believes that revised § 1.861–10 (e)(2)(iv), under which the 110 percent limitation imposed by paragraph (e)(2)(iv) does not apply with respect to base years in which the ratio of related group indebtedness to related CFC group assets does not exceed 0.10, will mitigate any potential disparity in the treatment of taxpayers with foreign base period ratios slightly higher and slightly lower, respectively, than 0.10. The new safe harbor rule of § 1.861–10 (e)(3)(vii), and revised § 1.861–10 (e)(3)(iv), will operate in an analogous manner with respect to the ratio of U.S. shareholder indebtedness to U.S. group assets.

Several commenters recommended that the aggregate value of U.S. group assets used to compute allowable U.S. shareholder indebtedness under § 1.861–10(e)(3)(iii)(A) not be reduced by the amount of excess related group indebtedness for the year (as determined under Step One in § 1.861–10(e)(2)). This suggestion has not been adopted, because this reduction is necessary to effectuate a dollar-for-dollar matching of disproportionate U.S. shareholder indebtedness to excess related group indebtedness under § 1.861–10(e)(4).

In response to taxpayer comments, § 1.861–10(e)(6) has been revised to provide that the aggregate asset value of a related CFC for any taxable year may be determined by reference to the asset values reflected on a Form 5471 (or attachment thereto) filed for such taxable year. Form 5471 asset values must be used consistently, however, for all related CFCs and for all taxable years. In addition, Form 5471 asset values may be used only if the taxable year of each related CFC begins with, or no more than one month earlier than, the taxable year of the U.S. group. Beginning of year asset values, whether for a related CFC or for the U.S. group, are the same as the corresponding asset values as of the end of the immediately preceding year.

Several commenters suggested that a provision similar to the fixed stock writeoff method provided in proposed regulation § 1.163(j)–5(e) be added to § 1.861–10(e) to accommodate the acquisition of a related CFC or U.S. group member by means of a stock acquisition for which a section 338 election is not made. The commenters noted that a stock acquisition of this type can result in a substantial, non-abusive increase in the relevant indebtedness-to-asset ratio for a U.S. group that values assets by reference to tax book value (rather than fair market value). The suggested modification was not adopted. However, the Service intends to consider the proper treatment of such stock acquisitions in the context of forthcoming final regulations under section 864(e) relating to the allocation and apportionment of interest expense.

In response to taxpayer comments, § 1.861–10(e)(8)(i) has been added to provide that all amounts of related group indebtedness and U.S. shareholder indebtedness and all related CFC group and U.S. group asset values that are denominated in a currency other than U.S. dollars are to be translated into dollars at an average exchange rate for the current taxable year. This translation rule applies with respect to indebtedness amounts and asset values for each of the five base years, as well as to amounts and values for the current year, and thus will require taxpayers to redetermine base year indebtedness amounts and asset values on an annual basis. Use of a current year exchange rate to translate all non-dollar amounts should prevent the application of § 1.861–10(e) to any taxpayer solely by virtue of exchange rate fluctuations.

Although proposed § 1.861–10(e)(8)(i) has been deleted, the Service will apply, for purposes of § 1.861–10(e), the definition of "indebtedness" contained in § 1.861–13T(a)(3). The Service anticipates that final regulations forthcoming under section 864(e) will incorporate a definition of "indebtedness" similar to that of § 1.861–13T(a)(3) and applicable for all purposes of the regulations under section 864(e).

Section § 1.861–10(e)(8)(iii) has been added to clarify that indebtedness which qualifies for direct allocation of interest expense under § 1.861–10T (b) or (c) is excluded from related group indebtedness or U.S. shareholder indebtedness, and the value of any asset which is the subject of qualified non-recourse indebtedness under § 1.861–10T(b) or an integrated financial transaction under § 1.861–10T(c) is excluded from the aggregate asset value of the related CFC group or the U.S. group. Exempt assets (within the meaning of § 1.861–8T(d)) are included, however, in determining aggregate asset values under § 1.861–10(e)(8)(ii).

New § 1.861–10(e)(8)(iv) has been added to clarify that receivables arising between related CFCs (or between members of the U.S. group) do not constitute assets of the related CFC (or U.S. group member) holding such receivables.

The special reclassification rule of § 1.861–10(e)(8)(v) has been revised to apply in the context of multiple tiers of CFCs. Section 1.861–10(e)(8)(vi) clarifies that its special reclassification rule does not apply to CFC stock that gives rise to a CFC deduction for dividends paid under an integrated tax system.

Several commenters suggested that § 1.861–10(e)(9)(i) provide a higher presumed ratio of related group indebtedness to related CFC group assets for base years in which a U.S. group holds no related CFC stock. This suggestion has not been adopted.

Several commenters requested additional guidance under § 1.861–10(e)(9)(iii)(A) and (v)(A) as to the manner in which the values of assets acquired or divested near the end or beginning of a year should be weighted to avoid substantial distortions. These sections have been revised to clarify that the Service is concerned only with transactions occurring within three months of the end or beginning of a year. While the appropriate weighting method will vary, depending upon the facts of a particular situation, one method likely to produce reasonable results in many situations would be to prorate asset values acquired or divested within three months of the end or beginning of a year.

The separate group acquisition and disposition elections of proposed § 1.861–10(e)(9) (iv) and (vi) have been replaced with new elections under which taxpayers may recompute base period ratios as if acquired (or divested) corporations had (or had not) been members of the taxpayer's U.S. group or related CFC group at the beginning of the acquisition (or disposition) year and during base years prior to the acquisition (or disposition) year. The Service believes that these new elections will be less complex to apply and will provide greater relief.

Several commenters suggested that relief be provided in § 1.861–10(e)(9) for acquisitions and dispositions of substantial assets. This suggestion was not adopted, in view of the many options available to taxpayers in structuring asset transactions. As a result, specific relief provisions would be prohibitively complex to contruct and administer. In addition, because taxpayers have greater flexibility in structuring asset transactions, relief provisions are less necessary in this context than in the context of stock transactions.

Commenters on the alternative version of Step Two described in the preamble to the proposed regulations suggested that this alternative be available on an elective basis. This suggestion was not adopted.

Special Analyses

It has been determined that these rules are not major rules as defined in Executive Order 12291. Therefore, a Regulatory Impact Analysis is not required. It also has been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) and the Regulatory Flexibility Act (5 U.S.C chapter 6) do not apply to these regulations, and therefore, a final Regulatory Flexibility Analysis is not required. Pursuant to section 7805(f) of the Internal Revenue Code, the proposed regulations were submitted to the Administrator of the Small Business Administration for comment on their impact on small business.

Drafting Information

The principal author of these regulations is Judith Cavell of the Office of the Associate Chief Counsel (International), within the Office of Chief Counsel, Internal Revenue Service. Other personnel from the Internal Revenue Service and Treasury Department participated in developing the regulations.

List of Subjects in 26 CFR 1.861–1 Through 1.864–12

Income taxes, United States investments abroad.

Adoption of Amendments to the Regulations

Accordingly, 26 CFR part 1 is amended as follows:

PART 1—INCOME TAX: TAXABLE YEARS BEGINNING AFTER DECEMBER 31, 1953

Paragraph 1. The authority citation for part 1 is amended by adding the following citation:

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

Section 1.861–10(e) also issued under 26 U.S.C. 863(a), 26 U.S.C. 864(e), 26 U.S.C. 865(i) and 26 U.S.C. 7701(f). * * *

Par. 2. Section 1.861–10 is added to read as follows:

§ 1.861–10 Special allocations of interest expense.

(a) through (d). [Reserved]

(e) *Treatment of certain related group indebtedness*—(1) *In general.* If, for any taxable year beginning after December 31, 1991, a U.S. shareholder (as defined in paragraph (e)(5)(i) of this section) has both—

(i) Excess related group indebtedness (as determined under Step One in paragraph (e)(2) of this section) and

(ii) Excess U.S. shareholder indebtedness (as determined under Step Two in paragraph (e)(3) of this section), the U.S. shareholder shall allocate, to its gross income in the various separate limitation categories described in section 904(d)(1), a portion of its interest expense paid or accrued to any obligee who is not a member of the affiliated group (as defined in § 1.861–11T(d)) of the U.S. shareholder ("third party interest expense"), excluding amounts allocated under paragraphs (b) and (c) of § 1.861–10T. The amount of third party interest expense so allocated shall equal the total amount of interest income derived by the U.S. shareholder during the year from related group indebtedness, multiplied by the ratio of the lesser of the foregoing two amounts of excess indebtedness for the year to related group indebtedness for the year. This amount of third party interest expense is allocated as described in Step Three in paragraph (e)(4) of this section.

(2) *Step One: Excess related group indebtedness.* (i) The excess related group indebtedness of a U.S. shareholder for the year equals the amount by which its related group indebtedness for the year exceeds its allowable related group indebtedness for the year.

(ii) The "related group indebtedness" of the U.S. shareholder is the average of the aggregate amounts at the beginning and end of the year of indebtedness owed to the U.S. shareholder by each controlled foreign corporation which is a related person (as defined in paragraph (e)(5)(ii) of this section) with respect to the U.S. shareholder.

(iii) The "allowable related group indebtedness" of a U.S. shareholder for the year equals—

(A) The average of the aggregate values at the beginning and end of the year of the assets (including stock holdings in and obligations of related persons, other than related controlled foreign corporations) of each related controlled foreign corporation, multiplied by

(B) The foreign base period ratio of the U.S. shareholder for the year.

(iv) The "foreign base period ratio" of the U.S. shareholder for the year is the average of the related group debt-to-asset ratios of the U.S. shareholder for each taxable year comprising the foreign base period for the current year (each a "base year"). For this purpose, however, the related group debt-to-asset ratio of the U.S. shareholder for any base year may not exceed 110 percent of the foreign base period ratio for that base year. This limitation shall not apply with respect to any of the five taxable years chosen as initial base years by the U.S. shareholder under paragraph (e)(2)(v) of this section or with respect to any base year for which the related group debt-to-asset ratio does not exceed 0.10.

(v)(A) The foreign base period for any current taxable year (except as described in paragraphs (e)(2)(v) (B) and

(C) of this section) shall consist of the five taxable years immediately preceding the current year.

(B) The U.S. shareholder may choose as foreign base periods for all of its first five taxable years for which this paragraph (e) is effective the following alternative base periods:

(*1*) For the first effective taxable year, the 1982, 1983, 1984, 1985 and 1986 taxable years;

(*2*) For the second effective taxable year, the 1983, 1984, 1985 and 1986 taxable years and the first effective taxable year;

(*3*) For the third effective taxable year, the 1984, 1985 and 1986 taxable years and the first and second effective taxable years;

(*4*) For the fourth effective taxable year, the 1985 and 1986 taxable years and the first, second and third effective taxable years; and

(*5*) For the fifth effective taxable year, the 1986 taxable year and the first, second, third and fourth effective taxable years.

(C) If, however, the U.S. shareholder does not choose, under paragraph (e)(10)(ii) of this section, to apply this paragraph (e) to one or more taxable years beginning before January 1, 1992, the U.S. shareholder may not include within any foreign base period the taxable year immediately preceding the first effective taxable year. Thus, for example, a U.S. shareholder for which the first effective taxable year is the taxable year beginning on October 1, 1992, may not include the taxable year beginning on October 1, 1991, in any foreign base period. Assuming that the U.S. shareholder does not elect the alternative base periods described in paragraph (e)(2)(v)(B) of this section, the initial foreign base period for the U.S. shareholder will consist of the taxable years beginning on October 1 of 1986, 1987, 1988, 1989, and 1990. The foreign base period for the U.S. shareholder for the following taxable year, beginning on October 1, 1993, will consist of the taxable years beginning on October 1 of 1987, 1988, 1989, 1990, and 1992.

(D) If the U.S. shareholder chooses the base periods described in paragraph (e)(2)(v)(B) of this section as foreign base periods, it must make a similar election under paragraph (e)(3)(v)(B) of this section with respect to its U.S. base periods.

(vi) The "related group debt-to-asset ratio" of a U.S. shareholder for a year is the ratio between—

(A) The related group indebtedness of the U.S. shareholder for the year (as determined under paragraph (e)(2)(ii) of this section); and

(B) The average of the aggregate values at the beginning and end of the year of the assets (including stock holdings in and obligations of related persons, other than related controlled foreign corporations) of each related controlled foreign corporation.

(vii) Notwithstanding paragraph (e)(2)(i) of this section, a U.S. shareholder is considered to have no excess related group indebtedness for the year if—

(A) Its related group indebtedness for the year does not exceed its allowable related group indebtedness for the immediately preceding year (as determined under paragraph (e)(2)(iii) of this section); or

(B) Its related group debt-to-asset ratio (as determined under paragraph (e)(2)(vi) of this section) for the year does not exceed 0.10.

(3) *Step Two: Excess U.S. shareholder indebtedness.* (i) The excess indebtedness of a U.S. shareholder for the year equals the amount by which its unaffiliated indebtedness for the year exceeds its allowable indebtedness for the year.

(ii) The "unaffiliated indebtedness of the U.S. shareholder is the average of the aggregate amounts at the beginning and end of the year of indebtedness owed by the U.S. shareholder to any obligee, other than a member of the affiliated group (as defined § 1.861–11T(d)) of the U.S shareholder.

(iii) The "allowable indebtedness" of a U.S. shareholder for the year equals—

(A) The average of the aggregate values at the beginning and end of the year of the assets of the U.S. shareholder (including stock holdings in and obligations of related controlled foreign corporations, but excluding stock holdings in the obligations of members of the affiliated group (as defined in § 1.861–11T(d)) of the U.S. shareholder), reduced by the amount of the excess related group indebtedness of the U.S. shareholder for the year (as determined under Step One in paragraph (e)(2) of this section), multiplied by

(B) The U.S. base period ratio of the U.S. shareholder for the year.

(iv) The "U.S. base period ratio" of the U.S. shareholder for the year is the average of the debt-to-asset ratios of the U.S. shareholder for each taxable year comprising the U.S. base period for the current year (each a "base year"). For this purpose, however, the debt-to-asset ratio of the U.S. shareholder for any base year may not exceed 110 percent of the U.S. base period ratio for that base year. This limitation shall not apply with respect to any of the five taxable years chosen as initial base years by the U.S. shareholder under paragraph (e)(3)(v) of this section or with respect to any base year for which of the debt-to-asset ratio does not exceed 0.10.

(v)(A) The U.S. base period for any current taxable year (except as described in paragraphs (e)(3)(v) (B) and (C) of this section) shall consist of the five taxable years immediately preceding the current year.

(B) The U.S. shareholder may choose as U.S. base periods for all of its first five taxable years for which this paragraph (e) is effective the following alternative base periods:

(*1*) For the first effective taxable year, the 1982, 1983, 1984, 1985 and 1986 taxable years;

(*2*) For the second effective taxable year, the 1983, 1984, 1985 and 1986 taxable years and the first effective taxable year;

(*3*) For the third effective taxable year, the 1984, 1985 and 1986 taxable years and the first and second effective taxable years;

(*4*) For the fourth effective taxable year, the 1985 and 1986 taxable years and the first, second and third effective taxable years; and

(*5*) For the fifth effective taxable year, the 1986 taxable year and the first, second, third and fourth effective taxable years.

(C) If, however, the U.S. shareholder does not choose, under paragraph (e)(10)(ii) of this section, to apply this paragraph (e) to one or more taxable years beginning before January 1, 1992, the U.S. shareholder may not include within any U.S. base period the taxable year immediately preceding the first effective taxable year. Thus, for example, a U.S. shareholder for which the first effective taxable year is the taxable year beginning on October 1, 1992, may not include the taxable year beginning on October 1, 1991, in any U.S. base period. Assuming that the U.S. shareholder does not elect the alternative base periods described in paragraph (e)(3)(v)(B) of this section, the initial U.S. base period for the U.S. shareholder will consist of the taxable years beginning on October 1, of 1986, 1987, 1988, 1989, and 1990. The U.S. base period for the U.S. shareholder for the following taxable year, beginning on October 1, 1993, will consist of the taxable years beginning on October 1, 1987, 1988, 1989, 1990, and 1992.

(D) If the U.S. shareholder chooses the base periods described in paragraph (e)(3)(v)(B) of this section as U.S. base periods, it must make a similar election under paragraph (e)(2)(v)(B) of this section with respect to its foreign base periods.

(vi) The "debt-to-asset ratio" of a U.S. shareholder for a year is the ratio between—

(A) The unaffiliated indebtedness of the U.S. shareholder for the year (as determined under paragraph (e)(3)(ii) of this section); and

(B) The average of the aggregate values at the beginning and end of the year of the assets of the U.S. shareholder. For this purpose, the assets of the U.S. shareholder include stock holdings in and obligations of related controlled foreign corporations but do not include stock holdings in and obligations of members of the affiliated group (as defined in § 1.861–11T(d)).

(vii) A U.S. shareholder is considered to have no excess indebtedness for the year if its debt-to-asset ratio (as determined under paragraph (e)(3)(vi) of this section) for the year does not exceed 0.10.

(4) *Step Three: Allocation of third party interest expense.* (i) A U.S. shareholder shall allocate to its gross income in the various separate limitation categories described in section 904(d)(1) a portion of its third party interest expense incurred during the year equal in amount to the interest income derived by the U.S. shareholder during the year from allocable related group indebtedness.

(ii) The "allocable related group indebtedness" of a U.S. shareholder for any year is an amount of related group indebtedness equal to the lesser of—

(A) The excess related group indebtedness of the U.S. shareholder for the year (determined under Step One in paragraph (e)(2) of this section); or

(B) The excess U.S. shareholder indebtedness for the year (determined under Step Two in paragraph (e)(3) of this section).

(iii) The amount of interest income derived by a U.S. shareholder from allocable related group indebtedness during the year equals the total amount of interest income derived by the U.S. shareholder during the year with respect to related group indebtedness, multiplied by the ratio of allocable related group indebtedness for the year to the aggregate amount of related group indebtedness for the year.

(iv) The portion of third party interest expense described in paragraph (e)(4)(i) of this section shall be allocated in proportion to the relative average amounts of related group indebtedness held by the U.S. shareholder in each separate limitation category during the year. The remaining portion of third party interest expense of the U.S. shareholder for the year shall be apportioned as provided in §§ 1.861–8T through 1.861–13T, excluding paragraph (e) of § 1.861–10T and this paragraph (e).

(v) The average amount of related group indebtedness held by the U.S. shareholder in each separate limitation category during the year equals the average of the aggregate amounts of such indebtedness in each separate limitation category at the beginning and end of the year. Solely for purposes of this paragraph (e)(4), each debt obligation of a related controlled foreign corporation held by the U.S. shareholder at the beginning or end of the year is attributed to separate limitation categories in the same manner as the stock of the obligor would be attributed under the rules of § 1.861–12T(c)(3), whether or not such stock is held directly by the U.S. shareholder.

(vi) The amount of third party interest expense of a U.S. shareholder allocated pursuant to this paragraph (e)(4) shall not exceed the total amount of the third party interest expense of the U.S. shareholder for the year (excluding any third party interest expense allocated under paragraphs (b) and (c) of § 1.861–10T).

(5) *Definitions.* For purposes of this paragraph (e), the following terms shall have the following meanings.

(i) *U.S. shareholder.* The term "U.S. shareholder" has the same meaning as the term "United States shareholder" when used in section 957, except that, in the case of a United States shareholder that is a member of an affiliated group (as defined in § 1.861–11T(d)), the entire affiliated group is considered to constitute a single U.S. shareholder.

(ii) *Related person.* For the definition of the term "related person", see § 1.861–8T(c)(2). A controlled foreign corporation is considered "related" to a U.S. shareholder if it is a related person with respect to the U.S. shareholder.

(6) *Determination of asset values.* A U.S. shareholder shall determine the values of the assets of each related controlled foreign corporation (for purposes of Step One in paragraph (e)(2) of this section) and the assets of the U.S. shareholder (for purposes of Step Two in paragraph (e)(3) of this section) for any year in accordance with the valuation method (tax book value of fair market value) elected for that year pursuant to § 1.861–9T(g). However, solely for purposes of this paragraph (e), a U.S. shareholder may instead choose to determine the values of the assets of all related controlled foreign corporations by reference to their values as reflected on Forms 5471 (the annual information return with respect to each related controlled foreign corporation), subject to the translation rules of paragraph (e)(8)(i) of this section. This method of valuation may be used only if the taxable years of each of the related controlled foreign corporations begin with, or no more than one month earlier than, the taxable year of the U.S. shareholder. Once chosen for a taxable year, this method of valuation must be used in each subsequent taxable year and may be changed only with the consent of the Commissioner.

(7) *Adjustments to asset value.* For purposes of apportioning remaining interest expense under § 1.861–9T, a U.S. shareholder shall reduce (but not below zero) the value of its assets for the year (as determined under § 1.861–9T (g) (3) or (h)) by an amount equal to the allocable related group indebtedness of the U.S. shareholder for the year (as determined under Step Three in paragraph (e)(4)(ii) of this section). This reduction is allocated among assets in each separate limitation category in proportion to the average amount of related group indebtedness held by the U.S. shareholder in each separate limitation category during the year (as determined under Step Three in paragraph (e)(4)(v) of this section).

(8) *Special rules*—(i) *Exchange rates.* All indebtedness amounts and asset values (including current year and base year amounts and values) denominated in a foreign currency shall be translated into U.S. dollars at the exchange rate for the current year. The exchange rate for the current year may be determined under any reasonable method (*e.g.*, average of month-end exchange rates for each month in the current year) if it is consistently applied to the current year and all base years. Once chosen for a taxable year, a method for determining an exchange rate must be used in each subsequent taxable year and will be treated as a method of accounting for purposes of section 446. A taxpayer may apply a different translation rule only with the prior consent of the Commissioner. In this regard, the Commissioner will be guided by the extent to which a different rule would reduce the comparability of dollar amounts of indebtedness and dollar asset values for the base years and the current year.

(ii) *Exempt assets.* Solely for purposes of this paragraph (e), any exempt assets otherwise excluded under section 864(e)(3) and § 1.861–8T(d) shall be included as assets of the U.S. shareholder or related controlled foreign corporation.

(iii) *Exclusion of certain directly allocated indebtedness and assets.* Qualified nonrecourse indebtedness (as defined in § 1.861–10T(b)(2)) and indebtedness incurred in connection

with an integrated financial transaction (as defined in § 1.861–10T(c)(2)) shall be excluded from U.S. shareholder indebtedness and related group indebtedness. In addition, assets which are the subject of qualified nonrecourse indebtedness or integrated financial transactions shall be excluded from the assets of the U.S. shareholder and each related controlled foreign corporation.

(iv) *Exclusion of certain receivables.* Receivables between related controlled foreign corporations (or between members of the affiliated group constituting the U.S. shareholder) shall be excluded from the assets of the related controlled foreign corporation (or affiliated group member) holding such receivables. See also § 1.861–11T(e)(1).

(v) *Classification of certain loans as related group indebtedness.* If—

(A) A U.S. shareholder owns stock in a related controlled foreign corporation which is a resident of a country that—

(*1*) Does not impose a withholding tax of 5 percent or more upon payments of dividends to a U.S. shareholder; and

(*2*) Does not, for the taxable year of the controlled foreign corporation, subject the income of the controlled foreign corporation to an income tax which is greater than that percentage specified under § 1.954–1T(d)(1)(i) of the maximum rate of tax specified under section 11 of the Code, and

(B) The controlled foreign corporation has outstanding a loan or loans to one or more other related controlled foreign corporations, or the controlled foreign corporation has made a direct or indirect capital contribution to one or more other related controlled foreign corporations which have outstanding a loan or loans to one or more other related controlled foreign corporations,

then, to the extent of the aggregate amount of its capital contributions in taxable years beginning after December 31, 1986, to the related controlled foreign corporation that made such loans or additional contributions, the U.S. shareholder itself shall be treated as having made the loans decribed in paragraph (e)(8)(v)(B) of this section and, thus, such loan amounts shall be considered related group indebtedness. However, for purposes of paragraph (e)(4) of this section, interest income derived by the U.S. shareholder during the year from related group indebtedness shall not include any income derived with respect to the U.S. shareholder's ownership of stock in the related controlled foreign corporation that made such loans or additional contributions.

(vi) *Classification of certain stock as related person indebtedness.* In determining the amount of its related group indebtedness for any taxable year, a U.S. shareholder must treat as related group indebtedness its holding of stock in a related controlled foreign corporation if, during such taxable year, such related controlled foreign corporation claims a deduction for interest under foreign law for distributions on such stock. However, for purposes of paragraph (e)(4) of this section, interest income derived by the U.S. shareholder during the year from related group indebtedness shall not include any income derived with respect to the U.S. shareholder's ownership of stock in the related controlled foreign corporation.

(9) *Corporate events*—(i) *Initial acquisition of a controlled foreign corporation.* If the foreign base period of the U.S. shareholder for any year includes a base year in which the U.S. shareholder did not hold stock in any related controlled foreign corporation, then, in computing the foreign base period ratio, the related group debt-to-asset ratio of the U.S. shareholder for any such base year shall be deemed to be 0.10.

(ii) *Incorporation of U.S. shareholder*—(A) *Nonapplication.* This paragraph (e) does not apply to the first taxable year of the U.S. shareholder. However, this paragraph (e) does apply to all following years, including years in which later members of the affiliated group may be incorporated.

(B) *Foreign and U.S. base period ratios.* In computing the foreign and U.S. base period ratios, the foreign and U.S. base periods of the U.S. shareholder shall be considered to be only the period prior to the current year that the U.S. shareholder was in existence if this prior period is less than five taxable years.

(iii) *Acquisition of additional corporations.* (A) If a U.S. shareholder acquires (directly or indirectly) stock of a foreign or domestic corporation which, by reason of the acquisition, then becomes a related controlled foreign corporation or a member of the affiliated group, then in determining excess related group indebtedness or excess U.S. shareholder indebtedness, the indebtedness and assets of the acquired corporation shall be taken into account only at the end of the acquisition year and in following years. Thus, amounts of indebtedness and assets and the various debt-to-asset ratios of the U.S. shareholder existing at the beginning of the acquisition year or relating to preceding years are not recalculated to take account of indebtedness and assets of the acquired corporation existing as of dates before the end of the year. If, however, a major acquisition is made within the last three months of the year and a substantial distortion of values for the year would otherwise result, the taxpaper must take into account the average values of the acquired indebtedness and assets weighted to reflect the time such indebtedness is owed and such assets are held by the taxpayer during the year.

(B) In the case of a reverse acquisition subject to this paragraph (e)(9), the rules of § 1.1502–75(d)(3) apply in determining which corporations are the acquiring and acquired corporations. For this purpose, whether corporations are affiliated is determined under § 1.861–11T(d).

(C) If the stock of a U.S. shareholder is acquired by (and, by reason of such acquisition, the U.S. shareholder becomes affiliated with) a corporation described below, then such U.S. shareholder shall be considered to have acquired such corporation for purposes of the application of the rules of this paragraph (e). A corporation to which this paragraph (e)(9)(iii)(C) applies is—

(*1*) A corporation which is not affiliated with any other corporation (other than other similarly described corporation); and

(*2*) Substantially all of the assets of which consist of cash, securities and stock.

(iv) *Election to compute base period ratios by including acquired corporations.* A U.S. shareholder may choose, solely for purposes of paragraph (e)(9) (i) and (iii) of this section, to compute its foreign and U.S. base period ratios for the acquisition year and all subsequent years by taking into account the indebtedness and asset values of the acquired corporation or corporations (including related group indebtedness owed to a former U.S. shareholder) at the beginning of the acquisition year and in each of the five base years preceding the acquisition year. This election, if made for an acquisition, must be made for all other acquisitions occurring during the same taxable year or initiated in that year and concluded in the following year.

(v) *Dispositions.* If a U.S. shareholder disposes of stock of a foreign or domestic corporation which, by reason of the disposition, then ceases to be a related controlled foreign corporation or a member of the affiliated group (unless liquidated or merged into a related corporation), in determining excess related group indebtedness or excess U.S. shareholder indebtedness, the indebtedness and assets of the divested

corporation shall be taken into account only at the beginning of the disposition year and for the relevant preceding years. Thus, amounts of indebtedness and assets and the various debt-to-asset ratios of the U.S. shareholder existing at the end of the year or relating to following years are not affected by indebtedness and assets of the divested corporation existing as of dates after the beginning of the year. If, however, a major disposition is made within the first three months of the year and a substantial distortion of values for the year would otherwise result, the taxpayer must take into account the average values of the divested indebtedness and assets weighted to reflect the time such indebtedness is owed and such assets are held by the taxpayer during the year.

(vi) *Election to compute base period ratios by excluding divested corporations.* A U.S. shareholder may choose, solely for purposes of paragraph (e) (9) (v) and (vii) of this section, to compute its foreign and U.S. base period ratios for the disposition year and all subsequent years without taking into account the indebtedness and asset values of the divested corporation or corporations at the beginning of the disposition year and in each of the five base years preceding the disposition year. This election, if made for a disposition, must be made for all other dispositions occurring during the same taxable year or initiated in that year and concluded in the following year.

(vii) *Section 355 transactions.* A U.S. corporation which becomes a separate U.S. shareholder as a result of a distribution of its stock to which section 355 applies shall be considered—

(A) As disposed of by the U.S. shareholder of the affiliated group of which the distributing corporation is a member, with this disposition subject to the rules of paragraphs (e) (9) (v) and (vi) of this section; and

(B) As having the same related group debt-to-asset ratio and debt-to-asset ratio as the distributing U.S. shareholder in each year preceding the year of distribution for purposes of applying this paragraph (e) to the year of distibution and subsequent years of the distributed corporation.

(10) *Effective date—(i) Taxable years beginning after December 31, 1991.* The provisions of this paragraph (e) apply to all taxable years beginning after December 31,1991.

(ii) *Taxable years beginning after December 31, 1987 and before January 1, 1992.* The provisions of § 1.861–10T (e) apply to taxable years beginning after December 31, 1987, and before January 1, 1992. The taxpayer may elect to apply the provisions of this paragraph (e) (in lieu of the provisions of § 1.861–10T (e)) for any taxable year beginning after December 31, 1987, but this paragraph (e) must then be applied to all subsequent taxable years.

(11) The following example illustrates the provisions of this paragraph (e):

Example. (i) *Facts.* X, a domestic corporation, elects to apply this paragraph (e) to its 1990 tax year. X has a calendar taxable year and apportions its interest expense on the basis of the tax book value of its assets. In 1990, X incurred deductible third-party interest expense of $24,960 on an average amount of indebtedness (determined on the basis of beginning-of-year and end-of-year amounts) of $249,600. X manufactures widgets, all of which are sold in the United States. X owns all of the stock of Y, a controlled foreign corporation that also has a calendar taxable year and is also engaged in the manufacture and sale of widgets. Y has no earnings and profits or deficit of earnings and profits attributable to taxable years prior to 1987. X's total assets and their average tax book values (determined on the basis of beginning-of-year and end-of-year tax book values) for 1990 are:

Asset	Average tax book value
Plant and equipment	$315,000
Corporate headquarters	60,000
Y stock	75,000
Y note	50,000
Total	500,000

Y had $25,000 of income before the deduction of any interest expense. Of this total, $5,000 is high withholding tax interest income. The remaining $20,000 is derived from widget sales, and constitutes foreign source general limitation income. Assume that Y has no deductions from gross income other than interest expense. During 1990, Y paid $5,000 of interest expense to X on the Y note and $10,000 of interest expense to third parties, giving Y total interest expense of $15,000. X elects pursuant to § 1.861–9T to apportion Y's interest expense under the gross income method prescribed in section 1.861–9T (j).

(ii) *Step 1:* Using a beginning and end of year average, X (the U.S. shareholder) held the following average amounts of indebtedness of Y and Y had the following average asset values:

	1985	1986–88	1989	1990
(A) Related group indebtedness	$11,000	24,000	26,000	50,000
(B) Average Value of Assets of Related CFC	100,000	200,000	200,000	250,000
(C) Related Group Debt-to-Asset Ratio	.11	.12	.13	.20

(*1*) X's "foreign base period ratio" for 1990, an average of its ratios of related group indebtedness to related group assets for 1985 through 1989, is:

(.11+.12+.12+.12+.13)/5=.12

(*2*) X's "allowable related group indebtedness" for 1990 is:

$250,000×.12=$30,000.

(*2*) X's "excess related group indebtedness" for 1990 is:

$50,000−×.12=$30,000

X's related group indebtedness of $50,000 for 1990 is greater than its allowable related group indebtedness of $24,000 fro 1989 (assuming a foreign base period ratio in 1989 of .12), and X's related group debt-to-asset ratio for 1990 is .20, which is greater than the ratio of .10 described in paragraph (e)(2)(vii)(B) of this section. Therefore, X's excess related group indebtedness for 1990 remains at 20,000.

(iii) *Step 2:* Using a beginning and end of year average, X has the following average amounts of U.S. and foreign indebtedness and average asset values:

	1985	1986	1987	1988	1989	1990
(1)	$231,400	225,000	225,000	225,000	220,800	249,600
(2)	445,000	450,000	450,000	450,000	460,000	180,000
						(a)
(3)	.52	.50	.50	.50	.48	.52

(1) U.S. and foreign indebtedness
(2) Average value of assets of U.S. shareholder
(3) Debt-to-Asset ratio of U.S. shareholder
(a) [500,000–20,000 (excess related group indebtedness determined in Step 1)]
X's "U.S. base period ratio" for 1990 is:
(.52+.50+.50+.50+.48)/5=.50
X's "allowable indebtedness" for 1990 is:
$480,000×.50=$240,000
X's "excess U.S. shareholder indebtedness" for 1990 is:
$249,000−$240,000=$9,600
X's debt-to-asset ratio for 1990 is .52, which is greater than the ratio of .10 described in paragraph (e)(3)(vii) of this section. Therefore, X's excess U.S. shareholder indebtedness for 1990 remains at $9,600.
(iv) *Step 3:* (a) Since X's excess U.S. shareholder indebtedness of $9,600 is less than its excess related group indebtedness of $20,000, X's allocable related group indebtedness for 1990 is $9,600. The amount of interest received by X during 1990 on allocable related group indebtedness is:
$5,000×$9,600/$50,000=$960
(b) Therefore, $969 of X's third party interest expense ($24,960) shall be allocated among various separate limitation categories in proportion to the relative average amounts of Y obligations held by X in each such category. The amount of Y obligations in each limitation category is determined in the same manner as the stock of Y would be attributed under the rules of § 1.861–12T(c)(3). Since Y's interest expense is apportioned under the gross income method prescribed in § 1.861–9T (j), the Y stock must be characterized under the gross income method described in § 1.861–12T(c)(3)(iii). Y's gross income net of interest expense is determined as follows:
Foreign source high withholding tax interest income—
=$5,000–[($15,000) multiplied by ($5,000)/($5,000+$20,000)]
=$2,000
and
Foreign source general limitation income—
=$20,000–[($15,000) multiplied by ($20,000)/($5,000+$20,000)]
=$8,000.
(c) Therefore, $192 [($960×$2,000/($2,000+$8,000)] of X's third party interest expense is allocated to foreign source high withholding tax interest income and $768 [$960×$8,000/($2,000+$8,000)] is allocated to foreign source general limitation income.
(v) As a result of these direct allocations, for purposes of apportioning X's remaining interest expense under § 1.861–9T, the value of X's assets generating foreign source general limitation income is reduced by the principal amount of indebtedness the interest on which is directly allocated to foreign source general limitation income ($7,680), and the value of X's assets generating foreign source high withholding tax interest income is reduced by the principal amount of indebtedness the interest on which is directly allocated to foreign source high withholding tax interest income ($1,920), determined as follows:
Reduction of X's assets generating foreign source general limitation income:

$$\text{X's allocable related group indebtedness} \times \frac{\text{Y's Foreign source general limitation income}}{\text{Y's Foreign source income}}$$

$$\$9{,}600 \times \frac{\$8{,}000}{(\$8{,}000+\$2{,}000)} = \$7{,}680$$

Reduction of X's assets generating foreign source high withholding tax interest income:

$$\text{X's allocable related group indebtedness} \times \frac{\text{Y's Foreign source high withholding tax interest income}}{\text{Y's Foreign source income}}$$

$$\$9{,}600 \times \frac{\$2{,}000}{(\$8{,}000+\$2{,}000)} = \$1{,}920$$

David G. Blattner,
Acting Commissioner of Internal Revenue.
Approved: January 24, 1992.
Kenneth W. Gideon.
Assistant Secretary of the Treasury.
[FR Doc. 92–8495 Filed 4–14–92; 8:45 am]
BILLING CODE 4830–01–M

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26 CFR Part 1

[T.D. 8394]

RIN 1545–AO37

Proceeds of Bonds Used for Reimbursement; Correction

AGENCY: Internal Revenue Service, Treasury.

ACTION: Correction to final regulations.

SUMMARY: This document contains corrections to the final regulations (T.D. 8394), which were published Thursday, January 30, 1992 (57 FR 3526). The regulations provide guidance as to when the allocation of bond proceeds to reimburse expenditures previously made by an issuer is treated as an expenditure of the bond proceeds.

EFFECTIVE DATE: The regulations and these corrections are effective for bonds issued after March 2, 1992.

FOR FURTHER INFORMATION CONTACT: William P. Cejudo (202) 566–3283 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The final regulations that are the subject of these corrections provide rules for allocating proceeds of "reimbursement bonds". Reimbursement bonds are bonds the proceeds of which are allocated to reimburse expenditures paid prior to the date of issue of the bonds.

Need for Correction

As published, the final regulations contain errors which may prove to be misleading and are in need of clarification.

Correction of Publication

Accordingly, the publication of the final regulations (T.D. 8394), which were the subject of FR Doc. 92–2023, is corrected as follows:

§ 1.103.18 [Corrected]

Paragraph 1. On page 3530, column 3, the title for the Table of Contents *"§ 1.103.18 Proceeds of bonds used for reimbursement"* is corrected to read *"§ 1.103–18 Proceeds of bonds used for reimbursement".*

Par. 2. On page 3531, in § 1.103–18, column 1, the entry for § 1.103–18(k)(1) is corrected to read "General rules.".

Par. 3. On page 3531, in § 1.103–18, column 1, a new entry § 1.103–18(l)(3) is added to read as follows:

(l) * * *
(3) Transition rule for form of official intent.

Par. 4. On page 3531, column 2, in § 1.103–18, paragraph (c)(2)(B), line 2, the language "placed in service." is corrected to read "placed in service as defined in § 1.103–8(d)(5))".

Par. 5. On page 3531, column 2, in § 1.103–18, paragraph (d), line 2, the language "*activity bonds.* In the case of a" is corrected to read "*activity bonds.* Except for any bond to which paragraph (c) of this section applies, in the case of a".

Par. 6. On page 3531, column 3, in § 1.103–18, paragraph (f)(2), line 15, the language "expected to be issued for such purposes." is corrected to read "expected to be issued for such reimbursement purposes.".

Par. 7. On page 3532, column 1, in § 1.103–18, paragraph (f)(2)(ii), the last line of the paragraph is corrected to read "improvements.".

Par. 8. On page 3532, column 3, in § 1.103–18, paragraph (g)(3)(ii), line 24, the language "that cause the issuer to reach its" is corrected to read "that causes the issuer to reach its".

Par. 9. On page 3533, column 2, in § 1.103–18, paragraph (k)(2), line 2, paragraph (k)(2)(l), Operating rule, is correctly designated as paragraph (k)(2)(i), Operating rule.

Par. 10. On page 3533, column 3, in § 1.103–18, paragraph (k)(3)(iv), lines 1 and 2 are corrected to read "To

reimburse any person for any expenditure or".

Par. 11. On page 3534, column 2, in § 1.103–18, paragraph (l)(2)(i), line 3, the language "before March 2, 1992", is corrected to read "before March 3, 1992".

Par. 12. On page 3534, column 2, in § 1.103–18, paragraph § 1.103–18(l)(3) is added to read as follows:

(l) * * *

(3) *Transition rule for form of official intent.* The requirement of paragraph (f)(1)(ii) of this section does not apply to any official intent declared before March 3, 1992.

* * * * *

§ 1.150–1 [Corrected]

Par. 13. On page 3534, column 3, in § 1.150–1, paragraph (g), lines 7 and 8, the language "installment sale obligation or similar obligation, to another entity (the obligor" is corrected to read "installment sale obligation, or similar obligation to another entity (the obligor".

Par. 14. On page 3534, column 3, the paragraph designated (h)(1), Effective date, is correctly designated as paragraph (i), Effective date.

Cynthia E. Grigsby,

Alternate Federal Register Liaison Officer, Assistant Chief Counsel (Corporate).

[FR Doc. 92–8567 Filed 4–14–92; 8:45 am]

BILLING CODE 4830–01–M

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26 CFR Parts 31, 35a, 301, and 602

[T.D. 8409]

RIN 1545–0112

Backup Withholding Due to Notification of an Incorrect Name/TIN Combination

AGENCY: Internal Revenue Service.

ACTION: Final regulations.

SUMMARY: This document contains final regulations under section 3406(a)(1)(B) of the Internal Revenue Code of 1986 (the Code) relating to the requirement to backup withhold on certain reportable payments made to a payee after notification that the payee has provided an incorrect name/taxpayer identification number combination (name/TIN combination). These regulations affect payors, brokers, and payees of certain reportable payments and provide guidance necessary to comply with the law.

DATES: The regulations are effective on September 1, 1990, and generally apply with respect to notices received on or after September 1, 1990.

FOR FURTHER INFORMATION CONTACT: Renay France of the Office of the Assistant Chief Counsel (Income Tax and Accounting), within the Office of the Chief Counsel, 1111 Constitution Avenue, NW., Washington, DC 20224, (202–377–7978, not a toll-free call).

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

The collection of information contained in this final regulation has been reviewed and approved by the Office of Management and Budget in accordance with the requirements of the Paperwork Reduction Act of 1980 (44 U.S.C. 3504(h)) under control number 1545–0112. The estimated average annual burden per respondent is approximately 30 minutes.

This estimate is an approximation of the average time expected to be necessary for a collection of information. It is based on such information as is available to the Internal Revenue Service. Individual respondents may require more or less time, depending on their particular circumstances.

Comments concerning the accuracy of this burden estimate and suggestions for reducing this burden should be directed to the Internal Revenue Service, Attn: IRS Reports Clearance Officer T:FP, Washington, DC 20224, and to the Office of Management and Budget, Attention: Desk Officer for the Department of the Treasury, Office of Information and Regulatory Affairs, Washington, DC 20503.

Background

This document contains final regulations to be added to part 31 of title 26 the Code of Federal Regulations (CFR) under sections 3406(a)(1)(B) of the Code. This provision was added to the Code by section 104 of the Interest and Dividend Tax Compliance Act of 1983 (Pub. L. 98–67, 97 Stat. 369, 371).

Section 3406(a)(1)(B) of the Code requires payors to backup withhold when the Service or a broker notifies a payor that the payee has provided an incorrect name/TIN combination (hereinafter "B notice withholding"). On November 23, 1987, the Internal Revenue Service published in the **Federal Register** temporary regulations (26 CFR part 35a.3406–1, T.D. 8163, 52 FR 44861) providing rules for backup withholding under section 3406(a)(1)(B) (the "B notice rules"). Amendments to these temporary regulations were published in the **Federal Register** on April 11, 1989 (T.D. 8248, 54 FR 14341), September 27, 1990 (T.D. 8309, 55 FR 39399), and September 23, 1991 (T.D. 8365, 56 FR 47904).

On September 27, 1990, the Service published in the **Federal Register** proposed regulations (55 FR 39427) that reorganized and restated, in traditional regulation form, the backup withholding rules in the temporary regulations relating to all four triggers under section 3406. The proposed regulations incorporated the substance of the B notice rules in the temporary regulations. Amendments to the proposed regulations were published in the **Federal Register** on September 23, 1991 (56 FR 47929).

The Service received many comments concerning the proposed regulations, and a public hearing was held on March 4, 1991. The Service also received comments on the amendments to the proposed regulations published on September 23, 1991, and a public hearing on those amendments was held on November 19, 1991.

The final regulations in this document contain rules relating only to B notice withholding. These rules were extensively modified by the April 11, 1989, amendments to the temporary regulations. The Service will issue final regulations covering the remainder of the backup withholding rules. Those final regulations will address, among other matters, certain miscellaneous rules that were included in the April 11, 1989, amendments. In particular, the final regulations will continue to allow payees who have religious objections to providing and certifying their taxpayer identification number on Form W–9 to provide instead a signed copy of Form 4029 or Form 8812 containing the information required therein (§ 35a.9999–1, A–10). The Service received comments concerning changes made by the April 11, 1989, amendments that provide that (1) a payor may refund amounts withheld under section 3406(a)(1)(C) if the Service directs the payor to do so (§ 35a.9999–3, A–38), and (2) a trustee of a grantor trust with 10 or fewer grantors is not treated as a payor (§ 35a.9999–3, A–54). Although the Service is reconsidering what the appropriate rules in these two areas should be, any modifications in the final regulations will apply only on a prospective basis.

Explanation of Provisions

The final regulations in this document adopt, in substance, the B notice rules contained in the proposed regulations with the changes discussed below.

Fiduciary and Nominee Accounts

Several commentators requested that the final regulations make permanent the exception from B notice withholding

for fiduciary and nominee accounts that was provided in the temporary regulations, but was proposed to expire upon issuance of final regulations. The Service adopted this exception because certain payors had indicated that they are likely to receive substantial numbers of B notices with respect to accounts maintained by fiduciaries or nominees even though the proper taxpayer identification number for the ultimate taxpayer had been provided. This could result, for example, because the Service's processing system reads only the first 80 characters of the registration on certain multi-name fiduciary or nominee accounts. The final regulations continue to exclude fiduciary and nominee accounts from B notice procedures and withholding. However, the Service will reconsider this issue in the future as it improves its systems.

Some commentators argued that the exception should be expanded to include accounts where the only name on the account registration is that of a trust or estate. The final regulations do not make this change because in these cases it is clear that the taxpayer identification number that should be used for information reporting purposes is the taxpayer identification number of the trust or estate (and not the taxpayer identification number of the beneficiaries). *See* the instructions to Form W-9.

The final regulations clarify that B notices are not required to be sent to payees of fiduciary and nominee accounts. In addition, under the final regulations, the receipt of a B notice on a fiduciary or nominee account does not count for purposes of the B notice rule where the payor receives B notices with respect to an account twice in three years (the "2/3 rule"). However, the receipt of a B notice with respect to these accounts continues to trigger certain solicitation requirements for purposes of the reasonable cause exception under section 6724. See § 301.6724-1(f)(3).

Payments Reportable on Form 1099-MISC

Several commentators argued that payments reportable on Form 1099-MISC, such as payments to independent service providers ("1099-MISC payments"), should be exempt from B notice witholding. The commentators indicated that payors of 1099-MISC payments often lack an ongoing, direct relationship with these payees and thus are not in a position to assure that correct name/TIN combinations are provided.

Commentators suggested that B notice withholding may be especially difficult to administer in the context of 1099-MISC payments to third-party payees under insurance policies or similar arrangements. For example, insurance companies usually maintain their business records on a policyholder basis, rather than on a payee basis. According to the commentators, significant problems thus may occur in coordinating B notice withholding with respect to payments made to the same payee under different policies.

The final regulations continue to subject accounts making 1099-MISC payments to B notice withholding. The Code specifically requires that backup withholding under section 3406(a)(1)(B) apply to these payments (unlike backup withholding under section 3406(a)(1) (C) or (D), which applies only to reportable interest and dividend payments). Moreover, underreporting of income attributable to these payments continues to be of serious concern to the Service.

The Service, however, is considering ways in which the concerns of commentators described above with respect to reportable payments to third-party payees under an insurance policy or similar arrangement can be addressed without compromising the integrity of the B notice withholding program. Toward this end, the Service is seeking additional comments on possible approaches with respect to such payments.

Certain Exceptions Clarified

Some commentators requested that the final regulations clarify that a payor receiving a B notice is not required to notify the payee of an account (or to backup withhold with respect to an account) if the B notice relates to payments that were made to an exempt recipient or that were not, in fact, reportable payments. The final regulations make the requested clarification.

Additional Responsibilities of Payors That Are Also Brokers

Some commentators asked for clarification of the rules requiring a broker to notify a payor of a readily tradable instrument that the payee is subject to B notice withholding. The final regulations provide that the notification requirement applies if: (1) The broker (in its capacity as payor) receives a B notice for the payee and is required to identify the account as having the incorrect name/TIN combination, (2) the payee acquires through the account a readily tradable instrument with respect to which the broker is not the payor, and (3) the acquisition occurs on any date more than 30 business days after the date that the broker received the B notice (or on any earlier date if the broker so chooses). Under the final regulations, the notification requirement ends simultaneously with the broker's obligation to backup withhold on the account in its capacity as a payor. See also the rules for dormant accounts discussed below.

Identification of Accounts Subject to B Notice Withholding

The rules in the final regulations for identification of accounts subject to B notice withholding where the payor receives the B notice from the Service are essentially unchanged from the proposed and temporary regulations. Accordingly, if the B notice contains an account number or designation, the payor need only determine whether the account or accounts corresponding to that number or designation have the incorrect name/TIN combination. The final regulations clarify that, where the B notice does not contain an account number or designation, the payor satisfies its duty to exercise reasonable care in identifying accounts if the payor searches the computer or record system that it can reasonably associate with the information return that generated the B notice. The final regulations also provide that a payor of a readily tradable instrument that receives notice from a broker (rather than the Service) need not determine if other accounts of that payee have the incorrect name/TIN combination.

The proposed and temporary regulations provide, in effect, that B notice procedures and withholding do not apply if the error in the taxpayer identification number is caused by an error by the payor (for example, because the payor transposed numbers in the taxpayer identification number when incorporating it into its business records). A commentator questioned whether this rule applies when the name on the account registration is wrong for the same reason. The final regulations provide that B notice procedures and withholding do not apply if, due to an error of the payor, the name or taxpayer identification number on such account is not the name or taxpayer identification number that was provided to the payor by the payee.

Joint Accounts

A number of commentators raised concerns about the rules in the temporary and proposed regulations concerning the treatment of joint accounts. The temporary and proposed regulations require a payor to treat the first person listed on a joint account as

the person subject to backup withholding. Commentators pointed out that this rule is inconsistent with the fact that a payor may use the name of another person on the account for information reporting purposes. Accordingly, the final regulations provide that with respect to a joint account the relevant name/TIN combination for B notice withholding purposes is the name/TIN combination used for information reporting purposes. (This rule is phased in to accommodate payors with systems keyed to the first person on the account.)

Commentators also suggested deletion of the requirement to continue backup withholding when the name/TIN combination on the B notice initially matches the first person listed on the account, but the order of names on the account is subsequently changed. The commentators explained that this rule is inconsistent with the rule allowing the payee to avoid B notice withholding by recertifying the existing name/TIN combination (subject to the 2/3 rule). The final regulations make the rule concerning a change in the order of names optional.

Requirements for the First B Notice to Payees

The final regulations continue to provide that the notice to payees must be provided within 15 days of the date that the payor is considered to receive the first B notice from the Service or a broker. The final regulations generally provide that rules governing the delivery of the notice to payees are to be provided by the Service in the Internal Revenue Bulletin. In connection with the issuance of the final regulations, therefore, the Service is issuing Rev. Proc. 92–32, 1992–17 I.R.B. (dated April 27, 1992).

In general, the rules for the first notice under Rev. Proc. 92–32 are the same as those in the temporary and proposed regulations, except for the following changes. First, Rev. Proc. 92–32 allows payors to follow the rules for a substitute notice provided in the temporary regulations (prior or subsequent to amendment by T.D. 8248, T.D. 8309, or T.D. 8365) only with respect to B notices received by payors prior to September 1, 1993. Second, under Rev. Proc. 92–32, a payor is required only to state in a substitute notice the date that the payor will begin backup withholding, rather than the dates that the payor received the B notice and is required to begin backup withholding under the Code. Third, Rev. Proc. 92–32 allows payors in a substitute notice not to give payees whose name has changed the option of providing both surnames (rather than contacting the Social Security Administration or the Service to correct the problem). Fourth, Rev. Proc. 92–32 allows payors to use envelopes marked either "Important Tax Document Enclosed" or "Important Tax Return Document Enclosed" and does not require them to enclose reply envelopes. Fifth, Rev. Proc. 92–32 allows payors to omit or revise material inapplicable (or add information to clarify material applicable) to the payee because of the status of the payee or a permitted practice of the payor.

Certification Required to Prevent Backup Withholding From Starting or to Stop It Once It Has Begun

As under the temporary and proposed regulations, a payee who receives a notice from a payor that the payee's name/TIN combination is incorrect is required to provide his name and taxpayer identification number and to certify, under penalties of perjury, that the taxpayer identification number is correct in order to prevent backup withholding from starting or to stop it once it has begun. One commentator asked whether a payee must also certify, under penalties of perjury, that the payee is not subject to backup withholding due to a notified payee underreporting under section 3406(a)(1)(C) of the Code. The final regulations clarify that a payee is not required to make that certification in order to prevent backup withholding under section 3406(a)(1)(B) from starting or to stop it once it has begun. The final regulations also provide that, effective for B notices received by payors after September 1, 1993, providing an awaiting-TIN certificate is not sufficient for these purposes.

Changes Related to the 2/3 Rule

The final regulations retain, with the changes discussed below, the 2/3 rule set forth in the temporary and proposed regulations (as modified by Notice 91–40, 1991–50 I.R.B. 11). Accordingly, the 2/3 rule generally applies to the receipt of two B notices with respect to the same account in any two calendar years during a rolling 3-year calendar period. For example, a B notice received in October 1992 is counted in determining whether the payor received two B notices with respect to the same payee for a 3-year-calendar period ending with 1992 and for another 3-year-calendar period ending with 1994.

The final regulations continue to provide that notice to payees must be provided within 15 days of the date that the payor is considered to receive the second B notice from the Service or a broker. The final regulations generally provide that rules governing the delivery of the notice to payees are to be provided by the Service in the Internal Revenue Bulletin. Rev. Proc. 92–32 supersedes Rev. Proc. 91–58, 1991–40 I.R.B. 119, and provides these rules.

In general, the rules under Rev. Proc. 92–32 are the same as under Rev. Proc. 91–58, with the following exceptions. First, Rev. Proc. 92–32 allows payors to follow the procedural rules provided in the temporary regulations (as amended by T.D. 8365) only with respect to B notices received by payors prior to September 1, 1993. Second, Rev. Proc. 92–32 requires a payor to instruct a payee to provide a copy of the notice from the payor to the Social Security Administration. This will allow the Social Security Administration to provide the account number back to the payor on Form SSA–7028. Third, under Rev. Proc. 92–32, certain rules described above for first notices (relating to the date when the payor will commence backup withholding; envelope markings; and omission, revision, or deletion of certain material) also apply to second notices. Fourth, Rev. Proc. 92–32 contains a sample second notice.

Notifying the Service of Corrected Name/TIN Combination

The final regulations clarify that there is a 30-day grace period with respect to the requirement that a payor use a corrected name/TIN combination on subsequent information returns.

Dormant Accounts

Some commentators questioned whether it is appropriate to require payors to track accounts subject to backup withholding even though no reportable payments have been made to the account for a long time. The final regulations provide that the requirement to backup withhold under the B notice rules (including the 2/3 rule) terminates no later than the close of the third calendar year ending after the date that the last reportable payment was made to the account (or, if later, the close of the third calendar year ending after the date the B notice was received).

Operational Issues

The Service received several comments raising operational issues relating to the Service's implementation of the B notice withholding. These include comments as to: (1) Whether B notices could be sent to a designated contact person, and (2) whether the Service could create and recognize an optional dummy number for payors whose computer system cannot process an information return with a missing

taxpayer identification number. The final regulations do not address these operational issues. However, the Service is continuing to consider them and will notify payors of any change in its procedures.

Special Analyses

It has been determined that these rules are not major rules as defined in Executive Order 12291. Therefore, a Regulatory Impact Analysis is not required. It has also been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C chapter 5) and the Regulatory Flexibility Act (5 U.S.C. chapter 6) do not apply to these regulations, and, therefore, a final Regulatory Flexibility Analysis is not required. Pursuant to section 7805(f) of the Internal Revenue Code, the notice of proposed rulemaking for the regulations was submitted to the Administrator of the Small Business Administration for comment on their impact on small business.

Drafting Information

The principal author of these regulations is Renay France of the Office of the Assistant Chief Counsel (Income Tax and Accounting), within the Office of the Chief Counsel, Internal Revenue Service. Other personnel from the Internal Revenue Service and the Treasury Department participated in developing these regulations on matters of both substance and style.

List of Subjects

26 CFR Part 31

Employment taxes, Fishing vessels, Gambling, Income taxes, Penalties, Pensions, Railroad retirement, Reporting and Recordkeeping requirements, Social security, Unemployment compensation.

26 CFR Part 35a

Employment taxes, Income taxes, Reporting and recordkeeping requirements.

26 CFR Part 301

Administrative practice and procedure, Alimony, Bankruptcy, Child support, Continental shelf, Courts, Crime, Employment taxes, Estate taxes, Excise taxes, Gift taxes, Income taxes, Investigations, Law enforcement, Oil pollution, Penalties, Pensions, Reporting and recordkeeping requirements, Statistics, Taxes.

26 CFR Part 602

Reporting and recordkeeping requirements.

Adoption of Amendments to the Regulations

Accordingly, 26 CFR, parts 31, 35a, 301, and 602 are amended as follows:

PART 31—EMPLOYMENT TAXES AND COLLECTION OF INCOME TAX AT SOURCE

Paragraph 1. The authority for part 31 is amended by adding the following citation:

Authority: * * * 26 U.S.C. 7805 * * * Sec. 31.3406(d)–5 also issued under 26 U.S.C. 3406(i). * * *

Par. 2. Section 31.3406–0 is added to subpart E to read as follows:

§ 31.3406–0 Outline of the backup withholding regulations.

This section lists the paragraphs contained in § 31.3406(d)–5.

§ 31.3406(d)–5 Backup withholding when the Service or a broker notifies the payor to withhold because the payee's taxpayer identification number is incorrect.

(a) Overview.
(b) Definitions and special rules.
(1) Definition of an incorrect name/TIN combination.
(2) Definition of account.
(3) Definition of business day.
(4) Certain exceptions.
(i) In general.
(ii) Definition of fiduciary or nominee account.
(c) Notice regarding an incorrect name/TIN combination.
(1) In general.
(2) Additional requirements for payors that are also brokers.
(i) In general.
(ii) Required information.
(iii) Termination of obligation to provide information.
(3) Payor identification of the account or accounts of the payee that have the incorrect taxpayer identification number.
(i) In general.
(ii) Reasonable care where no account number or designation is provided.
(iii) No identification if error is caused by payor.
(4) Special rule for joint accounts.
(i) In general.
(ii) Transitional rule.
(iii) Optional rule where names are switched.
(5) Date of receipt.
(d) Notice from payors of backup withholding due to an incorrect name/TIN combination.
(1) In general.
(2) Procedures.
(i) In general.
(ii) Two or more notices for an account in the same calendar year.
(e) Period during which backup withholding is required due to notification of an incorrect name/TIN combination.
(1) In general.
(2) Grace periods.
(i) Starting backup withholding.
(ii) Stopping backup withholding.
(3) Dormant accounts.
(f) Manner required for payee to furnish certified taxpayer identification number.
(g) Receipt of two notices within a 3-year period.
(1) In general.
(2) Notice to payee who has provided two incorrect name/TIN combinations within 3 calendar years.
(3) Period during which backup withholding is required due to a second notice of an incorrect name/TIN combination within 3 calendar years.
(i) In general.
(ii) Grace periods.
(iii) Dormant accounts.
(4) Receipt of two notices in one calendar year.
(5) Notification from the Social Security Administration (or the Internal Revenue Service) validating a name/TIN combination.
(h) Payors must use newly provided certified number.
(i) Effective date.
(j) Examples.

Par. 3. Section 31.3406(d)–5 is added to subpart E to read as follows:

§ 31.3406(d)–5 Backup withholding when the Service or a broker notifies the payor to withhold because the payee's taxpayer identification number is incorrect.

(a) *Overview.* Backup withholding under section 3406(a)(1)(B) applies to any reportable payment made with respect to an account of a payee if the Internal Revenue Service or a broker notifies a payor under paragraph (c)(1) or (2) of this section that the payee's name and taxpayer identification number combination (name/TIN combination) is incorrect and the payor is required under paragraph (c)(3) of this section to identify that account as having the same name/TIN combination. After receiving a notice from the Internal Revenue Service or a broker under paragraph (c)(1) or (2) of this section and identifying an account as having the incorrect name/TIN combination under paragraph (c)(3) of this section, the payor must notify the payee in accordance with paragraph (d) of this section. In addition, under paragraph (e) of this section, the payor must backup withhold on all reportable payments made to such account after the close of the 30th business day after the date that the payor receives the notice and on or before the close of the 30th calendar day after the date that the payor receives from the payee the certification required under paragraph (f) of this section. Under paragraph (g) of this section, if a payor receives 2 notices from the Internal Revenue Service or broker within 3 calendar years with respect to a payee's account, the payor must notify the payee in accordance with paragraph (g)(2) (rather than

paragraph (d)) of this section. In addition, the payor must backup withhold on all reportable payments made with respect to the account after the close of the 30th business day after the date that the payor receives the second notice and on or before the 30th calendar day after the date that the payor receives notification from the Social Security Administration (or the Internal Revenue Service) validating a name/TIN combination for the account. Paragraph (h) of this section requires a payor to use a corrected name/TIN combination on subsequent information returns.

(b) *Definitions and special rules.*—(1) *Definition of incorrect name/TIN combination.* An incorrect name/TIN combination is a combination of a name and taxpayer identification number provided on an information return with respect to which the Internal Revenue Service determines that the taxpayer identification number provided is not assigned under section 6109 to the name provided.

(2) *Definition of account.* The term "account" means any account, instrument, or other relationship with the payor.

(3) *Definition of business day.* The term "business day" means any day other than a Saturday, Sunday, or legal holiday (within the meaning of section 7503).

(4) *Certain exceptions*—(i) *In general.* This section does not apply with respect to any notice received under paragraph (c)(1) or (2) of this section with respect to payments that—

(A) Were made to a fiduciary or nominee account; or

(B) Were not reportable payments (for example, because the payments were made to an exempt recipient).

See § 301.6724–1(f)(3) of this chapter for certain solicitation rules applicable after receipt of a notice under paragraph (c)(1) or (2) of this section with respect to a fiduciary or nominee account.

(ii) *Definition of fiduciary or nominee account.* A fiduciary or nominee account is an account with respect to which at least one person named in the registration is identified as acting in the capacity as nominee or as administrator, conservator, custodian, receiver, tutor, curator, committee, executor, guardian, trustee, or other fiduciary capacity recognized under governing law.

(c) *Notice regarding an incorrect name/TIN combination*—(1) *In general.* If the Internal Revenue Service notifies a payor that a payee's name/TIN combination is incorrect and that the payor must commence backup withholding as required on reportable payments made with respect to accounts of the payee with the same name/TIN combination, the payor must—

(i) Identify under paragraph (c)(3) of this section any account or accounts of the payee having the same name/TIN combination;

(ii) Except as provided in paragraph (g) of this section, notify the payee and backup withhold on reportable payments made to the account or accounts under the rules of paragraphs (d), (e), and (f) of this section.

This paragraph (c)(1) also applies if the payor receives notice from a broker under paragraph (c)(2) of this section.

(2) *Additional requirements for payors that are also brokers*—(i) *In general.* A broker must notify the payor of an instrument of the information required under paragraph (c)(2)(ii) of this section, if—

(A) The broker (in its capacity as a payor) receives a notice from the Internal Revenue Service under paragraph (c)(1) of this section that a payee's name/TIN combination is incorrect and is required to identify an account of the payee pursuant to paragraph (c)(3) of this section as having the name/TIN combination;

(B) The payee acquires through the same account with the broker a readily tradable instrument with respect to which the broker is not the payor; and

(C) The acquisition of such instrument occurs after the close of the 30th business day after the date that the broker receives that notice (or on any earlier date that the broker chooses to begin applying this paragraph (c)(2)).

For purposes of this paragraph (c)(2)(i), with respect to notices under paragraph (c)(1) of this section received on or after September 1, 1992, an acquisition includes a transfer of an instrument out of street name into the name of the registered owner, *i.e.*, the payee.

(ii) *Required information.* The information required to be provided under this paragraph (c)(2)(ii) is:

(A) The fact that the broker was notified by the Internal Revenue Service that the payee furnished an incorrect name/TIN combination;

(B) The incorrect name/TIN combination; and

(C) The fact that the named payee is subject to backup withholding under section 3406(a)(1)(B).

The broker is required to provide this information to the payor of the instrument in connection with the transfer instructions for the acquisition.

(iii) *Termination of obligation to provide information.* The obligation of a broker to provide information to payors under this paragraph (c)(2) terminates simultaneously with the termination of the broker's obligation to backup withhold (in its capacity as payor) on reportable payments to the account.

(3) *Payor identification of the account or accounts of the payee that have the incorrect taxpayer identification number*—(i) *In general.* If an account number or designation is provided in the notice received under paragraph (c)(1) of this section, the payor need only identify any account or accounts corresponding to that number or designation that has the same name/TIN combination provided in the notice. If no account number or designation is provided in the notice received under paragraph (c)(1) of this section, the payor must identify, using reasonable care, all accounts of the payee having the same name/TIN combination provided in the notice. If a payor receives notice from a broker under paragraph (c)(2) of this section with respect to the acquisition of a readily tradable instrument, the payor is not required to identify any other account of the payee.

(ii) *Reasonable care where no account number or designation is provided.* A payor who satisfies the following two-part facts-and-circumstances test will be considered to have exercised reasonable care for purposes of this paragraph (c)(3).

(A) Part one of the test is satisfied if a payor searches for accounts of the payee on the computer or other recordkeeping system that the payor can reasonably associate with the information return that generated the notice under paragraph (c)(1) of this section. For example, a payor who maintains separate computer or recordkeeping systems for different product lines will have identified and used the appropriate system if the payor searches for accounts of the payee on the computer or recordkeeping system that contains the product line for the type of payments reported on the information return. A payor with the same product line on several nonintegrated computer or record systems will have identified and used the appropriate system if the payor searches for accounts of the payee on any computer or record system that the payor otherwise can reasonably associate with the information return.

(B) Part two of the test is satisfied if the payor inputs the name/TIN combination provided on the notice from the Internal Revenue Service under paragraph (c)(1) of this section into the system that is described in paragraph (c)(3)(ii)(A) of this section. If the system of a payor cannot utilize the name/TIN

combination, the payor must input appropriate data or criteria, as determined by the capability of the payor's computer or recordkeeping system.

(iii) *No identification if error is caused by payor.* A payor may treat an account as not having the incorrect name/TIN combination if the error resulted because the name or taxpayer identification number on such account is not the name or taxpayer identification number that was provided to the payor. This may occur, for example, where a payor transposes numbers in the taxpayer identification number when incorporating it into the payor's business records.

(4) *Special rules for joint accounts*—(i) *In general.* In the case of a joint account, the relevant name/TIN combination for purposes of this section is the name/TIN combination used for information reporting purposes.

(ii) *Transitional rule.* With respect to notices received under paragraph (c) (1) or (2) of this section prior to September 1, 1993, a payor may treat the name/TIN combination of the first person on a joint account as the relevant name/TIN combination, unless that person is an exempt foreign person and the account registration includes names of persons who are not foreign persons.

(iii) *Optional rule where names are switched.* A payor may backup withhold under this section on reportable payments made to a joint account if the order of the names (or taxpayer identification numbers) on the account is merely changed subsequent to receipt of a notice under paragraph (c) (1) or (2) of this section, provided that the name of the person to which the incorrect name/TIN combination originally applies remains on the account.

(5) *Date of receipt.* For purposes of this section, the date set forth on the notice from the Internal Revenue Service or broker under paragraph (c) (1) or (2) of this section is considered to be the date of receipt of the notice by the payor. However, if the payor demonstrates to the satisfaction of the Internal Revenue Service that the date of actual receipt of the notice is later than the date on the notice, the actual date of receipt is controlling.

(d) *Notice from payors of backup withholding due to an incorrect name/TIN combination*—(1) *In general.* Except as provided in paragraph (g) of this section, if a payor receives notice under paragraph (c)(1) or (2) of this section and is required to identify an account as having the incorrect name/TIN combination under paragraph (c)(3) of this section, the payor must send a copy of the notice (or an acceptable substitute notice) to the payee of the account in accordance with the procedures of paragraph (d)(2) of this section.

(2) *Procedures*—(i) *In general.* The notice that a payor must send to a payee under paragraph (d)(1) of this section must comply with such procedural requirements as the Internal Revenue Service provides in the Internal Revenue Bulletin such as to form and manner of delivery. A payor must send the notice to the payee within 15 business days after the date that the payor receives the notice from the Internal Revenue Service or a broker under paragraph (c)(1) or (2) of this section.

(ii) *Two or more notices for an account in the same calendar year.* A payor who receives, under the same payor taxpayer identification number, two or more notices under paragraph (c)(1) or (2) of this section in a calendar year with respect to the same account of a payee need only send one notice to the payee under this section.

(e) *Period during which backup withholding is required due to notification of an incorrect name/TIN combination*—(1) *In general.* Except as provided in paragraph (g) of this section, if a payor receives a notice under paragraph (c)(1) or (2) of this section and is required to identify an account as having the same name/TIN combination under paragraph (c)(3) of this section, the payor must impose backup withholding on all reportable payments made with respect to the account after the close of the 30th business day after the date the payor receives that notice and on or before the close of the 30th calendar day after the day the payor receives from the payee the certification required under paragraph (f) of this section.

(2) *Grace periods*—(i) *Starting backup withholding.* A payor may, on an account-by-account basis or in general, choose to begin backup withholding under this paragraph (e) at any time during the 30-business-day period described in paragraph (e)(1) of this section.

(ii) *Stopping backup withholding.* A payor may, on an account-by-account basis or in general, choose to stop backup withholding under this paragraph (e) at any time within 30 calendar days after the payor receives from the payee the certification required under paragraph (f) of this section.

(3) *Dormant accounts.* The requirement that a payor backup withhold under this paragraph (e) on reportable payments made with respect to an account terminates no later than the close of the third calendar year ending after the later of—

(i) The date that the last reportable payment was made to that account; or

(ii) The date that the payor received the notice under paragraph (c)(1) or (2) of this section.

(f) *Manner required for payee to furnish certified taxpayer identification number.* (1) Except as provided in paragraph (g) of this section, in order to prevent backup withholding under paragraph (e) of this section from starting, or to stop it once it has begun, a payee with respect to whom the payor has been notified under paragraph (c)(1) or (2) that the payee's name/TIN combination is incorrect is required on Form W-9 (or an acceptable substitute form) to—

(i) Provide the payee's name and taxpayer identification number; and

(ii) Certify, under penalties of perjury, that the taxpayer identification number being provided is correct.

(2) The certification must be made even if the account is a pre-1984 account and even if the payment to the account is a reportable payment other than interest, dividends, patronage dividends, original issue discount, or proceeds of a sale of a security or commodity. In order to prevent backup withholding under paragraph (e) of this section from starting or to stop it once it has begun, a payee is not required to certify, under penalties of perjury, that the payee is not subject to backup withholding due to notified payee underreporting under section 3406(a)(1)(C). With respect to notices received under paragraph (c)(1) or (2) of this section on or after September 1, 1993, the requirements of this paragraph (f) are not satisfied if a payee provides only an awaiting TIN certification. As a result, a payor must not fail to begin backup withholding under paragraph (e) of this section solely because the payee provided an awaiting TIN certification, or stop it once it has begun solely because the payee provided an awaiting TIN certification.

(g) *Receipt of two notices within a 3-year period*—(1) *In general.* If a payor receives notification under paragraph (c)(1) or (2) of this section twice within 3 calendar years, and in each case the payor is required to identify the same account as having the incorrect name/TIN combination, the payor must—

(i) Disregard any future certifications (described in paragraph (f) of this section) furnished by the payee with respect to the account until the payor receives notice from the Social Security Administration (or the Internal Revenue Service) validating a name/TIN combination under paragraph (g)(5) of this section;

(ii) Send the notice described in paragraph (g)(2) of this section to the payee (and not the notice required under paragraph (d) of this section) within 15 business days after the date that the payor receives the second notice; and

(iii) Impose backup withholding on the account for the period described in paragraph (g)(3) of this section.

The payor must maintain sufficient records to determine whether the payor has received notices under paragraph (c)(1) or (2) of this section twice within 3 calendar years with respect to the same account.

(2) *Notice to payee who has provided two incorrect name/TIN combinations within 3 calendar years.* The notice to the payee required by paragraph (g)(1) of this section must comply with such procedural requirements as the Internal Revenue Service provides in the Internal Revenue Bulletin such as to form and manner of delivery.

(3) *Period during which backup withholding is required due to a second notice of an incorrect name/taxpayer identification combination within 3 calendar years*—(i) *In general.* If paragraph (g)(1) of this section applies, the payor must backup withhold on all reportable payments made with respect to the account of the payee after the close of the 30th business day after the date that the payor receives the second notice under paragraph (c)(1) or (2) of this section and on or before the close of the 30th calendar day after the date that the payor receives notice from the Social Security Administration (or the Internal Revenue Service) validating a name/TIN combination under paragraph (g)(5) of this section for the account. However, a payor may choose not to commence backup withholding under this paragraph (g) until January 1, 1992.

(ii) *Grace periods*—(A) *Starting backup withholding.* A payor may, on an account-by-account basis or in general, choose to begin backup withholding under this paragraph (g) at any time during the 30-business-day period described in paragraph (g)(3)(i) of this section.

(B) *Stopping backup withholding.* A payor may, on an account-by-account basis or in general, choose to stop backup withholding under this paragraph (g) at any time within 30 calendar days after the date the payor receives notice from the Social Security Administration (or the Internal Revenue Service) validating a name/TIN combination under paragraph (g)(5) of this section for the account.

(iii) *Dormant accounts.* The requirement that a payor backup withhold under this paragraph (g) on reportable payments made with respect to an account terminates no later than the close of the third calendar year ending after the later of—

(A) The date that the last reportable payment was made to that account; or

(B) The date that the payor received the second notice under paragraph (c)(1) or (2) of this section.

(4) *Receipt of two notices in one calendar year.* A payor must treat the receipt of two or more notices under paragraph (c)(1) or (2) of this section in a calendar year with respect to an account as the receipt of one notice for purposes of this paragraph (g). The preceding sentence applies only if the two or more notices are received under the same payor taxpayer identification number.

(5) *Notification from the Social Security Administration (or the Internal Revenue Service) validating a name/TIN combination.* The Social Security Administration (or the Internal Revenue Service) will notify a payor after it validates a name/TIN combination that the payee provides for an account to which paragraph (g)(1) of this section applies. Notification from the Social Security Administration (or the Internal Revenue Service) validating a name/TIN combination satisfies the requirements of this paragraph (g)(5) only if it complies with such procedural requirements as the Internal Revenue Service provides in the Internal Revenue Bulletin such as to form and manner of delivery. In order to obtain notification from the Social Security Administration (or the Internal Revenue Service) validating a name/TIN combination for an account, a payee who receives notice from a payor under paragraph (g)(2) of this section should follow such procedures as the Internal Revenue Service provides in the Internal Revenue Bulletin.

(h) *Payor must use newly provided certified number.* If a payor receives a certification under paragraph (f) of this section or a notification under paragraph (g)(5) of this section for an account, the payor must use the name/TIN combination provided on such certification or notification on information returns for the account for which the due date (without regard to extensions) is more than 30 calendar days after the date that the payor receives the certification or notification. A payor who uses that name/TIN combination on the first such information return satisfies the requirement of section 3406(h)(9) to provide this information to the Internal Revenue Service. If the payor is not required to file any information returns with respect to the account after the date that the payor receives the certification or notification, a payor is deemed to satisfy the requirements of section 3406(h)(9).

(i) *Effective date.* Except as otherwise provided in this section, the provisions of this section are effective with respect to notices received on or after September 1, 1990, under paragraph (c)(1) or (2) of this section.

(j) *Examples.* The application of the provisions of this section may be illustrated by the following examples:

Example 1. D opened an account with Bank O prior to 1984 and furnished a taxpayer identification number to O at the time he opened the account. O pays interest on the account at the end of each calendar month, and the account is a pre-1984 account. On October 1, 1990, the Internal Revenue Service notifies Bank O that the name/TIN combination provided by D is incorrect. O timely notifies D as required in paragraph (d)(1) of this section. O does not receive the certification required under paragraph (f) of this section from D. O is required to backup withhold 20 percent of all reportable payments made after November 14, 1990 (which is 30 business days after the date the Internal Revenue Service notified O). Therefore, O is not required to backup withhold on the reportable payment made on October 31, 1990, but is required to backup withhold on the reportable payment made on November 30, 1990. O is required to continue to backup withhold under section 3406(a)(1)(B) until O receives the certification required under paragraph (f) of this section from D (or, if earlier, until backup withholding terminates under paragraph (e)(3) of this section).

Example 2. Assume the same facts as in *Example 1* except that D furnishes a new taxpayer identification number to O on November 1, 1990, but does not certify, under penalties of perjury, that it is his correct taxpayer identification number as required under paragraph (f) of this section. Even though the account is a pre-1984 account, O is required to withhold 20 percent of all reportable payments made after November 14, 1990 (which is 30 business days after the date the Internal Revenue Service notified O), and before the date O receives the certification required under paragraph (f) of this section from D.

Example 3. Assume the same facts as in *Example 2* except that D provides O with the certification required under paragraph (f) of this section on November 10, 1990. D elects pursuant to paragraph (e)(2)(ii) of this section to treat the certification as received on November 20, 1990. Even though D did not provide the certification to O within 30 business days after the Internal Revenue Service notified O that D provided an incorrect taxpayer identification number, O is not required to backup withhold under section 3406(a)(1)(B) because O did not make any reportable payment to D after 30 business days after notification of an incorrect name/TIN combination and before O received D's certification under paragraph

(f) of this section (or, if earlier, until backup withholding terminates under paragraph (e)(3) of this section).

Example 4. Individual F has two post-1983 accounts with Bank R that pay reportable interest: a savings account and a money market account. The money market account was opened in 1986, and the savings account was opened on February 1, 1991. R treats each of these accounts as a separate account on its books and records for business purposes. On October 1, 1990, the Internal Revenue Service notified R pursuant to paragraph (c)(1) of this section that F furnished an incorrect name/TIN combination with respect to the money market account. R timely sends F the notice required under paragraph (d) of this section and receives the certification required under paragraph (f) of this section from F on November 1, 1990. On October 1, 1991, the Internal Revenue Service again notifies R that F furnished an incorrect name/TIN combination with respect to the money market account. Further, R determines from its business records that two notifications of an incorrect name/TIN combination have been received with respect to the money market account within 3 calendar years. R must send F the notice required under paragraph (g)(2) of this section and must commence backup withholding on reportable interest paid on the money market account pursuant to paragraph (g)(3) of this section after November 14, 1991, which is 30 business days after R received the second notice. R must continue to backup withhold under paragraph (g) of this section on the money market account until R receives notification from the Social Security Administration as described in paragraph (g)(5) of this section (or, if earlier, until backup withholding terminates under paragraph (g)(3)(iii) of this section). R is not required to backup withhold on the savings account unless and until it receives notice under paragraph (c) (1) or (2) of this section with respect to the savings account.

PART 35a—TEMPORARY EMPLOYMENT TAX REGULATIONS UNDER THE INTEREST AND DIVIDEND TAX COMPLIANCE ACT OF 1983

Par. 4. The authority citation for part 35a is amended in part by removing the language "§ 35a.3406–1 also issued under 26 U.S.C. 3406 (a), (b), (e), (g), (h), and (i); 26 U.S.C. 6109; 26 U.S.C. 6676; and 26 U.S.C. 6721;" to read as follows:

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

§ 35a.3406–1 [Amended]

Par. 5. Section 35a.3406–1 is removed.

PART 301—PROCEDURE AND ADMINISTRATION

Par. 6. The authority citation for part 301 continues to read in part:

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

Par. 7. Section 301.6724–1 is amended as follows:

1. Paragraph (f)(1)(ii) is amended by removing the language "and § 35a.3406–1(c) and (f) of this chapter issued under the Interest and Dividend Tax Compliance Act of 1983".

2. Paragraph (f)(2) is revised to read as set forth below.

3. Paragraph (f)(3) is amended by removing the language "§ 35a.3406–1(a)(3)(x) of this chapter" and adding in lieu thereof "§ 31.3406(d)–5(b)(4)(i)(A) of this chapter".

4. Paragraph (g) is amended by adding the language "as in effect on December 31, 1989" after "§ 35a.9999–1 of this chapter *et seq.*".

5. Paragraph (h)(2)(i) is amended by adding the language "as in effect on December 31, 1989" after "§ 35a.9999–1 of this chapter".

Revised paragraph (f)(2) of § 301.6724–1 reads as follows:

§ 301.6724–1 Reasonable cause.

* * * * *

(f) * * *

(2) *Manner of making annual solicitation if notified pursuant to section 3406(a)(1)(B).* A filer that has been notified of an incorrect name/TIN combination pursuant to section 3406(a)(1)(B) (except filers to which § 31.3406(d)–5(b)(4)(i)(A) of this chapter applies) will satisfy the solicitation requirement of this paragraph (f) only if it makes a solicitation in the manner and within the time period required under § 31.3406(d)–5(d)(2) (i) or (g)(1)(ii) of this chapter, whichever applies. Section 31.3406(d)–5(d)(2) (i) and (g)(1)(ii) of this chapter generally requires that filer to notify a payee that the payee's account contains an incorrect taxpayer identification number within 15 business days after the date of the notice from the Internal Revenue Service or a broker.

* * * * *

PART 602—OMB CONTROL NUMBERS UNDER THE PAPERWORK REDUCTION ACT

Par. 4. The authority citation for part 602 continues to read as follows:

Authority: 26 U.S.C. 7805.

Par. 5. Section 602.101(c) is amended by removing the entry in the table for "35a.3406–1" and adding the entry—

"31.3406(d)–5..... 1545–0112".

Shirley D. Peterson,

Commissioner of Internal Revenue.

Approved: March 25, 1992.

Fred T. Goldberg, Jr.,

Assistant Secretary of the Treasury.

[FR Doc. 92–8339 Filed 4–10–92; 1:34 pm]

BILLING CODE 4830–01–M

26 CFR Part 301

[T.D. 8413]

RIN 1545–AG95

Reduction of Tax Overpayments by Amount of Past-Due, Legally Enforceable Debt Owed to a Federal Agency

AGENCY: Internal Revenue Service, Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations under section 6402(d), which permits the Service to reduce the amount of any overpayment payable to a taxpayer by the amount of a past-due, legally enforceable debt owed to any Federal agency, and under section 6402(e), which limits the review of such reductions. Changes to the applicable law were made by the Deficit Reduction Act of 1984. The regulations affect taxpayers who owe such debts and Federal agencies to which such debts are owed.

EFFECTIVE DATE: These regulations are effective after April 15, 1992.

FOR FURTHER INFORMATION CONTACT: Rochelle L. Pickard of the Office of the Assistant Chief Counsel (Income Tax and Accounting), Internal Revenue Service, 1111 Constitution Avenue NW., Washington, DC 20224 (Attention: CC:CORP:T) (202–566–3637, not a toll-free call).

SUPPLEMENTARY INFORMATION: This document contains final regulations amending the Procedure and Administration Regulations (26 CFR part 301), to provide rules under section 6402 (d) and (e) of the Internal Revenue Code of 1986 (the "Code"), relating to the authority to make credits or refunds.

Section 2653 of the Deficit Reduction Act of 1984 (Pub. L. 98–369, 98 Stat. 494, 1153) enacted section 3720A of subchapter II of chapter 37 of title 31, United States Code, relating to the reduction of a tax refund by the amount of a past-due, legally enforceable debt owed to a Federal agency, and amended section 6402 (d) and (e), relating to the authority to make credits and refunds, and section 6103, relating to confidentiality and disclosure of returns and information.

Section 2653 of the Deficit Reduction Act was amended by section 9402 of the Omnibus Budget Reconciliation Act of 1987 (Pub. L. 100–203, 101 Stat. 1330–1, 1330–376) (extending effective date); section 701 of the Family Support Act of 1988 (Pub. L. 100–485, 102 Stat. 2343, 2425) (further extending effective date); section 5129 of the Omnibus Budget

Reconciliation Act of 1990 (Pub. L. 101–508, 104 Stat. 1388, 1388–287) (permitting reduction of tax refund to collect OASDI overpayments); and section 401 of the Emergency Unemployment Compensation Act of 1991 (Pub. L. 105 Stat. 1049, 1061) (making permanent the provisions for the reduction of tax refunds to collect nontax Federal debts).

On September 30, 1985, the Internal Revenue Service published in the **Federal Register** a notice of proposed rulemaking (50 FR 39713) by cross reference to temporary regulations published the same day in the **Federal Register** (50 FR 39661) under Code section 6402 (d) and (e). Amendments to the notice of proposed rulemaking and temporary regulations were published in the **Federal Register** on May 13, 1987, and January 6, 1989, by notices of proposed rulemaking (52 FR 17989 and 54 FR 428) by cross reference to temporary regulations published the same days in the **Federal Register** (52 FR 17949 and 54 FR 400). The preambles of the temporary regulations contain an explanation of the temporary and proposed rules. After consideration of public comments, the proposed regulations are adopted as revised by this Treasury decision.

Explanation of Statutory Provisions

Code section 6402(d)(1) provides that the Secretary of the Treasury shall (1) reduce an overpayment due any person by the amount of a past-due, legally enforceable debt owed to any Federal agency upon receiving notice from a Federal agency that such person owes the debt and (2) pay the reduction to the Federal agency. The Service must notify the person making the overpayment that the overpayment has been reduced to satisfy such debt.

Code section 6402(d)(2) provides the priorities for offset. Section 6402(d)(3) provides special rules for offset to collect OASDI overpayments. OASDI overpayments are overpayments of benefits made to an individual under title II of the Social Security Act.

Code section 6402(e) provides that no court of the United States shall have jurisdiction to hear any action, whether legal or equitable, brought to restrain or review a reduction of an overpayment authorized under section 6402(d). No reduction of an overpayment under section 6402(d) shall be subject to review by the Secretary of the Treasury in an administrative proceeding. In addition, no action brought against the United States to recover the amount of such reduction shall be considered a suit for refund of tax. Section 6402(e) does not preclude any legal, equitable, or administrative action against any Federal agency to which the amount of such reduction was paid or any such action against the Secretary of Health and Human Services which is otherwise available with respect to recoveries of OASDI overpayments.

Code section 6103(l)(10) permits the disclosure to certain information of Federal agencies requesting a reduction of an overpayment of tax under section 6402(d).

Section 3720A(a) of title 31 of the United States Code instructs Federal agencies to notify the Secretary of the Treasury of persons owing past-due, legally enforceable debts to the agencies.

Section 3720A(b) of title 31 of the United States Code provides certain eligibility requirements that a Federal agency must meet before debts may be referred to the Service for offset. First, the Federal agency must notify the taxpayer that the debt will be referred to the Service for refund offset. Second, the Federal agency must give the taxpayer 60 days to present evidence that the debt is not past-due or not legally enforceable. Third, the Federal agency must consider such evidence and determine that an amount of the debt is past-due and legally enforceable. Fourth, a Federal agency must satisfy certain other conditions prescribed by the Secretary to ensure that the agency's determination is valid and that the agency has made a reasonable effort to collect the debt prior to notifying the Secretary.

Section 3720A(c) of title 31 of the United States Code provides rules for the Secretary of the Treasury to follow after he or she is notified by a Federal agency that a person owes the agency a past-due, legally enforceable debt. First, the Secretary must determine whether the taxpayer is due a refund. Second, the Secretary must reduce the refund by the amount of the debt and pay the amount of the reduction to the Federal agency. Finally, the Secretary must notify the agency of the taxpayer's home address so that the agency can notify the taxpayer of the intended offset.

Section 3720A(d) of title 31 of the United States Code provides that the Secretary of the Treasury shall issue regulations prescribing (1) the time and manner in which Federal agencies must notify the Secretary that a person owes a past-due, legally enforceable debt, (2) the minimum amount of debt that may be referred for offset, and (3) fee requirements to reimburse the Department of the Treasury for costs attributable to these procedures.

Section 3720A(e) of title 31 of the United States Code provides rules to correct erroneous payments made to an agency.

Section 3720A(f) of title 31 of the United States Code provides special rules for the recovery from individuals of overpayments of OASDI benefits.

Response to Public Comments

Section 301.6401–6T(a)(2) of the temporary regulations provides that, for purposes of the pilot program to reduce tax refunds to collect nontax debts owed to Federal agencies (the "program"), the Commissioner will identify those Federal agencies eligible to enter the program. Two commentators questioned whether the Commissioner should identify eligible agencies.

This issue is no longer relevant as a result of the Omnibus Budget Reconciliation Act of 1987. Section 9402(b)(2) of the Omnibus Budget Reconciliation Act of 1987 specifically extends the program to all agencies.

Therefore, it is now unnecessary to identify eligible agencies. If a Federal agency meets the requirements of § 301.6402–6(b) of the final regulations, the agency may participate in the program.

Section 301.6402–6T(b)(2) of the temporary regulations prohibits reduction of a refund for debts that have been delinquent for more than ten years. Two commentators recommended removing this ten-year limitation from the final regulations, reasoning that such a change would resolve the conflict among the Federal circuit courts regarding the meaning of "delinquent."

The final regulations do not remove the ten-year limitation. The Service and the Treasury believe that tax administration is best served by retention of a definite statute of limitations. However, § 301.6402–6(c)(1) of the final regulations clarifies that the ten-year limitation begins to run when the Federal agency's right of action with regard to the debt accrues.

The final regulations do not remove the three-month minimum delinquency period contained in § 301.6402–6T(b)(2) of the temporary regulations. This minimum delinquency period is unnecessary in light of § 301.6402–6(c) of the final regulations, relating to the eligibility of a debt for offset. This section ensures that the debt will be delinquent for at least three months before the debt is referred for offset. First, this section requires that the taxpayer be given at least 60 days to present evidence to the agency that all or part of the debt is not past-due or is not legally enforceable. Second, § 301.6402–6(c) (2), (3), and (5) requires that a Federal agency must attempt to

collect the debt by using salary and administrative offset and reporting to a consumer reporting agency before referring the debt to the Service for offset.

Three commentators opposed the eligibility requirements contained in § 301.6402–6T(b) (1), (3), (4), and (6) of the temporary regulations. Under these requirements, Federal agencies must attempt to collect the debt using salary and administrative offset and reporting to a consumer reporting agency prior to referring the debt for offset. These requirements have not been deleted. Salary and administrative offset and consumer reporting agency requirements contained in the temporary and final regulations ensure that the agency has made reasonable efforts to obtain payment of a debt prior to referring such debt to the Service for offset.

As a related issue, it was suggested that the Service grant waivers of these requirements in certain instances. Generally, waiving eligibility requirements is burdensome to administer and may lead to uncertainty. However, the regulations provide for waivers if an agency is specifically prohibited by law from complying with certain regulatory requirements. Section 301.6402–6(b)(2) of the final regulations sets forth procedures under which a Federal agency may request a waiver because of statutory prohibitions on debt collection practices. To receive a waiver, the final regulations require the Federal agency to notify the Service, in writing, of the statutory prohibition. The Service will then determine, also in writing, whether the agency is prohibited by statute from meeting any of the requirements contained in the regulations.

One commentator questioned whether the program will include corporate debtors. Section 9402(b)(1) of the Omnibus Reconciliation Act of 1987 specifically states that the program may be applied to corporations or any other category of persons. Therefore, the final regulations are drafted to apply to individuals, corporations, and other taxpayers equally (except provisions relating to OASDI overpayments and joint returns which by their terms apply only to individuals).

One commentator asked whether the final regulations should specifically require that eligible debts be "federal debts." Specific reference to "federal debts" is unnecessary. Section 6402(d) of the Code authorizes tax refund offset for debts owed to Federal agencies. Because the final regulations are published under section 6402(d), the requirement that the debt must be owed to a Federal agency is implicit in the final regulations.

The flush language of § 301.6402–6T(b) of the temporary regulations requires a Federal agency to send the 60-day notice to the address obtained from the Service pursuant to section 6103(m) (2), (4), or (5) of the Code. Two commentators requested clarification regarding whether the agency may use a more current address than the address provided by the Service. After consideration of this comment, the Service has determined that requiring Federal agencies to use the address obtained from the Service pursuant to section 6103(m) (2), (4), or (5) of the Code is too restrictive.

Section 301.6402–6(d)(2) of the final regulations requires a Federal agency to use the most recent address obtained from the Service pursuant to section 6103(m) (2), (4), or (5), unless the Federal agency receives clear and concise notification from the taxpayer that notices from the agency are to be sent to an address different from the address obtained from the Service. Clear and concise notification means that the taxpayer has provided the Federal agency with written notification including the taxpayer's name and identifying number (as defined in section 6109), the taxpayer's new address, and the taxpayer's intent to have notices from the Federal agency sent to the new address.

As a related issue, these commentators recommended allowing Federal agencies to use an address obtained from the Service within one year of mailing the notice to the taxpayer. The Service and the Treasury are concerned that this rule may not adequately protect taxpayers' interests in receiving notices. Therefore, the final regulations do not adopt this change.

One commentator recommended that the final regulations allow the Commissioner to suspend, cancel, or renegotiate participation in the program for the following reasons: (1) Validity and enforceability of the debts referred by the Federal agency for offset were successfully challenged or conceded as incorrectly determined by the agency; (2) on the basis of proceedings brought to recover offset amounts, a significant number of debts referred to the Service were incorrect in spite of apparently correct agency procedures; or (3) the Federal agency has not observed the restrictions on access to and use of confidential tax information.

The Memorandum of Understanding between the participating Federal agencies, the Service, and the Federal Management Service currently allows the Commissioner to suspend, cancel, or renegotiate participation in the program in the interest of sound tax administration. Because this agreement is the best vehicle to address these concerns, the final regulations do not contain such a provision.

Section 301.6402–6T(c) of the temporary regulations provides specific rules for the transmission of information to the Service on magnetic tape in the time and manner prescribed by a revenue procedure each year. In addition, § 301.6402–6T(f) provides that the Service will inform the agency of offsets on a monthly basis. Currently, Federal agencies transmit information both on magnetic tape and via electronic transfer, and the Service provides reports to the agencies weekly.

One commentator suggested that the final regulations conform with these current practices. However, such an approach would require amending the final regulations each time an informal procedural practice develops. Technology for transferring information is constantly improving and changing. If the final regulations specify the method of transferring information and the time in which such information is to be transferred, the final regulations will become obsolete each time program technology is improved. Therefore, procedural time and manner requirements are eliminated from the final regulations.

In addition, procedures relating solely to matters of internal management are not published; however, statements of internal practices and procedures that affect the rights and duties of taxpayers are published. Mere time and manner requirements (such as computer coding and dates for submission of computer tapes) for Federal agencies to transfer information to the Service are not practices and procedures that affect the rights and duties of taxpayers. Therefore, the final regulations eliminate the requirement that such time and manner requirements be published yearly in a revenue procedure.

Under § 301.6402–6T(b)(8) of the temporary regulations, a debt must be at least $25 to be eligible for offset, and under § 301.6402–6T(b)(6) a debt is not required to be reported to a consumer reporting agency if it does not exceed $100. Once commentator asked whether the threshold for referring a debt for offset should be the same as the threshold for referring a debt to a consumer reporting agency. The final regulations do not change these threshold amounts. There is no need to use the same threshold for these different purposes.

One commentator asked whether the final regulations should require a pre-deprivation notice and opportunity to present evidence. These requirements are already included in § 301.6402–6T(b) of the temporary regulations, which requires the Federal agency to allow the taxpayer at least 60 days to present evidence that the debt is not past-due or is not legally enforceable. This section also requires that the agency consider the evidence presented by the taxpayer.

Section 301.6402–6(c) of the final regulations also requires a pre-deprivation notice and opportunity to present evidence. In addition § 301.6402–6(d) clarifies the requirements for adequate notice and includes special protections for tax refund offset to collect overpayments of OASDI benefits from individuals.

One commenter asked whether all participating Federal agencies should be listed in the regulation. The list of participating agencies is constantly expanding. If such a list of participating agencies were included in the final regulations, the regulations would have been amended each time a new agency joined the program. Therefore, the final regulations do not include a list of all participating agencies.

Section 301.6402–6T(b) of the temporary regulations provides that, among other things, a debt will be eligible for offset if it is legally enforceable. "Legally enforceable" was not defined in the temporary regulations. One commentator asked that the term "legally enforceable" be defined in the final regulations.

Section 301.6402–6(c) of the final regulations provides that a Federal agency may only refer a debt for refund offset if, among other things, the debt is legally enforceable. Section 301.6402–6 (c)(4) and (d)(1) requires that the agency consider evidence that the debt is not past-due or legally enforceable. Section 6402(e) of the Code provides that any legal, equitable, or administrative action challenging the reduction of the overpayment must be brought against the Federal agency to which the reduction was paid. Therefore, prior to referring the debt to the Service for refund offset, a Federal agency must determine whether the debt is "legally enforceable." The taxpayer may challenge a Federal agency's determination that the debt is legally enforceable either in an administrative proceeding provided by the Federal agency referring the debt to the Service for refund offset or in a legal or equitable action against the Federal agency.

The time at which a debt becomes illegally enforceable is generally the time at which a right of action to collect the debt "accrues." The time at which a right of action to collect the debt accrues is a matter of Federal, state, and local law. The Service is unable to determine when the right of action for a particular debt accrues and, therefore, when the debt becomes legally enforceable. Only the Federal agency referring the debt for refund offset is in a position to determine when its right of action to collect a particular debt accrues. Therefore, the final regulations do not define when a debt becomes legally enforceable.

Special Analyses

It has been determined that these regulations are not major rules as defined in Executive Order 12291. Therefore, a Regulatory Impact Analysis is not required. It has also been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C chapter 5) and the Regulatory Flexibility Act (5 U.S.C. chapter 6) do not apply to these regulations, and, therefore, a final Regulatory Flexibility Analysis is not required. Pursuant to section 7805(f) of the Internal Revenue Code, notice of proposed rulemaking for the regulation that was issued January 6, 1989, was submitted to the Administrator of the Small Business Administration for comment on their impact on small business.

Drafting Information

The principal author of these final regulations is Rochelle L. Pickard of the Office of the Assistant Chief Counsel (Income Tax and Accounting), Internal Revenue Service. Personnel from other offices of the Internal Revenue Service and the Treasury Department participated in developing the regulations on matters of both substances and style.

List of Subjects

26 CFR Part 301

Administrative practice and procedure, Alimony, Bankruptcy, Child support, Continental shelf, Courts, Crime, Employment taxes, Estate taxes, Excise taxes, Gift taxes, Income taxes, Investigations, Law enforcement, Oil pollution, Penalties, Pensions, Reporting and recordkeeping requirements, Statistics, Taxes.

Accordingly, 26 CFR part 301 is amended as follows:

PART 301—PROCEDURE AND ADMINISTRATION

Paragraph 1. The authority citation for part 301 continues to read in part:

Authority: 68A Stat. 917; 26 U.S.C. 7805

* * *

Par. 2. Section 301.6402–6 is added to read as follows:

§ 301.6402–6 Offset of past-due, legally enforceable debt against overpayment.

(a) *General rule.* (1) A Federal agency (as defined in section 6402(f)) that has entered into an agreement with the Internal Revenue Service with regard to its participation in the tax refund offset program and that is owed a past-due, legally enforceable debt may refer the past-due, legally enforceable debt to the Internal Revenue Service to be collected by Federal tax refund offset. The Service shall, after making appropriate credits as provided by § 301.6402–3(a)(6) (i) and (ii), reduce the amount of any overpayment payable to a taxpayer by the amount of any past-due, legally enforceable debt owed to the agency and properly referred to the Service. This section does not apply to any debt subject to section 464 of the Social Security Act (past-due support).

(2)(i) This section applies to OASDI overpayments provided the requirements of 31 U.S.C. 3720A(f)(1) and (2) are met with respect to such overpayments.

(ii) For purposes of this section, "OASDI overpayment" means any overpayment of benefits made to an individual under title II of the Social Secutiry Act.

(b) *Eligible Federal agencies.* (1) A Federal agency is eligible to participate in the tax refund offset program if the agency—

(i) Has promulgated temporary of final regulations under 31 U.S.C. 3720A, governing the operation of the Federal Tax refund offset program in the agency;

(ii) Has promulgated temporary or final regulations under 31 U.S.C. 3716, governing the operation of the administrative offset program in the agency; and

(iii) Has promulgated temporary or final regulations under 5 U.S.C. 5514(a), governing the operation of the salary offset program in the agency (unless the agency has certified that, relying on the most current information reasonably available, it will not refer to the Service any names of present or former Federal employees or other persons whose debts are subject to offset under the provisions of 5 U.S.C. 5514(a)(1)).

(2) An agency prohibited by Federal law from meeting any of the requirements of paragraph (b)(1) or (c) of this section shall notify the Service in writing of the specific legal impediment

to meeting these requirements. This notification shall be made prior to entering into an agreement with the service to participate in the tax refund offset program. The Service will determine in writing whether the agency is prohibited by Federal law from meeting any of the requirements of paragraph (b)(1) or (c) of this section. The Service will waive in writing any requirement that it determines the agency is prohibited by Federal law from meeting.

(c) *Past-due, legally enforceable debt eligible for refund offset.* For purposes of this section, a Federal agency may refer a past-due, legally enforceable debt to the Service for offset if—

(1) Except in the case of a judgment debt or any debts specifically exempt from this requirement (for example, debts referred by the Department of Education that were pending on or after April 9, 1991, and referred to the Service for offset before November 15, 1992), the debt is referred for offset within ten years after the agency's right of action accrues;

(2) The debt cannot be currently collected pursuant to the salary offset provisions of 5 U.S.C. 5514(a)(1);

(3) The debt is ineligible for administrative offset under 31 U.S.C. 3716(a) by reason of 31 U.S.C. 3716(c)(2), or cannot be currently collected by administrative offset under 31 U.S.C. 3716(a) by the referring agency against amounts payable to the taxpayer by the referring agency;

(4) The agency has notified, or has made a reasonable attempt to notify, the taxpayer that the debt is past-due, and unless repaid within 60 days thereafter, will be referred to the Service for offset against an overpayment of tax;

(5) The agency has given the taxpayer at least 60 days to present evidence that all or part of the debt is not past-due or legally enforceable, has considered any evidence presented by the taxpayer, and has determined that the debt is past-due and legally enforceable;

(6) The debt has been disclosed by the agency to a consumer reporting agency as authorized by 31 U.S.C. 3711(f), unless the consumer reporting agency would be prohibited from reporting information concerning the debt by reason of 15 U.S.C. 1681c, or unless the amount of the debt does not exceed $100;

(7) The debt is at least $25; and

(8) In the case of an OASDI overpayment—

(i) The individual is not currently entitled to monthly insurance benefits under title II of the Social Security Act;

(ii) The notice describes conditions under which the Department of Health and Human Services is required to waive recovery of the overpayment, as provided under section 204(b) of the Social Security Act; and

(iii) If the taxpayer files for a waiver under section 204(b) of the Social Security Act within the 60-day notice period, the agency has considered the taxpayer's request.

(d) *Pre-offset notice and consideration of evidence.* (1) For purposes of paragraph (c)(4) of this section, an agency has made a reasonable attempt to notify the taxpayer if the agency uses the most recent address information obtained from the Service pursuant to section 6103(m) (2), (4), or (5) of the Code, unless the agency receives clear and concise notification from the taxpayer that notices from the agency are to be sent to an address different from the address obtained from the Service. Clear and concise notification means that the taxpayer has provided the agency with written notification including the taxpayer's name and identifying number (as defined in section 6109), the taxpayer's new address, and the taxpayer's intent to have agency notices sent to the new address.

(2) For purposes of paragraph (c)(5) of this section, if the evidence presented by the taxpayer is considered by an agent of the agency, or other entities or persons acting on the agency's behalf, the taxpayer must be accorded at least 30 days from the date the agent or other entity or person determines that all or part of the debt is past-due and legally enforceable to request review by an officer or employee of the agency of any unresolved dispute. The agency must then notify the taxpayer of its decision.

(e) *Referral of past-due, legally enforceable debt.* A Federal agency must refer a past-due, legally enforceable debt to the Service in the time and manner prescribed by the Service. The referral must contain—

(1) The name and identifying number (as defined in section 6109) of the taxpayer who is responsible for the debt;

(2) The amount of such past-due and legally enforceable debt;

(3) The date on which the debt became past-due;

(4) The designation of the Federal agency or subagency referring the debt; and

(5) In the case of an OASDI overpayment, a certification by the Secretary of Health and Human Services designating whether the amount payable to the agency is to be deposited in either the Federal Old-Age and Survivors Insurance Trust Fund or the Federal Disability Insurance Trust Fund, but not both.

(f) *Correction of referral.* If, after referring a past-due, legally enforceable debt to the Service as provided by paragraph (e) of this section, an agency determines that an error has been made with respect to the information transmitted to the Service, or if an agency receives a payment or credits a payment to the account of a taxpayer referred to the Service for offset, the agency shall promptly notify the Service. The Service shall make the appropriate correction of its records. However, this paragraph (f) does not permit an agency to increase the amount of a past-due, legally enforceable debt or refer additional debtors to the Service for offset after an agency makes its original referral of debts for tax refund offset. The agency may refer additional debts to the Service for refund offset in subsequent tax refund offset years.

(g) *Priorities for offset.* (1) An overpayment shall be reduced first by the amount of an outstanding liability for any tax under section 6402(a); second, by the amount of any past-due support assigned to a State under section 402(a)(26) or section 471(a)(17) of the Social Security Act which is to be offset under section 6402(c) and the regulations thereunder; third, by the amount of any past-due, legally enforceable debt owed to a Federal agency under section 6402(d) and this section; and fourth, by the amount of any qualifying past-due support not assigned to a State which is to be offset under section 6402(c) and the regulations thereunder.

(2) If a taxpayer owes more than one past-due, legally enforceable debt to a Federal agency or agencies, the overpayment shall be credited against the debts in the order in which the debts accrued. A debt shall be considered to have accrued at the time at which the agency determines that the debt became past due.

(3) Reduction of the overpayment pursuant to section 6402 (a), (c), and (d) shall occur prior to crediting the overpayment to any future liability for an internal revenue tax. Any amount remaining after offset under section 6402 (a), (c), and (d) shall be refunded to the taxpayer, or applied to estimated tax, if elected by the taxpayer.

(h) *Post-offset notice to the taxpayer and the agency.* (1) The Service shall notify the taxpayer in writing of the amount and date of the offset for a past-due, legally enforceable debt and of the Federal agency to which this amount has been paid or credited. For joint returns, see paragraph (i) of this section.

(2) The Service shall advise each agency of the names, mailing addresses, and identifying numbers of the taxpayers from whom amounts of past-due, legally enforceable debt were collected and of the amounts collected from each taxpayer. If the refund from which an amount of past-due, legally enforceable debt is to be withheld is based upon a joint return, the Service shall notify the agency and furnish the names and addresses of each taxpayer filing the joint return.

(i) *Offset made with regard to refund based upon joint return.* (1) In the case of an offset from a refund based on a joint return, the Service shall issue a notice in writing to any person who may have filed a joint return with the taxpayer, including the amount and date of any offset and the steps which the non-debtor spouse may take in order to secure his or her proper share of the refund (unless the non-debtor spouse has already taken these steps prior to offset).

(2) If the person filing the joint return with the taxpayer owing the past-due, legally enforceable debt takes appropriate action to secure his or her proper share of a refund from which an offset was made, the Service shall pay the person his or her share of the refund and shall deduct that amount from amounts payable to the agency.

(j) *Disposition of amounts collected.* Amounts collected under this section shall be transferred to a special account maintained by the Finanical Management Service (FMS) for each Federal agency. If an erroneous payment is made to any agency, the Service shall deduct the amount of such payment from amounts payable to the agency.

(k) *Fees.* The agency shall enter into a separate agreement with the Service and FMS to reimburse the Service and FMS for the full cost of administering the tax refund offset program. The fees shall be deducted from amounts collected prior to disposition. The fees shall be deposited in the United States Treasury and credited to the appropriation accounts which bore all or part of the costs involved in administering the refund offset procedures.

(l) *Review of offset of refunds.* Any reduction of a taxpayer's refund made pursuant to section 6402(c) or (d) shall not be subject to review by any court of the United States or by the Service in an administrative proceeding. No action brought against the United States to recover the amount of this reduction shall be considered to be a suit for refund of tax. Any legal, equitable, or administrative action by any person seeking to recover the amount of the reduction of the overpayment must be taken against the Federal agency to which the amount of the reduction was paid. Any action which is otherwise available with respect to recoveries of overpayments of benefits under section 204 of the Social Security Act must be taken against the Secretary of Health and Human Services.

(m) *Access to and use of confidential tax information.* Access to and use of confidential tax information in conneciton with the tax refund offset program are restricted by section 6103 of the code. However, section 6103(l)(10) permits Federal officers and employees of agencies participating in the tax refund offset program to have access to and use of confidential tax information. Agencies receiving such information are subject to the safeguard, recordkeeping, and reporting requirements of section 6103(p)(4) and the regulations thereunder. The agency shall inform its officers and employees who access or use confidential tax information of the restrictions and penalties under the Internal Revenue Code for misuse of confidential tax information.

(n) *Effective date.* This section applies to refunds payable under section 6402 of the Internal Revenue Code after April 15, 1992.

Approved: March 10, 1992.

David G. Blattner,

Chief Operations Officer.

Fred T. Goldberg, Jr.,

Assistant Secretary of the Treasury.

[FR Doc. 92-8569 Filed 4-14-92; 8:45 am]

BILLING CODE 4830-01-M

PENSION BENEFIT GUARANTY CORPORATION

29 CFR Parts 2610 and 2622

Late Premium Payments and Employer Liability Underpayments and Overpayments; Interest Rate for Determining Variable Rate Premium; Amendments to Interest Rates

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Final rule.

SUMMARY: This document notifies the public of the interest rate applicable to late premium payments and employer liability underpayments and overpayments for the calendar quarter beginning April 1, 1992. This interest rate is established quarterly by the Internal Revenue Service. This document also sets forth the interest rates for valuing unfunded vested benefits for premium purposes for plan years beginning in February through April 1992. These interest rates are established pursuant to section 4006 of the Employee Retirement Income Security Act of 1974, as amended. The effect of these amendments is to advise plan sponsors and pension practitioners of these new interest rates.

EFFECTIVE DATE: April 1, 1992.

FOR FURTHER INFORMATION CONTACT: Harold J. Ashner, Assistant General Counsel, Office of the General Counsel, Code 22500, Pension Benefit Guaranty Corporation, 2020 K Street, NW., Washington, DC 20006; telephone (202) 778-8850 ((202) 778-8859 for TTY and TTD). These are not toll-free numbers.

SUPPLEMENTARY INFORMATION: As part of title IV of the Employee Retirement Income Security Act of 1974, as amended ("ERISA"), the Pension Benefit Guaranty Corporation ("PBGC") collects premiums from ongoing plans to support the single-employer and multiemployer insurance programs. Under the single-employer program, the PBGC also collects employer liability from those persons described in ERISA section 4062(a). Under ERISA section 4007 and 29 CFR 2610.7, the interest rate to be charged on unpaid premiums is the rate established under section 6601 of the Internal Revenue Code ("Code"). Similarly, under 29 CFR 2622.7, the interest rate to be credited or charged with respect to overpayments or underpayments of employer liability is the section 6601 rate. These interest rates are published by the PBGC in appendix A to the premium regulation and appendix A to the employer liability regulation.

The Internal Revenue Service has announced that for the quarter beginning April 1, 1992, the interest charged on the underpayment of taxes will be at a rate of 8 percent. Accordingly, the PBGC is amending appendix A to 29 CFR part 2610 and appendix A to 29 CFR part 2622 to set forth this rate for the April 1, 1992, through June 30, 1992, quarter.

Under ERISA section 4006(a)(3)(E)(iii)(II), in determining a single-employer plan's unfunded vested benefits for premium computation purposes, plans must use an interest rate equal to 80% of the annual yield on 30-year Treasury securities for the month preceding the beginning of the plan year for which premiums are being paid. Under § 2610.23(b)(1) of the premium regulation, this value is determined by reference to 30-year Treasury constant maturities as reported in Federal Reserve Statistical Releases G.13 and H.15. The PBGC publishes these rates in appendix B to the regulation.

The PBGC publishes these monthly interest rates in appendix B on a quarterly basis to coincide with the publication of the late payment interest rate set forth in appendix A. (The PBGC publishes the appendix A rates every quarter, regardless of whether the rate has changed.) Unlike the appendix A rate, which is determined prospectively, the appendix B rate is not known until a short time after the first of the month for which it applies. Accordingly, the PBGC is hereby amending appendix B to part 2610 to add the vested benefits valuation rates for plan years beginning in February through April of 1992.

The appendices to 29 CFR parts 2610 and 2622 do not prescribe the interest rates under these regulations. Under both regulations, the appendix A rates are the rates determined under section 6601(a) of the Code. The interest rates in appendix B to part 2610 are prescribed by ERISA section 4006(a)(3)(E)(iii)(II) and § 2610.23(b)(1) of the regulation. These appendices merely collect and republish the interest rates in a convenient place. Thus, the interest rates in the appendices are informational only. Accordingly, the PBGC finds that notice of and public comment on these amendments would be unnecessary and contrary to the public interest. For the above reasons, the PBGC also believes that good cause exists for making these amendments effective immediately.

The PBGC has determined that none of these amendments is a "major rule" within the meaning of Executive Order 12291, because they will not have an annual effect on the economy of $100 million or more; nor create a major increase in costs or prices for consumers, individual industries, or geographic regions, nor have significant adverse effects on competition, employment, investment, innovation or the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

Because no general notice of proposed rulemaking is required for these amendments, the Regulatory Flexibility Act of 1980 does not apply. See 5 U.S.C. 601(2).

List of Subjects

29 CFR Part 2610

Employee benefit plans, Penalties, Pension insurance, Pensions, and Reporting and recordkeeping requirements.

29 CFR Part 2622

Business and industry, Employee benefit plans, Pension insurance, Pensions, Reporting and recordkeeping requirements, and Small businesses.

In consideration of the foregoing, appendix A and appendix B to part 2610 and appendix A to part 2622 of chapter XXVI of title 29, Code of Federal Regulations, are hereby amended as follows:

PART 2610—PAYMENT OF PREMIUMS

1. The authority citation for part 2610 continues to read as follows:

Authority: 29 U.S.C. 1302(b)(3), 1306, 1307, (1988), as amended by sec. 7881(h), Pub. L. 101–239, 103 Stat. 2106, 2242.

2. Appendix A to part 2610 is amended by adding a new entry for the quarter beginning April 1, 1992, to read as follows. The introductory text is republished for the convenience of the reader and remains unchanged.

Appendix A—Late Payment Interest Rates

The following table lists the late payment interest rates under § 2610.7(a) for the specified time periods:

From	Through	Interest rate (percent)
* * * * *		
April 1, 1992	June 30, 1992	8

3. Appendix B to part 2610 is amended by adding to the table of interest rates therein new entries for premium payment years beginning in February of 1992 through April of 1992, to read as follows. The introductory text is republished for the convenience of the reader and remains unchanged.

Appendix B—Interest Rates for Valuing Vested Benefits

The following table lists the required interest rates to be used in valuing a plan's vested benefits under § 2610.23(b) and in calculating a plan's adjusted vested benefits under § 2610.23(c)(1):

For premium payment years beginning in—	Required interest rate [1]
* * * * *	
February 1992	6.06
March 1992	6.28
April 1992	6.38

[1] The required interest rate listed above is equal to 80% of the annual yield for 30-year Treasury constant maturities, as reported in Federal Reserve Statistical Release G.13 and H.15 for the calendar month preceding the calendar month in which the premium payment year begins.

PART 2622—EMPLOYER LIABILITY FOR WITHDRAWALS FROM AND TERMINATIONS OF SINGLE-EMPLOYER PLANS

4. The authority citation for part 2622 continues to read as follows:

Authority: 29 U.S.C. 1302(b)(3), 1362–1364, 1367–68, as amended by secs. 9312, 9313, Pub. L. 100–203, 101 Stat. 1330.

5. Appendix A to part 2622 is amended by adding a new entry for the quarter beginning April 1, 1992, to read as follows. The introductory text is republished for the convenience of the reader and remains unchanged.

Appendix A—Late Payment and Overpayment Interest Rates

The following table lists the late payment and overpayment interest rates under § 2622.7 for the specified time periods:

From	Through	Interest rate (percent)
* * * * *		
April 1, 1992	June 30, 1992	8

Issued in Washington, DC, this 6th day of April 1992.

James B. Lockhart III,

Executive Director, Pension Benefit Guaranty Corporation.

[FR Doc. 92–8653 Filed 4–14–92; 8:45 am]

BILLING CODE 7708–01–M

29 CFR PART 2644

Notice and Collection of Withdrawal Liability; Adoption of New Interest Rate

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Final rule.

SUMMARY: This is an amendment to the Pension Benefit Guaranty Corporation's regulation on Notice and Collection of Withdrawal Liability That regulation incorporates certain interest rates published by another Federal agency. The effect of this amendment is to add to the appendix of that regulation a new interest rate to be effective from April 1, 1992, to June 30, 1992.

EFFECTIVE DATE: April 1, 1992.

FOR FURTHER INFORMATION CONTACT: Harold J. Ashner, Assistant General Counsel, Office of the General Counsel (22500), Pension Benefit Guaranty Corporation, 2020 K Street, NW., Washington, DC 20006; telephone 202

778–8850 (202–778–8859 or TTY and TDD). These are not toll-free numbers.

SUPPLEMENTARY INFORMATION: Under section 4219(c) of the Employee Retirement Income Security Act of 1974, as amended ("ERISA"), the Pension Benefit Guaranty Corporation ("the PBGC") promulgated a final regulation on Notice and Collection of Withdrawal Liability. That regulation, codified at 29 CFR part 2644, deals with the rate of interest to be charged by multiemployer pension plans on withdrawal liability payments that are overdue or in default, or to be credited by plans on overpayments of withdrawal liability. The regulation allows plans to set rates, subject to certain restrictions. Where a plan does not set the interest rate, § 2644.3(b) of the regulation provides that the rate to be charged or credited for any calendar quarter is the average quoted prime rate on short-term commercial loans for the fifteenth day (or the next business day if the fifteenth day is not a business day) of the month preceding the beginning of the quarter, as reported by the Board of Governors of the Federal Reserve System in Statistical Release H.15 ("Selected Interest Rates").

Because the regulation incorporates interest rates published in Statistical Release H.15, that release is the authoritative source for the rates that are to be applied under the regulation. As a convenience to persons using the regulation, however, the PBGC collects the applicable rates and republishes them in an appendix to part 2644. This amendment adds to this appendix the interest rate of 6½ percent, which will be effective from April 1, 1992 through June 30, 1992. This rate represents a decrease of one percent from the rate in effect for the first quarter of 1992. This rate is based on the prime rate in effect on March 16, 1992.

The appendix to 29 CFR part 2644 does not prescribe interest rates under the regulation; the rates prescribed in the regulation are those published in Statistical Release H.15. The appendix merely collects and republishes the rates in a convenient place. Thus, the interest rates in the appendix are informational only. Accordingly, the PBGC finds that notice of and public comment on this amendment would be unnecessary and contrary to the public interest. For the above reasons, the PBGC also believes that good cause exists for making this amendment effective immediately.

The PBGC has determined that this amendment is not a "major rule" within the meaning of Executive Order 12291, because it will not have an annual effect on the economy of $100 million or more; nor create a major increase in costs or prices for consumers, individual industries, or geographic regions, nor have significant adverse effects on competition, employment, investment, innovation or the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

Because no general notice of proposed rulemaking is required for this amendment, the Regulatory Flexibility Act of 1980 does not apply. See 5 U.S.C. 601(2).

List of Subjects in 29 CFR Part 2644

Employee benefit plans, Pensions.

In consideration of the foregoing, part 2644 of subchapter F of chapter XXVI of title 29, Code of Federal Regulations, is amended as follows:

PART 2644—NOTICE AND COLLECTION OF WITHDRAWAL LIABILITY

1. The authority citation for part 2644 continues to read as follows:

Authority: 29 U.S.C. 1302(b)(3) and 1399(c)(6).

Appendix A—[Amended]

(2). Appendix A is amended by adding to the end of the table therein a new entry as follows:

From	To	Date of quotation	Rate (percent)
*	*	*	*
04/01/92	06/30/92	03/16/92	6½

Issued in Washington, DC, on this 6th day of April 1992.

James B. Lockhart III,

Executive Director, Pension Benefit Guaranty Corporation.

[FR Doc. 92–8654 Filed 4–14–92; 8:45 am]

BILLING CODE 7708–01–M

29 CFR Part 2676

Valuation of Plan Benefits and Plan Assets Following Mass Withdrawal—Interest Rates

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Final rule.

SUMMARY: This is an amendment to the Pension Benefit Guaranty Corporation's regulation on Valuation of Plan Benefits and Plan Assets Following Mass Withdrawal (29 CFR part 2676). The regulation prescribes rules for valuing benefits and certain assets of multiemployer plans under sections 4219(c)(1)(D) and 4281(b) of the Employee Retirement Income Security Act of 1974. Section 2676.15(c) of the regulation contains a table setting forth, for each calendar month, a series of interest rates to be used in any valuation performed as of a valuation date within that calendar month. On or about the fifteenth of each month, the PBGC publishes a new entry in the table for the following month, whether or not the rates are changing. This amendment adds to the table the rate series for the month of May 1992.

EFFECTIVE DATE: May 1, 1992.

FOR FURTHER INFORMATION CONTACT: Deborah C. Murphy, Attorney, Office of the General Counsel (22500), Pension Benefit Guaranty Corporation, 2020 K Street, NW., Washington, DC 20006; 202–778–8820 (202–778–8859 for TTY and TDD). (These are not toll-free numbers.)

SUPPLEMENTARY INFORMATION: The PBGC finds that notice of and public comment on this amendment would be impracticable and contrary to the public interest, and that there is good cause for making this amendment effective immediately. These findings are based on the need to have the interest rates in this amendment reflect market conditions that are as nearly current as possible and the need to issue the interest rates promptly so that they are available to the public before the beginning of the period to which they apply. (See 5 U.S.C. 553 (b) and (d).) Because no general notice of proposed rulemaking is required for this amendment, the Regulatory Flexibility Act of 1980 does not apply (5 U.S.C. 601(2)).

The PBGC has also determined that this amendment is not a "major rule" within the meaning of Executive Order 12291 because it will not have an annual effect on the economy of $100 million or more; or create a major increase in costs or prices for consumers, individual industries, or geographic regions; or have significant adverse effects on competition, employment, investment, or innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

List of Subjects in 29 CFR Part 2676

Employee benefit plans and Pensions.

In consideration of the foregoing, part 2676 of subchapter H of chapter XXVI of title 29, Code of Federal Regulations, is amended as follows:

PART 2676—VALUATION OF PLAN BENEFITS AND PLAN ASSETS FOLLOWING MASS WITHDRAWAL

1. The authority citation for part 2676 continues to read as follows:

Authority: 29 U.S.C. 1302(b)(3), 1399(c)(1)(D), and 1441(b)(1).

2. In § 2676.15, paragraph (c) is amended by adding to the end of the table of interest rates therein the following new entry:

§ 2676.15 Interest.

* * * * * * *

(c) *Interest Rates.*

For valuation dates occurring in the month—	The values for i_k are—															
	i_1	i_2	i_3	i_4	i_5	i_6	i_7	i_8	i_9	i_{10}	i_{11}	i_{12}	i_{13}	i_{14}	i_{15}	i_u
*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
May 1992.....	.0675	.06625	.0650	.06375	.0625	.06125	.06125	.06125	.06125	.06125	.06	.06	.06	.06	.06	.05875

Issued at Washington, D.C., on this 6th day of April 1992.

James B. Lockhart III,

Executive Director, Pension Benefit Guaranty Corporation.

[FR Doc. 92-8655 Filed 4-14-92; 8:45 am]

BILLING CODE 7708-01-M

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 917

Kentucky Permanent Regulatory Program; Small Operator Assistance Program (SOAP)

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION: Final rule; approval of amendment.

SUMMARY: OSM is announcing the approval, with exceptions, of a proposed program amendment to the Kentucky permanent regulatory program (hereinafter referred to as the Kentucky program) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). The amendment consists of proposed modifications to Kentucky Administrative Regulations (KAR) at 405 KAR 7:080 Small Operator Assistance.

EFFECTIVE DATE: April 15, 1992.

FOR FURTHER INFORMATION CONTACT: William J. Kovacic, Director, Lexington Field Office, Office of Surface Mining Reclamation and Enforcement, 340 Legion Drive, Lexington, Kentucky 40504, Telephone (606) 233-2896.

SUPPLEMENTARY INFORMATION:

I. Background on the Kentucky Program

On May 18, 1982, the Secretary of the Interior conditionally approved the Kentucky program. Information pertinent to the general background, revisions, modifications, and amendments to the permanent program submission, as well as the Secretary's findings, the disposition of comments and a detailed explanation of the conditions of approval can be found in the May 18, 1982, **Federal Register** (47 FR 21404-21435). Subsequent actions concerning the conditions of approval and program amendments are identified at 30 CFR 917.11, 917.13, 917.15, 917.16, and 917.17.

II. Submission of the Amendment

By letter dated June 28, 1991, (Administrative Record Number KY-1059), Kentucky submitted a proposed program amendment modifying 19 regulations and incorporating two Technical Reclamation Memorandum No. 19 and No. 20.

OSM announced receipt of the proposed amendment in the July 22, 1991, **Federal Register** (56 FR 33398), and in the same notice, opened the public comment period and provided opportunity for a public hearing on the adequacy of the proposed amendment. The comment period closed on August 21, 1991.

The proposed amendment submitted by Kentucky on June 28, 1991, included modifications to regulations at 405 KAR 7:080 dealing with the State's Small Operator Assistance Program. These modifications were intended to make the State's regulations consistent with changes that had been made to section 507(c) of SMCRA.

By letter dated December 5, 1991, (Administrative Record Number KY-1085), Kentucky resubmitted the proposed amendment to 405 KAR 7:080. This resubmission identifies and incorporates Kentucky's Small Operator Assistance Program application form that has been revised to capture information required by the State's proposed small operator assistance regulation modifications.

Additionally, the resubmission contains some grammatical corrections for clarity and proper citation. In resubmitting the proposed amendment to 405 KAR 7:080, the State requested that this amendment be separated from the rest of the proposed program amendment package submitted on June 28, 1991.

OSM announced receipt of the State's December 5, 1991, submission in the December 31, 1991, **Federal Register** (56 FR 67558), and in the same notice, reopened the public comment period and provided opportunity for a public hearing on the adequacy of the December 5, 1991 submission. The comment period closed on January 15, 1992.

III. Director's Findings.

Set forth below pursuant to SMCRA and the Federal regulations at 30 CFR 732.15 and 732.17, are the Director's findings concerning the proposed amendment to the Kentucky program.

A. Revisions to Kentucky's Regulations That Are Substantively Identical to the Corresponding Federal Regulations

State regulations (405 KAR)	Subject	Federal counterpart
Section 10(a)	Definition of qualified laboratory.	30 CFR 795.3.

Because the above proposed revision is identical in meaning to the coresponding Federal regulation, the Director finds that Kentucky's proposed rule is no less effective than the Federal rule.

B. Revisions to Kentucky's Regulations That Are Not Substantively Identical to the Corresponding Federal Regulations

(1) Kentucky proposes to amend 405 KAR 7:080 Section 5(2) consistent with the change made to section 507(c) of SMCRA by section 6011 of the Federal Omnibus Budget Reconciliation Act of 1990. Section 6011 of the Federal Omnibus Budget Reconciliation Act revises section 507(c) of SMCRA, effective October 1, 1991, to increase from 100,000 tons to 300,000 tons the maximum annual coal production under which a mine operator is eligible for participation in the Small Operator Assistance Program. Kentucky is proposing to make a corresponding change in the SOAP eligibility tonnage figures in the Kentucky regulations. Kentucky proposes to substitute the 300,000–ton eligibility limit for the existing 100,000–ton eligibility limit at 405 KAR 7:080 Section 5(2).

While the State's proposed amendment to its regulations at 405 KAR 7:080 Section 5(2) is in accordance with section 507(c) of SMCRA, as amended by the Federal Omnibus Budget Reconciliation Act of 1990, the Federal regulations at 30 CFR 795.6(a)(2) still provides for a production level of 100,000 tons with respect to operator eligibility under the SOAP program. Thus, there appears to be an inconsistency between the Kentucky regulation and the Federal regulation. However, section 507(c) of SMCRA, as amended by the 1990 Act, supersedes in part 30 CFR 795.6(a)(2) to the extent that SOAP applicants may receive grants if their probable total and actual production from all locations during any 12 month period does not exceed 300,000 tons.

Therefore, the Director finds the State's proposal to be no less effective than 30 CFR 795.6(a)(2) as superseded in part by amended section 507(c) of SMCRA.

(2) Kentucky proposes to amend 405 KAR 7:080 Section 11(d) and (e) by changing the cited production levels of 100,000 tons to 300,000 tons with respect to the production limits that must be observed in order for the applicant and/or its successor to avoid liability for reimbursing the cabinet for costs of laboratory services performed pursuant to 405 KAR 7:080. While the proposed amendment is in accordance with the revision made by Section 6011 of the Federal Omnibus Budget Reconciliation Act of 1990 to section 507(c) of SMCRA in increasing the production level which the operator must meet to be eligible to participate in SOAP, in determining applicant liability the Kentucky proposal does not consider those applicants whose eligibility was determined under the 100,000–ton production level.

The Federal regulations at 30 CFR 795.12(a)(2) still provide for a 100,000–ton production level in determining an operator's liability. OSM is proposing to amend its regulations regarding applicant liability at 30 CFR 795.12(a)(2) by deleting reference to the 100,000–ton provision and adding language which refers to the coal tonnage governing SOAP eligibility in effect at the time assistance was approved, thereby defining a transition phase keyed to the time an operator is approved for assistance. In its proposed rule, OSM has indicated its willingness to consider comments on alternatives other than its proposal.

In order not to unduly delay the State's implementation of the new production levels for SOAP eligibility, the Director is approving the State's proposed amendment to the regulations at 405 KAR 7:080 Section 11(1) (d) and (e) with the understanding that reference to the 300,000-ton production level in determining applicant liability refers to those applicants whose eligibility for SOAP assistance is determined under the 300,000-ton production level effective with the publication of this final rule, and the liability of those applicants whose eligibility was determined under the 100,000-ton production level will continue to be based on 100,000 tons. The Director's approval is further based on the understanding that further amendment to the State's regulations may be required when OSM issues a final notice regarding its changes to 30 CFR Part 795.

C. Revisions to Kentucky's Regulations With No Corresponding Federal Regulations

(1) Kentucky proposes to revise the introductory paragraph (entitled, "Necessity and Function") to 405 KAR 7:080 by increasing from 100,000 tons to 300,000 tons the production levels for operator eligibility under SOAP.

While there is no Federal regulation which directly corresponds to the "Necessity and Function" section in the State regulations, the proposed change is in accordance with the revision made by Section 6011 of the Federal Omnibus Budget Reconciliation Act of 1990 to section 507(c) of SMCRA in increasing the production level which an operator must meet to be eligible to participate in SOAP. Therefore, the Director finds the proposal to be no less stringent than section 507(c) of SMCRA, as revised.

(2) Kentucky proposes to amend 405 KAR 7:080 Section 6 by incorporating by reference the revised application form "Kentucky Small Operator Application for Assistance". In addition, the location where a copy of the form may be reviewed or obtained is identified. Because the information required by the revised application form is not consistent with the information requirements of the Federal regulations at 30 CFR 795.7, the Director is deferring final action on the proposal until the State submits to OSM for approval a revised application form which is consistent with the requirements of the Federal regulations.

(3) Kentucky proposes to amend 405 KAR 7:080 Section 8(2) (a) and (b) which identifies specific sections of the State's regulations whose required permit application information can be supplied in connection with a SOAP application, by adding references to 405 KAR 8:030 and 8:040 Sections 20(2)(c)-Biological assessment of surface waters. However, 405 KAR 8:030 and 8:040 Sections 20(2)(c) are not currently part of the State's approved program, but are included in the proposed program amendment submitted by Kentucky on June 28, 1991. Therefore, further action on the State's proposed change to 405 KAR 7:080 Section 8(2) (a) and (b) is being deferred pending final action on proposed 405 KAR 8:030 and 8:040 Sections 20.

IV. Summary and Disposition of Comments

Public Comments

The public comment period and opportunity to request a public hearing was announced in the July 22, 1991, **Federal Register** (56 FR 33398). The comment period closed on August 21, 1991. No one requested an opportunity to testify at the scheduled public hearing so no hearing was held. Reopening of the public comment and opportunity to

request a public hearing, regarding proposed changes to 405 KAR 7:080, was announced in the December 31, 1991, Federal Register (56 FR 67558). The comment period closed on January 15, 1992. No one requested an opportunity to testify at the scheduled public hearing so no hearing was held.

By letter dated August 22, 1991, the Kentucky Resources Council (KRC) filed comments in response to the proposed rule published on July 22, 1991. KRC stated that Kentucky's proposed change to the annual tonnage eligibility threshold should be rewritten to comport with existing law until such time as the revision to section 507(c) of SMCRA became effective on October 1, 1991. KRC filed additional comments on January 7, 1992, in response to the proposed rule published on December 31, 1991. In its new submission, KRC withdrew its earlier objection since the effective date of the revision to section 507(c) of SMCRA had passed. In addition, KRC sought assurance that if OSM approved the proposed change to 405 KAR 7:080 Section 8(2) (a) and (b), such approval would not constitute express or implied approval of pending proposed changes to 405 KAR 8:030 Section 20 or 8:040 Section 20. As discussed herein in Finding C(2), the Director has deferred further action on proposed changes to 7:080 Section 8(2) (a) and (b) until such time as final action is taken on 8:030 Section 20. Therefore, no further action is necessary at this time regarding KRC's concern.

Agency Comments

Pursuant to section 503(b) of SMCRA and the implementing regulations at 30 CFR 732.17(h)(11)(i), comments were solicited from various Federal agencies with an actual or potential interest in the Kentucky program. The Bureau of Land Management, Soil Conservation Service, Mine Safety and Health Administration, U.S. Bureau of Mines, Tennessee Valley Authority, and the Kentucky Heritage Council generally considered the amendment to be acceptable or submitted an acknowledgement with no comment.

V. Director's Decision

Based on the findings discussed above, the Director is approving, with exceptions, the proposed amendment to Kentucky's Small Operator Assistance Program as submitted to OSM by the State on June 28, 1991, and revised on December 5, 1991. The Federal regulations at 30 CFR part 917 codifying decisions concerning the Kentucky program are being amended to implement this decision. The Director is approving these State rules with the understanding that they be promulgated in a form identical to that submitted to OSM and reviewed by the public. Any differences between these rules and the State's final promulgated rules will be processed as a separate amendment subject to public review at a later date. This final rule is being made effective immediately to expedite the State program amendment process and to encourage the State to conform its program with the Federal standards without delay. Consistency of State and Federal standards is required by SMCRA.

As discussed in Findings C (1) and (2), the Director is deferring action on 405 KAR 7:080 Section 6 and Section 8(2) (a) and (b).

EPA Concurrence

Under 30 CFR 732.17(h)(11)(ii), the Director is required to obtain the written concurrence of the Administrator of the Environmental Protection Agency (EPA) with respect to any provisions of a State program amendment that relate to air or water quality standards promulgated under the authority of the Clean Water Act (33 U.S.C. 1251 *et seq.*) or the Clean Air Act (42 U.S.C. 7401 *et seq.*). The Director has determined that this amendment contains no provisions in these categories and that EPA's concurrence is not required.

Effect of Director's Decision

Section 503 of SMCRA provides that a State may not exercise jurisdiction under SMCRA unless the State program is approved by the Secretary. Similarly, 30 CFR 732.17(a) requires that any alteration of an approved State program be submitted to OSM for review as a program amendment. Thus, any changes to the State program are not enforceable until approved by OSM. The Federal regulations at 30 CFR 732.17(g) prohibit any unilateral changes to approved State programs. In his oversight of the Kentucky program, the Director will recognize only the statutes, regulations and other materials approved by him, together with any consistent implementing policies, directives and other materials, and will require the enforcement by Kentucky of only such provisions.

VI. Procedural Determinations

National Environmental Policy Act

The Secretary has determined that, pursuant to section 702(d) of SMCRA (30 U.S.C. 1292(d)), no environmental impact statement need be prepared on this rulemaking.

Executive Order 12291 and the Regulatory Flexibility Act

On July 12, 1984, the Office of Management and Budget (OMB) granted OSM an exemption from sections 3, 4, 7, and 8 of Executive Order 12291 for actions directly related to approval or conditional approval of State regulatory programs. Therefore, this action is exempt from preparation of a regulatory impact analysis and regulatory review by OMB.

The Department of Interior has determined that this rule will not have a significant economic effect on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C 601 *et seq.*). This rule will not impose any requirements; rather, it will ensure that existing requirements established by SMCRA and the Federal rules will be met by the State.

Executive Order 12778

This rule has been reviewed under the principles set forth in section 2 of Executive Order 12778 (56 FR 55195, October 25, 1991) on Civil Justice Reform. DOI has determined that, to the extend allowed by law, the regulation meets the applicable standards of section 2(a) and 2(b) of Executive Order 12778. Under SMCRA section 405 and 30 CFR 884 and section 503(a) and 30 CFR 732.15 and 732.17(h)(10), the agency decision on State program submittals must be based solely on a determination of whether the submittal is consistent with SMCRA and the Federal regulations. The only decision allowed under law is approval, disapproval or conditional approval of State program amendments.

Paperwork Reduction Act

This rule does not contain information collection requirements that require approval by the Office of Managment and Budget under 44 U.S.C. 3507.

List of Subjects in 30 CFR Part 917

Intergovernmental relations, Surface mining, Underground mining.

Dated: February 14, 1992.

Jeffrey D. Jarett,

Acting Assistant Director, Eastern Support Center.

For the reasons set out in the preamble, title 30, chapter VII, subchapter T of the Code of Federal Regulations is amended as set forth below:

PART 917—KENTUCKY

1. The authority citation for part 917 continues to read as follows:

Authority 30 U.S.C. 1201 *et seq.*

2. 30 CFR 917.15, is amended by adding a new paragraph (jj) to read as follows:

§ 917.15 Approval of regulatory program amendments.

* * * * *

(jj) The amendement to the Kentucky Administrative Regulations (KAR) at 405 KAR 7:080, relating to the State's Small Operator Assistance Program, as submitted to OSM on June 28, 1991, and revised on December 5, 1991, is approved effective April 15, 1992, except for the revisions to 405 KAR 7:080 section 6 and section 8(2)(a) and (b), action on which is being deferred.

[FR Doc. 92-8709 Filed 4-14-92; 8:45 am]

BILLING CODE 4310-05-M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 80, 86, and 600

[AMS-FRL-4123-5]

Control of Air Pollution From New Motor Vehicles and New Motor Vehicle Engines; Refueling Emission Regulations for Gasoline-Fueled Light-Duty Vehicles and Trucks and Heavy-Duty Vehicles

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of Final Agency Action pursuant to section 202(a)(6) of the Clean Air Act regarding onboard control of refueling emissions.

SUMMARY: On March 27, 1992, EPA took final action to implement section 202(a)(6) of the Clean Air Act regarding onboard control of refueling emissions. This notice notifies readers that because EPA's final action involved in part the decision not to issue the rule initially proposed, that action is printed in the proposed rule section of the Federal Register.

DATES: Final agency action was taken on March 27, 1992.

ADDRESSES: Materials relevant to this notice are contained in public dockets A-87-11 and A-84-07, located in the Air Docket of the U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC and are available for review in room M-1500 between the hours of 8:30 a.m. to 12:30 p.m. and 1:30 p.m. to 3:30 p.m. on weekdays. As provided in 40 CFR part 2, a reasonable fee may be charged for copying.

FOR FURTHER INFORMATION CONTACT: Mr. James Bryson, U.S. Environmental Protection Agency, Regulatory Development and Support Division, 2526 Plymouth Rd., Ann Arbor, MI 48105, Telephone: 313-741-7828.

SUPPLEMENTARY INFORMATION: See Final Agency Action pursuant to section 202(a)(6) of the Clean Air Act Regarding Onboard Control of Refueling Emissions, which is published in the proposed rule section of today's **Federal Register.**

Dated: April 9, 1992.

Michael Shapiro,

Deputy Assistant Administrator for Air and Radiation.

[FR Doc. 92-8639 Filed 4-14-92; 8:45 am]

BILLING CODE 6560-50-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

42 CFR Part 59

Statutory Prohibition on Use of Appropriated Funds in Programs Where Abortion is a Method of Family Planning

CFR Correction

In title 42 of the Code of Federal Regulations, parts 1 to 60, revised as of October 1, 1991, the effective date notes following the text of § § 59.7 through 59.10 contained on pages 468 through 471 were inadvertently published and should be removed.

BILLING CODE 1505-01-D

Health Care Financing Administration

42 CFR Part 412

Medicare Program; Medicare Geographic Classification Review Board-Procedures and Criteria

CFR Correction

In title 42 of the Code of Federal Regulations, parts 400 to 429, revised as of October 1, 1991, in § 412.278, on p. 331, the introductory heading *Administrator decision* should be inserted following the paragraph designation (f)(1). The paragraph designated as (f)(3) should be correctly designated to read (f)(4), and paragraph (f)(3), inadvertently omitted, should be included to read as follows:

§ 412.278 Administrator's review

* * * * *

(f) * * *

(3) The Administrator's decision is the final Departmental decision.

* * * * *

BILLING CODE 1505-01-D

DEPARTMENT OF TRANSPORTATION

Maritime Administration

46 CFR Part 381

[Docket No. R.-142]

RIN 2133-AA95

Cargo Preference—U.S.-Flag Vessels

AGENCY: Maritime Administration, Department of Transportation.

ACTION: Final rule.

SUMMARY: This rule amends provisions in the cargo preference regulations at 46 CFR part 381 to correct the name and telephone number of a Maritime Administration (MARAD) office with program responsibilities and includes reference and an authority citation to the Food Security Act of 1985.

EFFECTIVE DATE: April 15, 1992.

FOR FURTHER INFORMATION CONTACT: Sharon Cassidy, Chief, Division of Agricultural Cargoes, 400 Seventh Street, SW., room 7209, Washington, DC 20590, telephone 202-366-5506.

SUPPLEMENTARY INFORMATION: Reference in § 381.3 to a "Cargo Preference Control Center" is no longer accurate. The functions of that office are now carried out by the Office of National Cargo and Compliance. In addition, the telephone number in § 381.6 for the Office of National Cargo and Compliance is no longer correct. Finally, reference to statutory authority for cargo preference in § 381.5 is being expanded to include the Food Security Act of 1985, Public Law 99-189, which amended the Merchant Marine Act, 1936, as amended, by effectively increasing the percentage of U.S.-flag carriage required by the Cargo Preference Act of 1954 from 50 to 75 percent for certain agricultural commodities.

Because this rule relates solely to agency organization, the notice and public comment procedure otherwise required by the Administrative Procedure Act, 5 U.S.C. 553(c), is unnecessary and good cause exists, pursuant to 5 U.S.C. 553(d)(3), to make the changes effective upon publication. This rule is not subject to the requirements of E.O. 12291.

List of Subjects in 46 CFR Part 381

Freight, Maritime carriers, Reporting requirements.

Accordingly, 46 CFR part 381 is amended as follows:

PART 381—CARGO PREFERENCE—U.S.-FLAG VESSELS

1. The authority citation for part 381 is revised to read as follows:

Authority: 46 App. U.S.C. 1114(b), 1122(d), 1241(b) and 1241e-o.

§ 381.3 [Amended]

2. Section 381.3 is amended as follows:

a. In paragraph (a) remove the words "Maritime Administration, Cargo Preference Control Center, Transportation Building" and add, in their place, "Office of National Cargo and Compliance, Maritime Administration, U.S. Department of Transportation".

b. In paragraph (c) remove the words "Maritime Administration, Cargo Preference Control Center" and add, in their place, "Office of National Cargo and Compliance".

§ 381.5 [Amended]

3. Section 381.5 introductory text is amended to add the words "and the Food Security Act of 1985" after the words "all preference cargoes required by that Act".

§ 381.6 [Amended]

4. Section 381.6(b) is amended to remove the telephone number "Area Code 202 phone 967–3325" and add, in its place, "(202) 366–4610".

Dated: April 9, 1992.

By Order of the Maritime Administrator.

James E. Saari,

Secretary, Maritime Administration.

[FR Doc. 92–8626 Filed 4–14–92; 8:45 am]

BILLING CODE 4910–81–M

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 15

[ET Docket No. 91–150; FCC 92–163]

Provision of Additional Frequencies for Auditory Assistance Devices for the Hearing Impaired

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The Commission is adopting rules that expand the frequency bands in which unlicensed auditory assistance devices are permitted to cooperate. This change is necessary because hearing-impaired persons using auditory assistance devices in the frequency bands currently available to them are experiencing interference from licensed radio transmitters. This action will improve the ability of educational institutions to meet the needs of hearing-impaired students and enhance the participation of hearing-impaired individuals at public gatherings.

EFFECTIVE DATE: May 15, 1992.

FOR FURTHER INFORMATION CONTACT: George Harenberg, Technical Standards Branch, Office of Engineering and Technology, (202) 653–7314.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Report and Order (R&O) in Gen. Docket No. 91–150, FCC 92–163, adopted on March 25, 1992 and released on April 7, 1992. The full text of this R&O, including the final regulatory flexibility analysis, is available for inspection and copying during normal business hours in the FCC Dockets Branch (room 230), 1919 M Street, NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractor, Downtown Copy Center, (202) 452–1422 1114 21st Street NW., Washington, DC 20036.

Summary of Notice

1. Auditory assistance devices operate on a no-licensed basis under part 15 of the Commission's rules. In a petition for rule making filed on December 12, 1989, Phonic Ear, Inc. ("Phonic Ear") stated that auditory assistance devices have been experiencing increasing amounts of interference due to growth in use of the 72–73 MHz and 75.4–76 MHz bands by the land mobile services. Phonic ear claimed hat the interference has degraded the performance of auditory assistance devices to the point where some educational institutions are now unable to use auditory assistance devices in many of their classrooms. In order to correct this situation, Phonic Ear requested that the frequency bands which auditory assistance devices are permitted to use be expanded to include the 74.6–74.8 MHz and 75.2–75.4 MHz bands. This spectrum became available for fixed and mobile services after the two guardbands protecting aeronautical marker beacons at 75.0 MHz were narrowed from 400 kHz to 200 kHz on January 1, 1990. Phonic Ear stated that auditory assistance devices would not experience significant interference on the 74.6–74.8 MHz and 75.2–75.4 MHz bands because there is no exiting use of these frequencies and any potential new services on these frequencies must be limited to a maximum power of one watt.

2. On May 24, 1991, the Commission adopted a Notice of Proposed Rule Making (Notice), released June 18, 1991, 56 FR 28735 (June 24, 1991), proposing to amend Part 15 of the rules (47 CFR part 15) to allow auditory assistance devices to be operated in the 74.6–74.8 MHz and 75.2–75.4 MHz bands. The Commission also proposed to allow general part 15 usage of these frequency bands at the reduced radiated emission limits contained in 47 CFR 15.209. Three parties opposed allowing these frequencies to be used for auditory assistance devices. The Manufacturer's Radio Frequency Advisory Committee and the Telemotive Industrial Group of Maxtec International Corporation expressed concern about possible interference to future land mobile operations on the same frequencies. The Association for Maximum Service Television stated that operation of auditory assistance devices could cause interference to television reception.

3. Based on the record in this proceeding, the Commission finds that auditory assistance device users need additional frequencies to remedy interference problems and to meet increasing demands for service. More specifically, the Commission believes that the public interest is best served by making the frequency bands 74.6–74.8 MHz and 75.2–75.4 MHz available for use by auditory assistance devices, as proposed in the Notice.

4. The Commission was not persuaded that auditory assistance devices operating in the new frequency bands device will cause harmful interference to land mobile operations in the same frequency bands or to television reception. Furthermore, the Commission did not believe it was necessary to prohibit usage of the 74.6–74.8 MHz and 75.2–75.4 MHz frequency bands by other radio users.

5. In light of the foregoing considerations, the Commission is amending part 15 of the rules to allow auditory assistance devices and other part 15 devices to operate in the 74.6–74.8 MHz and 75.2–75.4 MHz bands. The administrative and technical requirements for operation in these bands are identical to those existing before this amendment.

6. Accordingly, *it is ordered* that under the authority contained in sections 4(i), 302, and 303 of the Communications Act of 1934, as amended, 47 U.S.C. 154(i), 302, and 303, Part 15 of the Commission's Rules and Regulations are amended as set forth

below. These rules are effective May 15, 1992. *It is further ordered* that this proceeding *is terminated.*

List of Subjects in 47 CFR Part 15

Americans with disabilities, Communications equipment, Computer technology, Education of handicapped, Handicapped, Labelling, Radio, Reporting and recordkeeping requirements, Security, Telephone, Wiretapping and electronic surveillance.

Federal Communications Commission.

William F. Caton,

Acting Secretary.

Title 47 of the Code of Federal Regulations, part 15 is amended as follows:

PART 15—RADIO FREQUENCY DEVICES

1. The authority citation for part 15 continues to read as follows:

Authority: Sec. 4, 302, 303, 304, and 307 of the Communications Act of 1934, as amended, 47 U.S.C. 154, 302, 303, 304, and 307.

2. Section 15.205 paragraph (a) is revised to read as follows:

§ 15.205 Restricted bands of operation.

(a) Except as shown in paragraph (d) of this section, only spurious emissions are permitted in any of the frequency bands listed below:

MHz	MHz	MHz	GHz
0.090–0.110	156.7–156.9	2200–2300	9.0–9.2
0.49–0.51	162.0125–167.17	2310–2390	9.3–9.5
2.1735–2.1905	167.72–173.2	2483.5–2500	10.6–12.7
8.362–8.366	240–285	2655–2900	13.25–13.4
13.36–13.41	322–335.4	3260–3267	14.47–14.5
25.5–25.67	399.9–410	3332–3339	15.35–16.2
37.5–38.25	608–614	3345.8–3358	17.7–21.4
73–74.6	960–1240	3600–4400	22.01–23.12
74.8–75.2	1300–1427	4500–5250	23.6–24.0
108–121.94	1435–1626.5	5350–5460	31.2–31.8
123–138	1660–1710	7250–7750	36.43–36.5
149.9–150.05	1718.8–1722.2	8025–8500	Above 38.6

3. The heading of § 15.237 is revised to read as follows:

* * * * *

§ 15.237 Operation in the bands 72.0–73.0 MHz, 74.6–74.8 MHz and 75.2–76.0 MHz.

* * * * *

[FR Doc. 92–8728 Filed 4–14–92; 8:45 am]

BILLING CODE 6712–01–M

DEPARTMENT OF DEFENSE

48 CFR Chapter 2

Department of Defense Acquisition Regulations; Defense Federal Acquisition Regulation Supplement

CFR Correction

In title 48 of the Code of Federal Regulations, chapter 2 (parts 201 to 251), revised as of December 31, 1991, item 2 of the editorial note and the listing of manuals and supplements contained on pages four and five should be removed and the following note inserted:

Note: Although the text of Manuals and Supplements to the Defense FAR Supplement are not published in the Code of Federal Regulations, they were listed for the convenience of the user. All of the Supplements have been deleted. The only manuals which remain in effect are: Armed Services Pricing Manual (1986) and Armed Services Pricing Manual, Volume 2, Price Analysis (1987).

BILLING CODE 1505–01–D

INTERSTATE COMMERCE COMMISSION

49 CFR Parts 1011 and 1152

[Ex Parte No. 274 (Sub-No. 12C)]

Rail Abandonments—Public Use Conditions—Revision

AGENCY: Interstate Commerce Commission.

ACTION: Final rule.

SUMMARY: The Commission modifies its regulations concerning the imposition of public use conditions in abandonments for the sake of clarity and the convenience of those seeking public use conditions. The modifications: (1) Impose deadlines for the filing of requests for such conditions, (2) clarify that public use conditions may be sought in all abandonment proceedings, and (3) clarify the date when our jurisdiction to impose such conditions expires. The modifications appear below.

EFFECTIVE DATE: These changes are effective on April 15, 1992.

FOR FURTHER INFORMATION CONTACT: Richard B. Felder: (202) 927–5610. [TDD for hearing impaired: (202) 927–5721].

SUPPLEMENTARY INFORMATION: Additional information is contained in the Commission's decision in Ex Parte No. 274 (Sub-No. 12C). To purchase a copy of this decision, write to, call, or pick up in person from: Dynamic Concepts, Inc., room 2229, Interstate Commerce Commission Building, Washington, DC 20423. Telephone (202) 289–4357/4359. [Assistance for the hearing impaired is available through TDD services, (202) 927–5721.]

Environmental and Energy Considerations

We conclude that this action will not significantly affect either the quality of the human environment or the conservation of energy resources.

Regulatory Flexibility Analysis

Pursuant to 5 U.S.C. 603, the Commission is required to examine specifically the impact of this action on small business and small organizations. We conclude that this decision will not have a significant impact on a substantial number of small entities because its purpose is merely to clarify and codify our current regulations and practices.

List of Subjects

49 CFR Part 1011

Authority delegations, Organization and functions.

49 CFR Part 1152

Administrative practice and procedure, Railroads.

Decided: April 3, 1992.

By the Commission, Chairman Philbin, Vice Chairman McDonald, Commissioners Simmons, Phillips, and Emmett.

Sidney L. Strickland, Jr.,

Secretary.

For reasons set forth in the preamble, title 49, chapter X, parts 1011 and 1152 of the Code of Federal Regulations are amended as follows:

PART 1011—COMMISSION ORGANIZATION; DELEGATIONS OF AUTHORITY

1. The authority citation for part 1011 continues to read as follows:

Authority: 49 U.S.C. 10301, 10302, 10304, 10305, 10321; 31 U.S.C. 9701; 5 U.S.C. 553.

§ 1011.8 [Amended]

2. Section 1011.8(c)(3) is amended by insertion of the following after the first word on the first line: "to impose public use conditions in abandonment application proceedings and whether".

PART 1152—ABANDONMENT AND DISCONTINUANCE OF RAIL LINES AND RAIL TRANSPORTATION UNDER 49 U.S.C. 10903

3. The authority citation for part 1152 continues to read as follows:

Authority: 5 U.S.C. 553, 559, and 704; 11 U.S.C. 1170; 16 U.S.C. 1247(d), and 1248; and 49 U.S.C. 10321, 10362, 10505, 10903, 10904, 10905, 10906, 11161, and 11163.

§ 1152.25 [Amended]

4. Section 1152.25(a)(2)(iv) is amended by removing the words "(See § 1152.28(a)(2))".

5. Section 1152.25(c)(1) is amended by adding after the first sentence: "Requests for public use conditions (see § 1152.28(a)(3)) may be filed no later than 10 days after the date of publication in the **Federal Register** of the notice of findings that the public convenience and necessity require or permit the abandonment or discontinuance."

6. Section 1152.28 is amended by adding the following new paragraph (a)(3) and by adding a sentence to the end of paragraph (b) as follows:

§ 1152.28 Public use procedures.

(a) * * *

(3) For applications filed under part 1152, subpart C, a request for a public use condition must be filed not more than 10 days from the date of publication of the notice of findings in the **Federal Register**. A decision on the public use request will be issued by the Director of the Office of Proceedings prior to the effective date of the abandonment. For abandonment exemptions under part 1152, subpart F or exemptions granted on the basis of an individual petition filed under 49 U.S.C. 10505, a request for a public use condition must be filed not more than 20 days from the date of publication of the notice of exemption in the **Federal Register**.

(b) * * * Jurisdiction to impose such conditions expires after 180 days from the effective date of the decision authorizing the abandonment or discontinuance.

§ 1152.50 [Amended]

7. In § 1152.50, paragraph (a)(2) is amended by adding the words "and § 1152.28" immediately following the work "1152.27".

[FR Doc. 92-8714 Filed 4-14-92; 8:45 am]

BILLING CODE 7035-01-M

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 380

[Docket No. 920378-2078]

Antarctic Marine Living Resources Convention Act of 1984

AGENCY: National Marine Fisheries Service (NMFS), NOAA, Commerce.

ACTION: Final rule.

SUMMARY: The Secretary of Commerce (Secretary) amends the regulations governing harvesting and reporting of Antarctic living marine resource catches. The regulations implement conservation and management measures promulgated by the Commission for the Conservation of Antarctic Marine Living Resources (CCAMLR or Commission) and accepted in whole by the Government of the United States to regulate catches in Convention for the Conservation of Antarctic Marine Living Resources (Convention) statistical reporting area 48 and subarea 58.4. These measures restrict the use of gear, restrict the directed taking and bycatch of certain species of fish, prohibit the taking of other species, require real-time and other reporting of the harvest of certain species, and require notification when Commission members are considering initiating a new fishery.

EFFECTIVE DATE: April 15, 1992.

ADDRESSES: A copy of the framework environmental assessment may be obtained from the Assistant Administrator for Fisheries, NOAA, National Marine Fisheries Service, 1335 East-West Highway, Silver Spring, MD 20910.

Comments regarding burden estimates or collection of information aspects of this rule should be sent to Robin Tuttle, National Marine Fisheries Service, 1335 East-West Highway, room 7256, Silver Spring, MD 20910, and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC, Attention: Paperwork Reduction Act Project 0648-0194.

FOR FURTHER INFORMATION CONTACT: Robin Tuttle (NMFS International Organizations and Agreements Division), 301-713-2282.

SUPPLEMENTARY INFORMATION:

Background

At its annual meeting in Hobart, Tasmania, in 1986, CCAMLR, of which the United States is a member, adopted a conservation measure requiring the Commission at subsequent meetings to adopt limitations on catch, or equivalent measures, binding for species upon which fisheries are permitted in Convention subarea 48.3 (South Georgia), depicted at figure 1 of 50 CFR part 380. The Commission has, in addition, adopted measures that apply to other Convention subareas.

The measures concerning the 1991/92 fishing season adopted by CCAMLR at its annual meeting in 1991 are based upon the advice of the Scientific Committee and take into account research conducted by Commission members and the reports and recommendations of the Scientific Committee's Working Groups on Fish Stock Assessment; Krill; and CCAMLR Ecosystem Monitoring Program (CEMP). The 1991/92 fishing season is defined as the period from November 2, 1991, to the end of the Commission meeting in 1992 (likely November 6, 1992). The measures were announced and public comments invited (until February 3, 1992) by **Federal Register** notice on January 6, 1992 (57 FR 421). No comments were received.

(i) Subarea 48.3

The Commission took most of its actions with respect to subarea 48.3 and adopted the following measures for the 1991/92 fishing season:

The total catch of *Dissostichus eleginoides* (Patagonian toothfish) is limited to 3,500 tons. Catch-and-effort data is due on an every-5-day reporting period.

Directed fishing on *Champsocephalus gunnari* (mackerel icefish), *Notothenia gibberifrons* (humped rockcod), *Chaenocephalus aceratus* (blackfin icefish), *Pseudochaenichthys georgianus* (South Georgia icefish), *Notothenia*

squamifrons (grey rockcod), and *Patagonotothen brevicauda guntheri* (Patagonian rockcod) is prohibited. The prohibition on directed fishing for *Notothenia rossii* (marbled rockcod) adopted as a conservation measure in 1985 is continued.

The total catch of *Electrona carlsbergi* (lanternfish) is limited to an amount not to exceed 245,000 tons. In addition, the total catch of *E. carlsbergi* shall not exceed 53,000 tons in the Shag Rocks region.

The bycatch of *N. gibberifrons* is limited to no more than 500 tons and the bycatch of any of *N. rossii, N. squamifrons, C. aceratus, P. georgianus,* and *C. gunnari* is limited to 300 tons. The fishery in subarea 48.3 will close if the bycatch of any of these species reaches their bycatch limit or if the total catch of *E. carlsbergi* reaches 245,000 tons, whichever comes first. The fishery in the Shag Rocks region will close if the bycatch of any of these species reaches their bycatch limit or if the total catch of *E. carlsbergi* reaches 53,000 tons, whichever comes first. If, in the course of the directed fishery for *E. carlsbergi*, the bycatch of any one haul of any of the bycatch species exceeds 5 percent, the fishing vessel must move to another fishing ground within the subarea.

Each month, the length composition of a minimum of 500 *E. carlsbergi*, randomly collected from the commercial fishery, will be measured and the information passed to the Executive Secretary not later than the end of the following month. Every calendar-month reporting of catch and effort is required for the fishery.

The monthly reporting of representative samples of length composition measurements using forms provided by the Commission is required for *D. eleginoides* during the 1991/92 fishing season. Monthly measurement of a minimum of 500 fish was required in 1990/91. Failure by any Contracting Party, including the United States, to submit length composition data for three consecutive reporting periods results in the closure of the fishery to the vessels of the Contracting Party.

The Commission continued in operation the basic framework of the every-5-day reporting method for catch and effort adopted in 1989 for subarea 48.3, changing the method by which the Executive Director is to estimate the date upon which the total allowable catch (TAC) for the species being reported is likely to be reached for that season.

(ii) Subareas 48.1 and 48.2

The Commission continued the 1990/91 prohibition on the taking of all species of finfish, other than for scientific research purposes, in subareas 48.1 and 48.2 during the 1991/92 fishing season.

(iii) Subarea 58.4

The Commission prohibited fishing for *N. squamifrons* on the Ob and Lena Banks in statistical division 58.4.4. for the 1991/92 fishing season. A limited fishery of 267 and 305 tons, respectively, was permitted in 1990/91.

(iv) Precautionary Catch Limits on Euphausia Superba

The total catch of *E. superba* in statistical area 48 was limited by the Commission to 1.5 million tons in any fishing season. A fishing season for purposes of the precautionary cap begins on July 1 and concludes on June 30 of the following year. The limit will be kept under review by the Commission, taking into account the advice of the Scientific Committee.

Precautionary limits to be agreed to by the Commission on the basis of advice of the Scientific Committee will be applied to subareas, or on such basis as the Scientific Committee may advise, if the total catch in subareas 48.1, 48.2, and 48.3 in any fishing season exceeds 620,000 tons. For purposes of implementing this measure, catches are to be reported to the Commission on a monthly basis.

(v) Monthly Catch and Reporting System

The Commission adopted a new measure establishing a 1-calendar month reporting period. It requires that each Contracting Party, including the United States, obtain from each of its vessels throughout the Convention Area, total catch and total days and hours fished on certain species for which catch limitations have been set for each reporting period and cable or telex the aggregated catch and days and hours fished to the Executive Secretary not later than the end of the next reporting period. The Executive Secretary uses the total aggregate data for the season to date to estimate the date upon which the TAC for the reported species is likely to be reached and close the fishery accordingly.

(vi) Net Monitor Cables

The use of net monitor cables on harvesting vessels in the Convention Area is prohibited beginning in the 1994/95 fishing season.

(vii) Notification of New Fisheries

The Commission adopted a measure requiring prior notification by Members of any proposal to initiate a new fishery. A new fishery is defined as a fishery on a species using a particular fishing method in a statistical subarea for which: (1) Information on distribution, abundance, demography, potential yield and stock identity from comprehensive research/surveys or exploratory fishing have not been submitted to CCAMLR; or (2) catch and effort data from this statistical subarea have never been submitted to CCAMLR; or (3) catch and effort data from the two most recent seasons in which fishing occurred have not been submitted to CCAMLR. Notification is required not less than 3 months in advance of the next regular meeting of the Commission. The new fishery may not be initiated until the nature and impacts of the fishery are considered by the Scientific Committee and reviewed by the Commission. The Scientific Committee and Commission will consider the nature of the proposed fishery, including target species, methods of fishing, proposed region and any minimum level of catches that would be required to develop a viable fishery; biological information from comprehensive research/ survey cruises, such as distribution, abundance, demographic data and information on stock identity; details of dependent and associated species and the likelihood of them being affected by the proposed fishery; and information from other fisheries in the region or similar fisheries elsewhere that may assist in the valuation of potential yield. Based upon the review of this information, and taking full account of the recommendations and advice of the Scientific Committee, the Commission may then take such action as it deems necessary.

This rule requires individuals proposing a new fishery to notify the Assistant Administrator for Fisheries, NOAA (Assistant Administrator), by permit application no later than July 1 of the year in which he or she proposes to initiate a new fishery and to submit the information described above in support of the application. The U.S. Government will provide the information to CCAMLR and the Assistant Administrator will weight CCAMLR advice in considering the permit request.

(viii) Crab Fishing

The Assistant Administrator has issued a permit under the harvesting permit sections of these regulations for a fishery on stone and king crabs in the Convention Area. As a condition of the permit, the permit holder is required to keep and submit a Commercial Vessel Daily Activity Logbook, comprising an Information Record and a Daily Activity

Record; a Commercial Vessel Fishing Effort Logbook; and a Commercial Vessel CCAMLR Subsample Logbook. The regulations are expanded to require all Antarctic crab fishery permit holders to keep and submit these records.

Classification

The Secretary has determined that this rule is necessary to implement the Antarctic Marine Living Resources Convention Act of 1984 (the Act) and to give effect to the management measures adopted by CCAMLR and agreed to by the United States.

The Assistant Administrator prepared a framework environmental assessment (EA) for the Act in 1987. NMFS reviewed this rule and determined that the actions that it requires are generally summarized in the framework EA and are thus excluded from further National Environmental Policy Act analysis.

This action is exempt from Executive Order 12291 and section 553 of the Administrative Procedure Act because it involves a foreign affairs function of the United States.

Because notice and comment rulemaking is not required for this rule, the Regulatory Flexibility Act does not apply; therefore, a regulatory flexibility analysis has not been prepared. At present, except for research purposes and for an exploratory crab fishery permitted under the harvesting permit sections of the regulations, there are no U.S. vessels subject to the jurisdiction of the United States harvesting Antarctic marine living resources within the area to which these regulations apply. The only other Antarctic marine living resources affected are scientific specimens taken under National Science Foundation permits and by the U.S. Antarctic Marine Living Resources directed research program.

This rule contains a collection-of-information requirement subject to the Paperwork Reduction Act. The collection of information has been approved by the Office of Management and Budget under OMB Control Number 0648-0194, which expires July 31, 1994.

The annual reporting burden for this collection of information is estimated to average 6.5 hours per finfish harvester and 37 hours per crab harvester, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Applicants for a permit to undertake a new fishery will average 8 hours in researching and preparing information in support of the application. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Robin Tuttle, National Marine Fisheries Services, and to the Office of Information and Regulatory Affairs (see **ADDRESSES**).

This rule does not contain policies with federalism implications sufficient to warrant preparation of a federalism assessment under Executive Order 12612.

This rule does not directly affect the coastal zone of any state with an approved coastal zone management program.

List of Subjects in 50 CFR Part 380

Antarctic, Fish and wildlife, Reporting and recordkeeping requirements.

Dated: April 8, 1992.

Samuel W. McKeen,

Acting Assistant Administrator for Fisheries, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR part 380 is amended as follows:

PART 380—ANTARCTIC MARINE LIVING RESOURCES CONVENTION ACT OF 1984

1. The authority citation for part 380 continues to read as follows:

Authority: 16 U.S.C 2431 *et seq.*

2. Section 380.23 is revised to read as follows:

§ 380.23 Catch restrictions.

(a) The following catch restrictions apply to *E. superba* in statistical area 48 (see Figure 1):

(1) The total catch of *E. superba* shall not exceed 1.5 million tons in any fishing season.

(2) For purposes of applying this limit, a fishing season begins on July 1 and ends on June 30 of the following year.

(3) For purposes of implementing this restriction, catches shall be reported to the Commission on a monthly basis.

(b) The following catch restrictions apply to subarea 48.3 (see Figure 1) during the period from November 2, 1991, through November 6, 1992:

(1) Directed fishing on *C. gunnari, N. rossii, N. gibberifrons, C. aceratus, P. georgianus, N. squamifrons* and *P. b. guntheri* is prohibited.

(2) The total catch of *D. eleginoides* shall not exceed 3,500 tons.

(3) The total catch of *E. carlsbergi* shall not exceed 245,000 tons.

(4) The total catch of *E. carlsbergi* shall not exceed 53,000 tons in the Shag Rocks region, defined as the area bounded by 52° 30'S. latitude, 40° W. longitude; 52° 30'S. latitude, 44° W. longitude; 54° 30'S. latitude, 40° W. longitude; and 54° 30'S. latitude, 44° W. longitude.

(5) The bycatch of *N. gibberifrons* shall not exceed 500 tons.

(6) The bycatch of any of the following species: *N. rossii, N. squamifrons, C. aceratus, P. georgianus,* and *C. gunnari* shall not exceed 300 tons.

(7) The bycatch limit of *P. b. guntheri* is 1 percent of all Antarctic fishes onboard a vessel in the subarea.

(8) If, in the course of the directed fishery for *E. carlsbergi,* the bycatch of any of the species named in paragraphs (b)(5) and (b)(6) of this section exceeds 5 percent, the fishing vessel shall move to another fishing ground within the subarea.

(c) The taking of finfish, other than for scientific research purposes, is prohibited in subareas 48.1 and 48.2 (see Figure 1) during the period from November 2, 1991, through November 6, 1992.

(d) The taking of *N. squamifrons,* other than for scientific research purposes, is prohibited in statistical division 58.4.4 (see Figure 1) during the period from November 2, 1991, through November 6, 1992.

3. Section 380.24 is revised to read as follows:

§ 380.24 Reporting requirements.

(a) The following statistical reporting is required in subarea 48.3 during the period from November 2, 1991, through November 6, 1992, on all species for which there are catch restrictions, except *E. superba* and *E. carlsbergi:*

(1) The calendar month is divided into six reporting periods: Day 1 to day 5 is period A, day 6 to day 10 is period B, day 11 to day 15 is period C, day 16 to day 20 is period D, day 21 to day 25 is period E, and day 26 to the end of the month is period F.

(2) The operator of any vessel fishing in subarea 48.3 must, within 2 days of the end of a reporting period, report his or her catch and bycatch to NMFS. The report must be made in writing, by cable, telex, rapidfax, or other appropriate method to the address or number specified in the vessel's permit, and must include the vessel name, permit number, month and reporting period, and its catch in metric tons (to the nearest tenth of a metric ton). If no restricted species are taken during a reporting period, the operator must submit a report showing no catch.

(b) The following monthly statistical reporting is required for *E. carlsbergi* taken in subarea 48.3 and for *E. superba* taken in area 48:

(1) For purposes of this catch and effort reporting system, the reporting period shall be defined as 1 calendar month.

(2) At the end of each reporting period, the operator of each vessel must, within 2 days of the end of a reporting period, report his or her total catch and total days and hours fished for that period. The report must be made to NMFS in writing, by cable, telex, or other appropriate method to the address or number specified in the vessel's permit, and must include the vessel name, permit number, and month to which the report refers.

(c) For purposes of reporting biological data for *E. carlsbergi* taken in subarea 48.3, the length composition of a minimum of 500 fish, randomly collected by each vessel, must be measured each month. Reports of these measurements must be made to NMFS in writing by cable, telex, rapidfax, or other appropriate method to the address or number specified in the vessel's permit, and must include the vessel's name, permit number, and month no later than 2 days after the end of the month in which the measurements were taken.

(d) For purposes of reporting biological data for *D. eleginoides* taken in subarea 48.3, the length composition of a minimum of 5 percent of each haul, must be measured each month. Reports of these measurements must be made to NMFS in writing by cable, telex, rapidfax, or other appropriate method to the address or number specified in the vessel's permit, and must include the vessel's name, permit number, and month no later than 2 days after the end of the month in which the measurements were taken.

(e) The following logbooks provided by NMFS to Antarctic crab fishery permit holders must be kept and submitted to NMFS as indicated in the instructions to the logbooks:

(1) Commercial Vessel Daily Activity Logbook;

(2) Commercial Vessel Fishing Effort Logbook;

(3) Commercial Vessel CCAMLR Subsample Logbook.

4. Section 380.26 is revised to read as follows:

§ 380.26 Closures.

(a) The fishery for *E. carlsbergi* shall close if the bycatch of any of the species *N. gibberifrons*, *N. rossii*, *N. squamifrons*, *C. aceratus*, *P. georgianus*, or *C. gunnari* reaches their bycatch limit or if the total catch of *E. carlsbergi* reaches 245,000 tons, whichever comes first.

(b) The fishery in the Shag Rocks region shall close if the bycatch of any of the species named in paragraph (a) of this section reach their bycatch limit or if the total catch of *E. carlsbergi* reaches 53,000 tons, whichever comes first.

(c) The fishery for *D. eleginoides* shall close if the total catch reaches 3500 tons.

5. Section 380.27 is revised to read as follows:

§ 380.27 Gear restrictions.

(a) Longline fishing is prohibited in Convention waters.

(b) The use of net monitor cables on harvesting vessels in the Convention Area (see Figure 1) is prohibited beginning July 1, 1994.

6. A new § 380.29 is added to read as follows:

§ 380.29 Initiating a new fishery.

(a) A new fishery, for purposes of this section, is a fishery on a species using a particular method in a statistical subarea for which:

(1) Information on distribution, abundance, demography, potential yield and stock identity from comprehensive research/surveys or exploratory fishing have not been submitted to CCAMLR; or

(2) Catch and effort data have never been submitted to CCAMLR; or

(3) Catch and effort data from the two most recent seasons in which fishing occurred have not been submitted to CCAMLR.

(b) An individual subject to these regulations intending to develop a new fishery shall notify the Assistant Administrator no later than July 1 of the year in which he or she intends to initiate the fishery and shall not initiate the fishery pending CCAMLR review.

(c) The notification shall be accompanied by information on:

(1) The nature of the proposed fishery, including target species, methods of fishing, proposed region and any minimum level of catches that would be required to develop a viable fishery;

(2) Biological information from comprehensive research/survey cruises, such as distribution, abundance, demographic data and information on stock identity;

(3) Details of dependent and associated species and the likelihood of them being affected by the proposed fishery; and

(4) Information from other fisheries in the region or similar fisheries elsewhere that may assist in the valuation of potential yield.

[FR Doc. 92-8649 Filed 4-14-92; 8:45 am]
BILLING CODE 3510-22-M

Proposed Rules

Federal Register
Vol. 57, No. 73
Wednesday, April 15, 1992

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Part 327

[Docket No. 92-007P]

Restoration of Nicaragua to the List of Countries Eligible to Import Meat Products Into the United States

AGENCY: Food Safety and Inspection Service (FSIS), USDA.

ACTION: Proposed rule.

SUMMARY: In 1986, FSIS representatives were not able to make required reviews of the Nicaraguan meat inspection system because their personal safety could not be assured. Therefore, FSIS could not obtain current information and make the determinations necessary for maintenance of Nicaragua's eligibility to export meat and meat products to the United States. On September 17, 1986, FSIS published a final rule (51 FR 32903) withdrawing the country of Nicaragua from the list of countries eligible to export meat to the United States.

In April 1990, Nicaragua requested relistment as a country eligible to export meat to the United States. Since nearly 4 years have passed since its eligibility status was withdrawn, Nicaragua had to reestablish its eligibility by providing FSIS with current information on how its meat inspection system assures compliance with requirements that are "at least equal to" the provisions of the Federal Meat Inspection Act (FMIA) and regulations issued thereunder. Nicaragua has now demonstrated, through FSIS's eligibility process, that its meat inspection system imposes requirements that are "at least equal to" those of the United States, and FSIS is proposing to amend 9 CFR 327.2(b) by listing Nicaragua as a country eligible to export its meat products from cattle, sheep, swine, and goats to the United States.

DATES: Comments must be received on or before May 15, 1992.

ADDRESSES: Written comments to Policy Office, Attention: Linda Carey, FSIS Hearing Clerk, room 3171, South Agriculture Building, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250.

FOR FURTHER INFORMATION CONTACT: Dr. Lawrence Skinner, Director, Foreign Programs Division, International Programs, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250, (202) 720-6933.

SUPPLEMENTARY INFORMATION:

Executive Order 12291

The Agency has determined in accordance with Executive Order 12291 that this proposed rule is not a "major rule." It will not result in an annual effect on the economy of $100 million or more. There will be no major increase in costs or prices for consumers, individual industries, Federal, State or local government agencies, or geographic regions, and it will not have a significant effect on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets. The proposal would restore Nicaragua as a country from which meat products are eligible to be imported into the United States.

In 1983, its last full year of exporting meat to the United States, Nicaragua exported 26.4 million pounds of beef products. In 1984, when export activity to the United States was suspended temporarily due to problems with adequate residue testing and species verification programs, 11.1 million pounds of beef products were exported during a 9-month period. During a 4-month period in 1985, before the prohibition of all imports of goods and services of Nicaraguan origin under Executive Order 12513, Nicaragua exported 9.6 million pounds of beef products to the United States. Therefore, based on a monthly average of 1.8 million pounds (47.1 million pounds/25 months) for the 25-month period during 1983–1985, it is estimated that Nicaragua would export about 22.6 million pounds (1.88 million pounds/12 months) of beef products to the United States if its eligibility were restored. This amount would represent only 0.06 percent of the total U.S. meat production, based on U.S. production of 39.6 billion pounds in 1989, and would have little, if any, impact on domestic producers.

Executive Order 12778

This proposed rule has been reviewed under Executive Order 12778, Civil Justice Reform. If this rule is adopted all State and local laws, regulations or policies except those that are consistent with the proposed rule and apply to imported meat and meat products after entry into the United States are preempted. This proposed rule is not intended to have retroactive effect. There are no applicable administrative procedures that must be exhausted prior to any judicial challenge to the provisions of this rule or the implementation of its provision.

Effect on Small Entities

The Administrator, FSIS, has determined that the proposed rule would not have a significant economic impact on a substantial number of small entities as defined by the Regulatory Flexibility Act (5 U.S.C. 601), because the amount of product estimated to be imported into the United States from Nicaragua represents only 0.06 percent (22.6 million pounds/39.6 billion pounds) of the U.S. domestic production.

Comments

Interested persons are invited to submit written comments concerning this proposal. Written comments should be sent in duplicate to the Policy Office. Please include the docket number which appears in the heading of this document. All comments submitted in response to the proposal will be available for public inspection in the Policy Office from 9 a.m. to 12:30 p.m., and from 1:30 p.m. to 4 p.m., Monday through Friday.

Background

Pursuant to the FMIA (21 U.S.C. 601 *et seq.*), the Secretary of Agriculture is responsible for administering the programs which are designed to ensure that meat products distributed to consumers are wholesome, not adulterated, and properly marked, labeled and packaged. The Secretary has delegated to the Administrator of FSIS the authority to issue regulations and implement appropriate procedures to ensure compliance with the requirements of the FMIA. In these regulations, the Administrator has established procedures by which foreign

countries desiring to export meat products to the United States may become eligible to do so.

To obtain such eligibility, a country's inspection system must undergo a complete evaluation by FSIS personnel to assure compliance with requirements that are "at least equal to" the requirements of the FMIA and regulations thereunder as applied to official establishments in the United States. This evaluation consists of two processes, a document review and an on-site review of the inspection system operations.

The document review process begins when FSIS assesses the laws and regulations governing the country's inspection system for equivalency to U.S. standards and requires a foreign country to respond to a series of questionnaires which focus on its inspection controls in five risk areas: Contamination, disease, processing, residue control, and compliance and economic fraud. FSIS then evaluates the responses to these questionnaires to assure that the critical points in each of the risk areas are being addressed satisfactorily.

When the document review proves to be satisfactory, FSIS sends a multi-disciplinary team on an on-site review to evaluate all aspects of the country's inspection system, including its laboratories and individual plants. On-site reviews are designed to further explore areas determined to require more detailed evaluation, and are also undertaken to allow FSIS to observe the system in its daily operations.

When this review is satisfactorily concluded, rulemaking is undertaken to list the country in the Code of Federal Regulations as being eligible to import meat into the United States. Once a country is listed, FSIS monitors the foreign inspection system through a continuing oversight function to assure that the inspection system maintains the "at least equal to" requirements. This includes reinspections of a random sample for foreign meat products at U.S. ports-of-entry, and routine on-site reviews of the foreign inspection system.

Whenever the Administrator cannot obtain current information about the system of meat inspection being maintained by a foreign country, the Administrator has the authority, under 9 CFR 327.2(a)(4), to withdraw the eligibility of the foreign inspection system to export meat products into the United States.

In 1986, FSIS representatives could not make the required on-site reviews of the Nicaraguan meat inspection system because their personal safety could not be assured. As a result, on September 17, 1986, an amendment to 9 CFR 327.2(b) of the Federal meat inspection regulations was published in the **Federal Register** (51 FR 32903) withdrawing the eligibility of Nicaragua to export meat products to the United States.

In April 1990, Nicaragua requested relistment as a country eligible to export meat products to the United States. Because of the considerable lapse of time since its eligibility was withdrawn, it was necessary for Nicaragua to provide FSIS with current information demonstrating that its inspection system imposes requirements "at least equal to" all the provisions of the FMIA and the regulations promulgated thereunder, and therefore can be considered as eligible to have its meat and meat products imported into the United States.

Nicaragua—Review Results

Nicaragua's eligibility determination process effectively began in October 1990, with the receipt of questionnaire responses relating to the five risk areas, as well as official copies of its relevant meat inspection laws and regulations. The preliminary phase of the document review was conducted in November 1990, and Nicaragua was requested to provide additional information regarding controls in several key areas concerning prevention of diseased meat, contamination, residue monitoring, processing, and compliance and economic fraud. Additional information was provided in December 1990; however, further clarification was still necessary for some of the risk areas. Discussions between FSIS and Nicaragua's inspection officials were held during 1991 to satisfactorily complete the document review process.

In January 1992, FSIS conducted an on-site review of Nicaragua's meat inspection system. The review team visited three meat plants and a government meat inspection laboratory. During the review process, the FSIS team noted minor variations in the application of requirements which were resolved through discussions with inspection officials. Therefore, based on the findings of the document and on-site reviews, and discussions with senior government meat inspection officials and various plant and laboratory personnel, FSIS believes the meat inspection system of Nicaragua to be "at least equal to" that of the United States.

Accordingly, FSIS is proposing to amend 9 CFR 327.2(b) of the Federal meat inspection regulations to add Nicaragua to the lists of countries from which meat products may be eligible for importation into the United States. Although a foreign country may be listed as approved for importation of meat products, the meat products of such foreign country must also comply with other Federal laws including restrictions under the Animal and Plant Health Inspection Service regulations (9 CFR Part 94), relating to the importation of meat products from foreign countries into the United States.

The Proposal

For the reasons set forth in the preamble, FSIS Is amending 9 CFR part 327 of the Federal meat inspection regulations as set forth below.

PART 327—IMPORTED PRODUCTS

1. The authority citation for part 327 would continue to read as follows:

Authority: 21 U.S.C. 601–695; 7 CFR 2.17, 2.55.

§ 327.2 [Amended]

2. Section 327.2(b) would be amended by adding "Nicaragua" to the alphabetical list of countries eligible to import cattle, sheep, swine, and goat products into the United States.

Done at Washington, DC, on March 24, 1992.

H. Russell Cross,

Administrator, Food Safety and Inspection Service.

[FR Doc. 92–8722 Filed 4–14–92; 8:45 am]

BILLING CODE 3410-DM-M

FEDERAL ELECTION COMMISSION

11 CFR Part 110

[Notice 1992–7]

Transfers of Funds From State to Federal Campaigns

AGENCY: Federal Election Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Federal Election Commission today seeks comments on proposed changes in its regulations regarding the transfer of funds from state campaigns to federal campaigns. The Commission is considering changes in its transfer regulations in response to a Petition for Rulemaking filed by Congressman William Thomas. 56 FR 66866 (Dec. 26, 1991). Congressman Thomas' Petition alleges that the current regulations are ineffective, because they fail to prevent the indirect use of impermissible funds in federal elections. According to the Petition, these regulations allow state campaigns to use impermissible funds to raise additional permissible funds that they can transfer to a federal campaign committee for use in a federal campaign. The proposal

would amend 11 CFR 110.3(c)(6) to prohibit the transfer of contributions raised using funds that are not permissible under the Federal Election Campaign Act, as amended, 2 U.S.C. 431 et seq. ["FECA" or "the Act"]. Further information is provided in the supplementary information which follows.

DATES: Comments must be received on or before May 15, 1992.

ADDRESSES: Comments must be in writing and addressed to: Ms. Susan E. Propper, Assistant General Counsel, 999 E. Street, NW., Washington, DC 20463.

FOR FURTHER INFORMATION CONTACT: Ms. Susan E. Propper, Assistant General Counsel, 999 E Street, NW., Washington, DC 20463, (202) 219–3690 or (800) 424–9530.

SUPPLEMENTARY INFORMATION: On December 5, 1991, Congressman William Thomas filed a petition for rulemaking urging the Commission to revise its regulations regarding the transfer of funds from state campaign committees to federal campaign committees. These regulations, set forth at 11 CFR 110.3(c)(6), allow state campaign committees to transfer funds to federal committees so long as the funds transferred do not contain contributions that are impermissible under the FECA, so called "soft money." The Petition alleges that the current regulations are ineffective, because they fail to prevent the indirect use of impermissible funds in federal elections. The Petition urges the Commission to "conduct a rule-making procedure to ensure that Federal Election Law is fully enforced to the extent that 'soft money' is not indirectly used by nonfederal committees to raise funds that will be used in Federal races."

The Commission published a Notice of Availability on December 26, 1991, which sought public comments on the Petition. See 56 FR 66866 (Dec. 26, 1991). The Commission received four written comments from the regulated community and two supplementary submissions from the Petitioner. Three of the comments and the two supplementary submissions support the Petition. The fourth comment seeks clarification of the Petition, and urges the Commission to limit the scope of any rulemaking procedure undertaken in response to it.

The Commission notes that it has a long-standing policy of permitting the transfer of funds from state campaigns to federal campaigns. This policy can be traced to Advisory Opinion 1975–10, part (B), in which the Commission permitted the transfer of surplus funds from a state campaign to a federal political committee so long as the transfer did not contain any contributions from prohibited sources or in excess of the individual limits. The Commission has consistently supported this policy in the advisory opinions it has issued since AO 1975–10. See AOs 1975–66, 1980–117, 1982–52, 1983–34, 1984–3, 1984–46, 1985–1, 1987–12, 1990–16. The current regulations, which were promulgated in 1989, are based on this series of Advisory Opinions. See Explanation and Justification of Final Rule, 54 FR 34098, 34104 (Aug. 17, 1989).

However, in recent years the Commission has been more closely regulating the indirect use of impermissible funds in federal election activities. *See, e.g.*, Methods of Allocation Between Federal and Non-Federal Accounts, 55 FR 26058 (June 26, 1990). Congressman Thomas' Petition raises questions related to this issue. It suggests that the Commission's current transfer rules may permit the indirect use of impermissible funds in federal elections by allowing state campaigns to transfer funds to a federal campaign without regard to how those funds were raised.

Therefore, the Commission is publishing this Notice of Proposed Rulemaking ("NPRM"), seeking comments on proposed changes in the transfer rules. The proposed rule would permit transfers of funds from state campaigns to federal campaigns provided that the candidate can demonstrate that the transferred funds were not raised using funds that would be impermissible under the Act. The rule would also require a state campaign to inform the contributors of the funds to be transferred of its intention to make the transfer, and exclude from those funds the contribution of any contributor who does not provide authorization in writing for the transfer. Although it is not included in the proposed rule, the Commission is also considering requiring federal campaigns to certify that the funds transferred were raised using permissible funds when they submit reports notifying the Commission of the transfer.

The Commission recognizes that the proposal raises some significant practical questions, and urges the regulated community to address these questions in its response to the NPRM. Perhaps the most significant question is how to determine what funds were used to raise the specific funds being transferred and, thus, which transfers should be prohibited by the rule. For example, if a candidate determines that a fundraising activity was partially paid for with impermissible funds, should all of the contributions received from that fundraiser be ineligible for transfer to a federal campaign? Or, should only a portion of the contributions received be ineligible? If the latter rule is preferable, what portion should be eligible? Should the percentage of contributions eligible for transfer be linked to the percentage of permissible funds used to finance that fundraising activity?

Linking the percentage of permissible funds eligible for transfer to the percentage used to finance the fundraising activity would raise additional questions, particularly in those situations where the candidate pays for a fundraising activity by making multiple disbursements on several different days. When the disbursements occur on different days, how should the candidate determine what percentage of the expenses for that fundraising activity were paid for with permissible funds? Should the candidate be required to examine the contents of his or her state campaign account on the day of each disbursement, and determine what portion of the disbursement came from contributions that would be permissible under the Act?

What should the candidate do if, after making this determination, he or she discovered that the ratio of permissible to impermissible funds in the account on some disbursement days was lower than the ratio of permissible to impermissible funds ultimately received from that fundraising activity? Should this shortfall reduce the amount of funds eligible for transfer to the federal campaign? Or, should the candidate be able to offset lower ratios on some disbursement days with higher ratios on other disbursement days, thereby maximizing the amount of hard dollars eligible for transfer to the federal campaign?

The proposed rule would also require a state campaign to inform contributors of its intention to transfer their contributions, and exclude from the transfer the contribution of any contributor who does not provide written authorization for the transfer. As drafted, this rule would require the contributor to affirmatively authorize the transfer. However, the Commission is also considering an alternative formulation. The alternative approach would also require contributor notification, but would allow the state campaign committee to transfer the contribution of any contributor who does not object to the transfer. No affirmative authorization of the transfer would be required.

Although the draft rule incorporates the "affirmative authorization" rather than the "no objection" approach, the

Commission has not made a decision on this issue. Commenters are urged to address it in their responses to the NPRM. One additional question that is raised by the "no objection" approach is whether the state campaign should be required to allow contributors a minimum amount of time to object before making the transfer. If so, what should that time period be?

The Commission is also interested in comments on how the proposed rule would interact with existing regulations regarding federal political committees and federal candidate status. Some state campaign committees may choose to set up separate accounts for permissible and impermissible funds in order to simplify the recordkeeping process for future transfers. If they do so, the Commission could view this as testing the waters activity that does not trigger federal candidate status. See 11 CFR 100.7(b)(1). On the other hand, segregating these funds could be viewed as activity meant to influence a federal election, in which case is my trigger federal status under 11 CFR 200.3. See also AO 1990–16 for examples of activities that could trigger federal political committee status. Commenters are encouraged to comment on each possible approach.

The Commission recognizes the difficulty of showing that contributions received were raised with permissible funds. Therefore, it is also seeking comments on an alternative proposal. The alternative rule would prohibit all transfers of funds from state campaigns to federal campaigns. The Commission is interested in comments on whether such a prohibition would be preferable to the rule proposed by this notice.

The Commission is aware that, since this NPRM is being published after the start of the 1992 election campaign, implementation of the proposals under consideration during this election cycle could cause problems for campaigns already in progress. Therefore, should the Commission decide to promulgate a new rule in this area, it does not intend to make the rule effective until after conclusion of this election cycle.

The Commission welcomes comments on the issues raised by the proposed rule, and on the general question of whether any rulemaking is warranted at this time. Those interested are also welcome to raise other issues that should be addressed if Commission decides to issue final rules in this area.

Certification of No Effect Pursuant to 5 U.S.C. 605(b) (Regulatory Flexibility Act)

I certify that the attached proposed rule will not have a significant economic impact on a substantial number of small entities. The basis of this certification is that the proposed rule would modify the requirements for transferring funds from a state campaign to a federal campaign for use in federal election activity. This does not impose a significant economic burden, because any small entities affected are already required to comply with the Act's requirements if they engage in activity designed to influence a federal election.

List of Subjects in 11 CFR Part 110

Campaign funds, Political candidates.

For the reasons set out in the preamble, it is proposed to amend subchapter A, chapter I of title 11 of the Code of Federal Regulations as follows:

PART 110—CONTRIBUTION AND EXPENDITURE LIMITATIONS AND PROHIBITIONS

1. The authority citation for part 110 would continue to read as follows:

Authority: U.S.C. 431(8), 431(9), 432(c)(2), 437d(a)(8), 438(a)(8), 441a, 441b, 441d, 441e, 441f, 441g and 441h.

2. Section 110.3 would be amended by revising the introductory text of paragraph (c)(6) and paragraph (c)(6)(i) to read as follows:

§ 110.3 Contribution limitations for affiliated committees and political party committees; Transfers (2 U.S.C. 441a(a)(5), 441a(a)(4)).

* * * * *

(c) * * *

(6) Transfers of funds from a candidate's campaign committee for a nonfederal election to his or her principal campaign committee or other authorized committee for a Federal election, provided that the funds transferred are composed of, and were raised using funds composed of, contributions permissible under the Act. Before making any such transfer, the nonfederal committee shall inform contributors whose contributions are to be transferred of the committee's intention to make the transfer, and shall exclude the contributions of any contributor who does not provide authorization in writing for the transfer.

(i) The cash on hand from which the transfer is made shall be considered to consist of the funds most recently received by the transferor committee. The transferor committee must be able to demonstrate that such cash on hand contains sufficient funds at the time of the transfer that comply with the limitations and prohibitions of the Act to cover the amount transferred. The transferor committee must also be able to demonstrate that the fundraising programs or activities that generated the transferred funds were paid for with funds permissible under the Act. A contribution shall be excluded from the amount transferred if the making or acceptance of such contribution in connection with an election for Federal office is prohibited by the Act. A contibution shall also be excluded from the amount transferred if it resulted from a fundraising activity or program that was paid for with funds that are prohibited by the Act. Moreover, a contribution shall be excluded from the amount transferred if the contributor does not provide authorization in writing for the transfer. The amount transferred per contributor shall not exceed the limitations on contributions set forth at 11 CFR 110.1 or 110.2, as appropriate. The campaign committee transferring the funds shall keep records of the sources of the funds in the account from which the transfer is made and, upon request, shall make such records available for examination by the Commission.

* * * * *

Dated: April 9, 1992.

Joan D. Aikens,

Chairman, Federal Election Commission.

[FR Doc. 92–8680 Filed 4–14–92; 8:45 am]

BILLING CODE 6715–01–M

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11 CFR Parts 102 and 110

[Notice 1992–6]

Special Fundraising Projects by Political Committees

AGENCY: Federal Election Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Federal Election Commission is seeking comments on proposed amendments to 11 CFR parts 102 and 110, regarding an unauthorized committee's use of a candidate's name in a special fundraising project on behalf of the unauthorized committee. The first amendment would require an unauthorized committee that solicited funds using the name of a candidate in the project title to include a disclaimer notice stating the name of the committee paying for the solicitation, and whether the solicitation is authorized by the candiate whose name appears in the project's title. The second would prohibit a political committee from accepting checks mailed in response to such a solicitation, unless the checks were made out to the registered name of the committee. The Commission is also seeking comments on whether it would differentiate between party committees and other political committees in this context, as well as on a proposal to ban

use of a candidate's name in the title of a special fundraising project, unless specifically permitted by the candidate. Finally, the Commission is proposing an amendment to 11 CFR 110.11(a)(1)(iv)(A), which deals with disclaimers by unauthorized committees, to bring the language in that paragraph into conformance with 2 U.S.C. 441d. Further information is provided in the supplementary information which follows.

DATES: Comments must be received on or before May 15, 1992.

ADDRESSES: Comments must be made in writing and addressed to: Ms. Susan E. Propper, Assistant General Counsel, 999 E Street, NW., Washington, DC 20463.

FOR FURTHER INFORMATION CONTACT: Ms. Susan E. Propper, Assistant General Counsel, (202) 219–3690 or (800) 424–9530.

SUPPLEMENTARY INFORMATION: The Federal Election Campaign Act ["FECA" or "the Act"] prohibits the use of a candidate's name in the name of an unauthorized political committee. 2 U.S.C. 432(e)(4); 11 CFR 102.14. In *Commond Cause* v. *FEC*, 842 F.2d 436 (D.C.Cir. 1988), the United States Court of Appeals for the District of Columbia Circuit upheld the Commission's view that this prohibition can be read as applying only to the name under which the committee registers with the Commission [the "registered name"], rejecting the argument that it had to be interpreted to also include the names of any fundraising projects sponsored by that committee.

Current Commission regulations at 11 CFR 110.11(a)(1)(iv)(A) provide that, whenever an unauthorized committee solicits contributions through general public political advertising, the communication must include a disclaimer, "presented in a clear and conspicuous manner," which clearly identifies the payor. The Act, at 2 U.S.C. § 441d, also requires the disclaimer to state whether the communication is authorized by any candidate or candidate's committee. The proposed rules would include this further statutory requirement in the text of paragraph 110.11(a)(1)(iv)(A). The Notice excludes national party committees from this latter requirement, due to their special circumstances.

Even if amended as proposed in this Notice, however, the rule would still not be sufficiently specific with regard to the situation where an unauthorized committee uses a candidate's name in the title of a special fundraising project. The Commission is concerned about the potential for confusion or abuse in these situations, in that a person who receives the communication might not understand that it is made on behalf of the committee rather than the candidate whose name appears in the project's title. Potential donors might think they are giving money to the candidate named in the project's title, when this is not the case.

For example, assume that the "XYZ Committee," a committee registered under that name with the Commission, establishes a special fundraising project called "Americans for Q." Although Q is a federal candidate, he has not authorized the XYZ Committee to use his name in this manner; and the committee plans to use contributions received from the special project to support other federal candidates. Even if the solicitation contains the disclaimer required under current law, a potential donor might believe he or she was contributing to Q's campaign, when this was not so.

The Commission is proposing two amendments to its rules, to minimize the current potential for confusion or possible abuse in this situation. Under the first, the political committee sponsoring the project would be required to include in the required disclaimer the name of the committee paying for the project, as well as a statement of whether the project had been authorized by the candidate whose name appeared in the title, or by any other candidate. Second, the committee could not accept checks received in response to the special project unless they were made payable to the registered name of the committee. All other checks would have to be returned or refunded.

To continue with the above example, if these proposals were adopted, solicitations mailed as part of the "Americans for Q" project would be required to contain a disclaimer stating, "Paid for by the XYZ Committee. Not authorized by Q [or any other federal candidate]." The committee could not accept checks mailed in response to this solicitation unless they were made payable to its registered name, "the XYZ Committee." Those made out to "Q," "Americans for Q," or to any other person or entity would have to be returned or refunded to the contributors. The Commission believes that these amendments would do much to eliminate the potential for confusion or possible abuse when the names of nonauthorizing candidates are used in these special fundraising projects.

The Commission is also requesting comments on whether party committees should be treated differently from other political committees in dealing with this situation, given party committees' interest in using the name of a candidate in a fundraising event for another candidate or as part of a general fundraising appeal. If different treatment is appropriate, the Commission welcomes comments on what distinctions should be made between party and non-party committees.

The Commission is requesting comments on whether an additional change should be made: whether the Commission should bar the use of a candidate's name in the name or title of a fundraising project by an unauthorized committee, unless the candidate permits his or her name to be used in this manner. The court in *Common Cause* v. *FEC, supra*, indicated that this approach, as well as the Commission's current approach, would be valid under 2 U.S.C. 432(e)(4). The Commission welcomes comments on whether this broader approach is now preferable.

Finally, the Commission is seeking comments on whether the revised disclaimer rule should include specific size and/or location requirements; and, if so, what these requirements should be. For example, the size requirement could be tied to the size of the candidate's name as it appears in the solicitation, or to the solicitation's text size. The adoption of either or both of these requirements could help ensure that the required disclaimer is clearly visible to recipients of the solicitation.

Certification of No Effect Pursuant to 5 U.S.C. 605(b) [Regulatory Flexibility Act]

These proposed rules will not, if promulgated, have a significant economic impact on a substantial number of small entities. The basis for this certification is that any small entities affected are already required to comply with the requirements of the Act in these areas.

List of Subjects

11 CFR Part 102

Campaign funds, Political candidates, Political committees and parties, Reporting and recordkeeping requirements.

11 CFR Part 110

Campaign funds, Political candidates, Political committees and parties.

For the reasons set out in the preamble, it is proposed to amend subchapter A, chapter I of title 11 of the Code of Federal Regulations as follows:

PART 102—REGISTRATION, ORGANIZATION, AND RECORDKEEPING BY POLITICAL COMMITTEES (2 U.S.C. 433)

1. The authority citation for part 102 would continue to read as follows:

Authority: 2 U.S.C. 432, 433, 438(a)(8), 441d.

2. Section 102.14 would be amended by adding paragraph (d), to read as follows:

§ 102.14 Names of political committees (2 U.S.C. 432(e)(4) and (5)).

* * * * *

(d) If an unauthorized political committee solicits contributions for itself under the name of a special fundraising project that includes in its title the name of a candidate, the committee shall return or refund all checks received in response to the solicitation which are not made out to the committee's registered name. For purposes of this paragraph, the committee's "registered name" is the name under which the committee has registered with the Federal Election Commission pursuant to 11 CFR 102.2(a)(1)(i).

PART 110—CONTRIBUTION AND EXPENDITURE LIMITATIONS AND PROHIBITIONS

3. The authority citation for Part 110 would continue to read as follows:

Authority: 2 U.S.C. 431(8), 431(9), 432(c)(2), 437d(a)(8), 438(a)(8), 441a, 441b, 441d, 441e, 441f, 441g, and 441h.

4. Section 110.11 would be revised by revising paragraph (a)(1)(iv)(A), redesignating paragraph (a)(1)(iv)(B) as paragraph (a)(1)(iv)(C), adding new paragraph (a)(1)(iv)(B), and revising paragraph (a)(1)(iv)(C), to read as follows:

§ 110.11 Communications; advertising (2 U.S.C. 441d).

(a) * * *

(1) * * *

(iv)(A) For solicitations directed to the general public on behalf of a political committee which is not an authorized committee of a candidate, such solicitation shall clearly state the full name of the person who paid for the communication, and, except for national party committees, whether it is authorized by any candidate or candidate's committee.

(B) If a political committee which is not an authorized committee of a candidate solicits contributions for itself under the name of a special fundraising project which includes in its title the name of any candidate, each solicitation made on behalf of the special project shall clearly state the name of the committee that is paying for the solicitation; and, except for national party committees, whether the solicitation is authorized by the candidate whose name is included in the title of the project, such candidate's committee, or any other candidate.

(C) For purposes of this section, whenever a separate segregated fund solicits contributions to the fund from those persons it may solicit under the applicable provisions of 11 CFR part 114, such communication shall not be considered a form of general public advertising and need not contain the disclaimers set forth in paragraphs (a)(1)(iv)(A) and (B) of this section.

* * * * *

Dated: April 9, 1992.

Joan D. Aikens,

Chairman, Federal Election Commission.

[FR Doc. 92-8546 Filed 4-14-92; 8:45 am]

BILLING CODE 6715-01-M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Parts 21 and 25

[Docket No. NM-69; Notice SC-92-3-NM]

Special Conditions: Canadair CL-600-2B19, Regional Jet Airplane; Lightning and High Intensity Radiated Fields (HIRF)

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed special conditions.

SUMMARY: This notice proposes special conditions for the Canadair CL-600-2B19, Regional Jet airplane. This airplane will have novel or unusual design features associated with a number of high technology avionic systems including cathode ray tube engine and flight information displays, digital engine control and electronically controlled braking. The applicable regulations do not contain adequate or appropriate safety standards for the protection of these systems from the effects of lightning and high-intensity radiated fields (HIRF). This notice proposes additional safety standards which the Administrator considers necessary to ensure that the critical and essential functions that these systems perform are maintained when the airplane is exposed to lightning and HIRF.

DATES: Comments must be received on or before June 1, 1992.

ADDRESSES: Comments on this proposal may be mailed in duplicate to: Federal Aviation Administration, Office of the Assistant Chief Counsel, Attention: Rules Docket (ANM-7), Docket No. NM-69, 1601 Lind Avenue SW., Renton, Washington 98055-4056; or delivered in duplicate to the Office of the Assistant Chief Counsel at the above address. Comments must be marked: Docket No. NM-69. Comments may be inspected in the Rules Docket weekdays, except Federal holidays, between 7:30 a.m. and 4 p.m.

FOR FURTHER INFORMATION CONTACT: Gary Lium, FAA, Standardization Branch, ANM-113, Transport Airplane Directorate, Aircraft Certification Service, 1601 Lind Avenue SW., Renton, Washington 98055-4056; telephone (206) 227-1112.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of these proposed special conditions by submitting such written data, views, or arguments as they may desire. Communications should identify the regulatory docket or notice number and be submitted in duplicate to the address specified above. All communications received on or before the closing date for comments will be considered by the administrator before further rulemaking action on this proposal is taken. The proposals contained in this Notice may be changed in light of the comments received. All comments received will be available, both before and after the closing date for comments, in the Rule Docket for examination by interested parties. A report summarizing each substantive public contact with FAA personnel concerning this rulemaking will be filed in the docket. Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must include a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket No. NM-69." The postcard will be date stamped and returned to the commenter.

Background

On May 26, 1988, Transport Canada, on behalf of Canadair, applied for an amendment to their Type Certificate No. A21EA to include their new Model CL-600-2B19 Regional Jet for an increase in size and the addition of a Collins integrated avionics suite in their Model CL-600-2B19. The Model CL-600-2B19, which is a derivative of the Model CL-600-2B16 currently approved under Type

Certificate No. A21EA, is a Regional Jet with a length of 88 ft. 5 inches, a wingspan of 70 ft. 4 inches, a passenger capacity of 50, a maximum takeoff weight of 51,000 lbs., and a range of 1400 nautical miles with two General Electric CF–34–3A1 engines. The Collins integrated avionics suite (essentially Proline IV) on the airplane incorporates a number of novel or unusual design features, such as digital avionics including, but not necessarily limited to, an Electronic Flight Instrument System (EFIS), engine and flight information displays, digital engine control and electronically controlled braking, which are vulnerable to lightning and high-intensity radiated fields (HIRF) external to the airplane.

Type Certification Basis

Under the provisions of § 21.101 of the FAR, Canadair must show that the Model CL–600–2B19 meets the applicable provisions of the regulations incorporated by reference in Type Certificate No. A21EA or the applicable regulations in effect on the date of application for the change to the Model CL–600–2B16. The regulations incorporated by reference in the type certificate are commonly referred to as the "original type certification basis". The regulations incorporated by reference in Type Certificate No A21EA are as follows: Part 25 of the FAR dated February 1, 1965, including Amendments 25–1 through 25–37. The certification basis also includes certain later amended sections of part 25 and special conditions that are not relevant to these proposed special conditions.

In addition, if the regulations incorporated by reference do not provide adequate standards with respect to the change, the applicant must comply with certain regulations in effect on the date of application for the change. The FAA has determined that the Model CL–600–2B19 must also be shown to comply with the following:

The Collins integrated avionics suite installation for the Regional Jet would be required to comply with part 25, as amended by Amendment 25–1 through Amendment 25–62, except for §§ 25.832 and 25.1438; § 25.109, as amended by Amendment 25–41; § 25.773(b)(2) as amended by Amendment 25–72; and § 25.1401 as amended by Amendment 25–40. In addition, part 34 of the FAR, in effect at the time of awarding the type certificate, and part 36 of the FAR, in effect on the date the noise tests are performed, must be met. The special conditions which may be developed as a result of this notice will form an additional part of the type certification basis.

If the Administrator finds that the applicable airworthiness regulations (i.e., Part 25 as amended) do not contain adequate or inappropriate safety standards for the Model CL–600–2B19 with Collins integrated avionics suite because of a novel or unusual design feature, special conditions are prescribed under the provisions of § 21.16.

Special conditions, as apropriate, are issued in accordance with § 11.49 of the FAR after public notice, as required by §§ 11.28 and 11.29(b), and become part of the type certification basis in accordance with § 21.101(b)(2).

In addition to the applicable airworthiness regulations and special conditions, the Model CL–600–2B19 must comply with the fuel vent and exhaust emission requirements of part 34 and the noise certification requirements of part 36.

Discussion

The existing lighting protection airworthiness certification requirements are insufficient to provide an acceptable level of safety with the new technology avionic systems. There are two regulations that specifically pertain to lightning protection: One for the airframe in general (§ 25.581), and the other for fuel system protection (§ 25.954). There are, however, no regulations that deal specifically with protection of electrical and electronic systems from lightning. The loss of a critical function of these systems due to lightning would prevent continued safe flight and landing of the airplane. Although the loss of an essential function would not prevent continued safe flight and landing, it would significantly impact the safety level of the airplane.

There is also no specific regulation that addresses protection requirements for electrical and electronic systems from high-intensity radiated fields (HIRF). Increased power levels from ground based radio transmitters and the growing use of sensitive electrical and electronic systems to command and control airplanes have made it necessary to provide adequate protection.

To ensure that a level of safety is achieved equivalent to that intended by the regulations incorporated by reference, special conditions are proposed for the Model CL–600–2B19 Collins integrated avionics suite which would require that new technology electrical and electronic systems, such as the electronic flight instrument system (EFIS), engine and flight information displays, digital engine control, and electronically controlled braking, be designed and installed to preclude component damage and interruption of function due to both the direct and indirect effects of lightning and HIRF.

Lightning

To provide a means of compliance with the proposed special conditions, a clarification on the threat definition of lightning is needed. The following "threat definition," based on FAA Advisory Circular 20–136, Protection of Aircraft Electrical/Electronic Systems Against the Indirect Effects of Lightning, dated March 5, 190, is proposed as a basis to use in demonstrating compliance with the proposed lightning protection special condition.

The lightning current waveforms (Components A, D, and H) defined below, along with the voltage waveforms in AC 20–53A, will provide a consistent and reasonable standard which is acceptable for use in evaluating the effects of lighting on the airplane. These waveforms depict threats that are external to the airplane. How these threats affect the airplane and its systems depend upon their installation configuration, materials, shielding, airplane geometry, etc. Therefore, tests (including tests on the completed airplane or an adequate simulation) and/or verified analyses need to be conducted in order to obtain the resultant internal threat to the installed systems. The electronic systems may then be evaluated with this internal threat in order to determine their susceptibility to upset and/or malfunction.

To evaluate the induced effects to these systems, three considerations are required:

1. *First Return Stroke:* (Severe Strike—Component A, or Restrike-Component D). This external threat needs to be evaluated to obtain the resultant internal threat and to verify that the level of the induced currents and voltages is sufficiently below the equipment "hardness" level; then

2. *Multiple Stroke Flash:* (½ Component D). A lightning strike is often composed of a number of successive strokes, referred to as multiple strokes. Although multiple strokes are not necessarily a salient factor in a damage assessment, they can be the primary factor in a system upset analysis. Multiple strokes can induce a sequence of transients over an extended period of time. While a single event upset of input/output signals may not affect system performance, multiple signal upsets over an extended period of time (2 seconds) may affect the systems

under consideration. Repetitive pulse testing and/or analysis needs to be carried out in response to the multiple stroke environment to demonstrate that the system response meets the safety objective. This external multiple stroke environment consists of 24 pulses and is described as a single Component A followed by 23 randomly spaced restrikes of ½ magnitude of Component D (peak aptitude of 50,000 amps). The 23 restrikes are distributed over a period of up to 2 seconds according to the following constraints: (1) The minimum time between subsequent strokes is 10 ms, and (2) the maximum time between subsequent strokes is 200 ms. An analysis or test needs to be accomplished in order to obtain the resultant internal threat environment for the system under evaluation. And,

3. *Multiple Burst:* (Component H). In-flight data gathering projects have shown bursts of multiple, low amplitude, fast rates of rise, short duration pulses accompanying the airplane lightning strike process. While insufficient energy exists in these pulses to cause physical damage, it is possible that transients resulting from this environment may cause upset to some digital processing systems.

The representation of this interference environment is a repetition of short duration, low amplitude, high peak rate of rise, double exponential pulses which represent the multiple bursts of current pulses observed in these flight data gathering projects. This component is intended for an analytical (or test) assessment of functional upset of the system. Again, it is necessary that this component be translated into an internal environmental threat in order to be used. This "Multiple Burst" consists of 24 random sets of 20 strokes each, distributed over a period of 2 seconds. Each set of 20 strokes is made up to 20 repetitive Component H waveforms distributed within a period of one millisecond. The minimum time between individual Component H pulses within a burst is 10 microseconds, the maximum is 50 microseconds. The 24 bursts are distributed over a period of up to 2 seconds according to the following constraints: (1) The minimum time between subsequent strokes is 10ms, and (2) the maximum time between subsequent strokes is 200ms. The individual "Multiple Burst" Compnent H waveform is defined below.

The following current waveforms constitute the "Severe Strike" (Component A), "Restrike" (Component D), "Multiple Stroke" (½ Component D), and the "Multiple Burst" (Component H).

These components are defined by the following double exponential equation:

$$i(t) = I_o(e^{-at} - e^{-bt})$$

where:

t = time in seconds,

i = current in amperes, and

	Severe strike (component A)	Restrike (compondnt D)	Multiple stroke (½ component D)	Multiple burst (component H)
I_o, amp	=218,810	109,405	54,703	10,572
a, sec^{-1}	=11,354	22,708	22,708	187,191
b, sec^{-1}	=647,265	1,294,530	1,294,530	19,105,100
This equation produces the following characteristics:				
i_{peak}	=200 KA	100 KA	50 KA	10 KA
and,				
$(di/dt)_{max}$(amp/sec)	1.4×10^{11} @t=0+sec	1.4×10^{11} @t=0+sec	0.7×10^{11} @t=0+sec	2.0×10^{11} @t=0+sec
di/dt, (amp/sec)	$=1.0\times10^{11}$ @t=.5μs	1.0×10^{11} @t=.25μs	0.5×10^{11} @t=.25μs	
Action Integral (amp^2 sec)	2.0×10^6	0.25×10^6	0.625×10^6	

High-Intensity Radiated Fields (HIRF)

With the trend toward increased power levels from ground based transmitters, plus the advent of space and satellite communications, coupled with electronic command and control of the airplane, the immunity of critical digital avionics systems, such as EFIS, to HIRF must be established.

It is not possible to precisely define the HRF to which the airplane will be exposed in service. There is also uncertainty concerning the effectiveness of airframe shielding for HIRF. Furthermore, coupling to cockpit installed equipment through the cockpit window apertures is undefined. Based on surveys and analysis of existing HIRF emitters, an adequate level of protection exists when complince with the HIRF protection special condition is shown with either paragraphs 1 or 2 below:

1. A minimum threat of 100 volts per meter peak electric field strength from 10 KHz to 18 GHz.

a. The threat must be applied to the system elements and their associated wiring harnesses without the benefit of airframe shielding.

b. Demonstration of this level of protection is established through system tests and analysis.

2. A threat external to the airframe of the following field strengths for the frequency ranges indicated.

Frequency	Peak (V/M)	Average (V/M)
10 KHz–500 KHz	60	60
500 KHz–2 MHz	80	80
2 MHz–30 MHz	200	200
30 MHz–100 MHz	33	33
100 MHz–200 MHz	150	33
200 MHz–400 MHz	56	33
400 MHz–1 GHz	4,020	935
1 GHz–2 GHz	7,850	1,750
2 GHz–4 GHz	6,000	1,150
4 GHz–6 GHz	6,800	310
6 GHz–8 GHz	3,600	666
8 GHz–12 GHz	5,100	1,270
12 GHz–20 GHz	3,500	551
20 GHz–40	2,400	750

The envelope given in paragraph 2 above is a revision to the envelope used in previously issued special conditions in other certification projects. It is based on new data and SAE AE4R subcommittee reommendations. This revised envelope includes data from Western Europe and the U.S.

Conclusion

This action affects only certain unusual or novel design features on one model of airplane. It is not a rule of general applicability and affects only the manufacturer who applied to the FAA for approval of these features on the airplane.

List of Subjects in 14 CFR Parts 21 and 25

Air transportation, Aircraft, Aviation safety, Safety.

The authority citation for these special conditions is as follows:

Authority: 49 U.S.C. 1344, 1348(c), 1352, 1354(a), 1355, 1421 through 1431, 1502,

1651(b)(2), 42 U.S.C.1857f-10, 4321 et seq.; E.O. 11514; and 49 U.S.C. 106(g).

The Proposed Special Conditions

Accordingly, the Federal Aviation Administration (FAA) proposes the following special conditions as part of the type certification basis for the Canadair Model CL-600-2B19 Regional Jet with Collins integrated avionics suite:

1. Lightning Protection

a. Each electrical and electronic system that performs critical functions must be designed and installed to ensure that the operation and operational capability of these systems to perform critical functions are not adversely affected when the airplane is exposed to lightning.

b. Each essential function of electrical or electronic systems or installation must be protected to ensure that the function can be recovered in a timely manner after the airplane has been exposed to lightning.

2. Protection from Unwanted Effects of High-Intensity Radiated Fields (HIRF)

Each electrical and electronic system that performs critical functions must be designed and installed to ensure that the operation and operational capability of these systems to perform critical functions are not adversely affected when the airplane is exposed to high-intensity radiated field external to the airplane.

3. The following definitions apply with respect to these special conditions:

Critical Functions. Functions whose failure would contribute to or cause a failure condition that would prevent the continued safe flight and landing of the airplane.

Essential Functions. Functions whose failure would contribute to or cause a failure condition that would significantly impact the safety of the airplane or the ability of the flightcrew to cope with adverse operating conditions.

Issued in Renton, Washington, on April 6, 1992.

Donald L. Riggin,

Acting Manager, Transport Airplane Directorate, Aircraft Certficate Service.

[FR Doc. 92-8674 Filed 4-14-92; 8:45 am]

BILLING CODE 4910-13-M

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14 CFR Parts 21 and 25

[Docket No. NM-68; Notice No. SC-92-2-NM]

Special Conditions: McDonnell Douglas Model MD-90 Series Airplanes; High Intensity Radiated Fields (HIRF) Protection

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed special conditions.

SUMMARY: This notice proposes a special condition for the McDonnell Douglas Model MD-90 series airplanes. These airplanes are equipped with high technology digital avionic systems which will perform critical functions. Examples of these systems are the Electronic Flight Instrument System (EFIS), Full Authority Digital Engine Control (FADEC), Inertial Reference System (IRS), and the Auxiliary Control System (ACS). The applicable regulations do not contain adequate or appropriate safety standards for the protection of these systems from the effects of High Intensity Radiated Fields (HIRF). This notice proposes an additional safety standard which the Administrator considers necessary to ensure that the critical functions that these systems perform are maintained when airplanes are exposed to HIRF.

DATES: Comments must be received on or before June 1, 1992.

ADDRESSES: Comments on this proposal may be mailed in duplicate to: Federal Aviation Administration, Office of the Assistant Chief Counsel, Attn: Rules Docket (ANM-7), Docket No. NM-68, 1601 Lind Avenue SW., Renton, Washington 98055-4056; or delivered in duplicate to the Office of the Assistant Chief Counsel at the above address. Comments must be marked: Docket No. NM-68. Comments may be inspected in the Rules Docket weekdays, except Federal holidays, between 7:30 a.m. and 4 p.m.

FOR FURTHER INFORMATION CONTACT: Gene Vandermolen, FAA Flight Test and Systems Branch, ANM-111, Transport Airplane Directorate, Aircraft Ceratificatioin Service, 1601 Lind Avenue SW., Renton, WA 98055-4056; telephone (206) 227-2135.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the proposed special conditions by submitting such written data, views, or arguments as they may desire. Communications should identify the regulatory docket or notice number and be submitted in duplicate to the address specified above. All communications received on or before the closing date for comments will be considered by the Administrator before taking action on this proposal. The proposal contained in this notice may be changed in light of comments received. All comments submitted will be available in the Rules Docket for examination by interested persons, both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerning this rulemaking will be filed in the docket. Persons wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket No. NM-68." The postcard will be date stamped and returned to the commenter.

Background

On December 6, 1989, McDonnell Douglas applied for an amendment to Type Certificate No. A6WE to include the new Model MD-90. The Model MD-90 is a re-engine derivative of the currently certified Model MD;80. It will be powered by two high bypass turbofan International Aero Engines (IAE) V2500 series engines. The fuel, hydraulic, environmental, pneumatic, anti-ice and electrical systems will be modified as necessary for compatibility with the V2500 engines. This airplane incorporates a number of novel or unusual design features, such as digital avionics including, but not necessarily limited to, EFIS, FADES, IRS, ACS, etc. The ACS, which is specifically designed for the MD-90, will provide automatic servo-control and monitoring functions related to the elevator, rudder, and horizontal stabilizer.

Proposed Type Certification Basis

If the Administrator finds that the applicable airworthiness regulations (i.e. Part 25, as amended) do not contain adequate or appropriate safety standards because of a novel or unusual design feature, special conditions are prescribed under the provisions of § 21.16 to establish a level of safety equivalent to that established in the regulations. Special conditions, as appropriate, are issued in accordance with § 11.49 of the FAR after Public Notice as required by § 11.28 and 11.29, and become part become part of the type certification basis in accordance with § 21.17(a)(2). The FAA has determined that the Model MD-90 series does include novel or unusual design features for which the additional special conditions proposed in this notice are warranted.

In addition to the special conditions that may be adopted as a result of this notice, the type certification basis proposed under the provisions of § 21.101 of the FAR for the Model MD-90 includes:

1. Part 25 of the FAR as amended by Amendment 25-70, except for § 25.1309 as amended by Amendment 25-22 (or 25-41 for certain specified equipment and equipment installations), and certain other exceptions that are not

relevant to the special conditions proposed in this notice.

2. Existing Special Condition No. 25–ANM–15, dated October 19, 1987, "Lightning Protection for New Electronic Systems," and other special conditions and an exemption that are not relevant to the special conditions proposed in this notice.

3. The emission and noise standards of parts 34 and 36 of the FAR, respectively.

Discussion

Airplane designs which utilize metal skins and mechanical means to command and control the airplane and engines have traditionally been shown to be immune to the effects of HIRF from ground based transmitters. With the trend toward increased HIRF levels from these sources, plus the advent of space and satellite communications, coupled with digital electronic command and control of the airplane systems, the airplane's immunity to HIRF is in question.

The MD–90 is being designed and built with EFIS displaying airplane attitude information, the propulsion systems using FADEC, and the IRS outputs interfacing with a number of different systems. These systems can be susceptible to disruption of both the command/response signals and the operational mode logic as a result of HIRF interference. To ensure that a level of safety is achieved equivalent to that of existing airplanes, a special condition is being proposed which requires that the components providing critical functions be designed and installed to preclude component damage and interruption of function due to HIRF.

It is not possible to precisely define the HIRF environment to which the airplane will be exposed in service. There is also uncertainty concerning the effectiveness of airframe shielding for HIRF. Furthermore, coupling to cockpit installed equipment through the cockpit window apertures is undefined. Based on surveys and analysis of existing HIRF emitters, an adequate level of protection exists when compliance with the HIRF protection special condition is shown with either paragraphs 1 or 2 below:

1. A minimum threat of 100 volts per meter peak electric field strength from 10KHz to 18GHz.

a. The threat must be applied to the system elements and their associated wiring harnesses without the benefit of airframe shielding.

b. Demonstration of this level of protection is established through system test and anlaysis.

2. A threat external to the airframe of the following field strengths for the frequency ranges indicated.

Frequency	Peak (V/M)	Average (V/M)
10 KHz–500 KHz	60	60
500 KHz–2 MHz	80	80
2 MHz–30 MHz	200	200
30 MHz–100 MHz	33	33
100 MHz–200 MHz	150	33
200 MHz–400 MHz	56	33
400 MHz–1 GHz	4,020	935
1 GHz–2 GHz	7,850	1,750
2 GHz–4 GHz	6,000	1,150
4 GHz–6 GHz	6,800	310
6 GHz–8 GHz	3,600	666
8 GHz–12 GHz	5,100	1,270
12 GHz–18 GHz	3,500	551
18 GHz–40 GHz	2,400	750

The envelope given in Paragraph 2 above is a revision to the envelope used in previously issued special conditions in other certification projects. It is based on new data and SAE AE4R Subcommittee recommendations. This revised envelope includes data from Western Europe and the U.S.

Conclusion

This action affects only certain unusual or novel design features on one model series of airplanes. It is not a rule of general applicability and affects only the manufacturer who applied to the FAA for approval of these features on the airplane.

List of Subjects in 14 CFR Parts 21 and 25

Air transportation, Aircraft, Aviation safety, Safety.

The authority citation for these special conditions is as follows:

Authority: 49 U.S.C. 1344, 1348(c), 1352, 1354(a), 1355, 1421 through 1431, 1502, 1651(b)(2), 42 U.S.C. 1857f–10, 4321 et seq.; E.O. 11514; 49 U.S.C. 106(g) (Revised Pub. L. 97–449, January 12, 1983).

The Proposed Special Conditions

Accordingly, the Federal Aviation Administration (FAA) proposes the following special condition as part of the type certification basis for the McDonnell Douglas Model MD–90 series airplanes:

Protection from Unwanted Effects of High Intensity Radiated Fields (HIRF)

Each new or significantly modified electrical and electronic system which performs critical functions must be designed and installed to ensure that the operation and operational capability of these systems to perform critical functions are not adversely affected when the airplane is exposed to High Intensity Radiated Fields.

The following definition applies to this special condition: *Critical Functions.* Functions whose failure would contribute to or cause a failure condition that would prevent the continued safe flight and landing of the airplane.

Issued in Renton, Washington, on April 6, 1992.

Donald L. Riggin,

Acting Manager, Transport Airplane Directorate, Aircraft Certificaiton Service, ANM–100.

[FR Doc. 92–8672 Filed 4–14–92; 8:45 am]

BILLING CODE 4910–13–M

14 CFR Part 39

[Docket No. 92–CE–16–AD]

Airworthiness Directives, Cessna Model 441 Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This notice proposes to adopt a new airworthiness directive (AD) that would be applicable to certain Cessna Model 441 airplanes. The proposed action would require repetitive inspections of the horizontal stabilizer forward attach bulkhead for cracks until the installation of reinforcement modification; and replacement of the bulkhead and installation of this reinforcement modification if found cracked. The Federal Aviation Administration (FAA) has received reports of several Cessna Model 441 airplanes developing cracks in the horizontal stabilizer forward attach bulkhead at Fuselage Station (FS) 387.22. The actions specified by the proposed AD are intended to prevent loss of horizontal stabilizer front spar structural support caused by cracks in the fuselage bulkhead.

DATES: Comments must be received on or before June 19, 1992.

ADDRESSES: Submit comments in triplicate to the FAA, Central Region, Office of the Assistant Chief Counsel, Attention: Rules Docket No. 92–CE–16–AD, room 1558, 601 E. 12th Street, Kansas City, Missouri 64106. Comments may be inspected at this location between 8 a.m. and 4 p.m., Monday through Friday, holidays excepted.

Service information that is applicable to this AD may be obtained from the Cessna Aircraft Company, P.O. Box 7704, Wichita, Kansas 67277. This information also may be examined at the Rules Docket at the address above.

FOR FURTHER INFORMATION CONTACT: Mr. Larry Abbott, Aerospace Engineer, FAA, Wichita Aircraft Certification Office, 1801 Airport Road, room 100, Mid-Continent Airport, Wichita, Kansas:

Telephone (316) 946–4120; Facsimile (316) 946–4407.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications should identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this 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 that summarizes 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 No. 92–CE–16–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, Central Region, Office of the Assistant Chief Counsel, Attention: Rules Docket No. 92–CE–16–AD, Room 1558, 601 E. 12th Street, Kansas City, Missouri 64106.

Discussion

The FAA has received reports of several Cessna Model 441 airplanes developing cracks in the horizontal stabilizer forward attach bulkhead at Fuselage Station (FS) 387.22. If not detected and corrected, this condition could result in loss of horizontal stabilizer front spar structural support.

Cessna has issued Service Bulletin (SB) CQB91–1, Revision 1, and Attachment to SB CQB91–1R11, both dated June 21, 1991. This service information specifies criteria and procedures for inspecting the horizontal stabilizer forward attach bulkhead at FS 387.22 on Cessna Model 441 airplanes.

After examining the circumstances and reviewing all available information related to the incidents described above, the FAA has determined that AD action should be taken to prevent loss of horizontal stabilizer front spar structural support caused by cracks in the fuselage bulkhead.

Since the condition described is likely to exist or develop in other Cessna Model 441 airplanes of the same type design, the proposed AD would require repetitive inspections of the horizontal stabilizer forward attach bulkhead for cracks until installation of a reinforcement modification; and replacement of the bulkhead and installation of this reinforcement modification if found cracked. The actions would be done in accordance with the ACCOMPLISHMENT INSTRUCTIONS in Cessna Attachment to SB CQB91–1R1, dated June 21, 1991.

The FAA estimates that 362 airplanes in the U.S. registry would be affected by the proposed AD, that it would take approximately 34 hours per airplane to accomplish the proposed inspections, and that the average labor rate is approximately $55 an hour. Based on these figures, the total cost impact of the proposed AD on U.S. operators is estimated to be $676,940.

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 action (1) is not a "major rule" under Executive Order 12291; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the draft regulatory evaluation prepared for this action has been placed in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption "**ADDRESSES**".

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

Authority: 49 U.S.C. 1354(a), 1421 and 1423; 49 U.S.C. 106(g); and 14 CFR 11.89.

§ 39.13 [Amended]

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

Cessna: Docket No. 92–CE–16–AD.

Applicability: Model 441 airplanes (serial numbers 441–0001 through 441–0362), certificated in any category.

Compliance: Required initially upon the accumulation of 3,000 hours time-in-service (TIS) or within the next 200 hours after the effective date of this AD, whichever occurs later, and thereafter at intervals not to exceed 2,000 hours TIS, unless already accomplished.

To prevent loss of horizontal stabilizer front spar structural support caused by cracks in the fuselage bulkhead, accomplish the following:

(a) Gain access to and dye penetrant inspect the horizontal stabilizer forward attach bulkhead at Fuselage Station (FS) 387.22 in accordance with the ACCOMPLISHMENT INSTRUCTIONS section of Cessna Attachment to Service Bulletin (SB) CQB91–1R1, dated June 21, 1991.

(b) If cracks are found as a result of the inspection required by paragraph (a) of this AD, prior to further flight, replace the horizontal stabilizer forward attach bulkhead at FS 387.22 and install Service Kit SK 441–103A in accordance with the ACCOMPLISHMENT INSTRUCTIONS section of Cessna Service Kit SK441–103A, dated June 21, 1991.

(c) The installation of Service Kit SK 441–103A in accordance with the ACCOMPLISHMENT INSTRUCTIONS section of Cessna Service Kit SK441–103A, dated June 21, 1991, is considered terminating action for the inspection requirements of this AD. Although not required, this installation may be accomplished at any time after the initial inspection.

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

(e) An alternative method of compliance or adjustment of the compliance times that provides an equivalent level of safety may be approved by the Manager, Wichita Aircraft Certification Office, FAA, 1801 Airport Road, Mid-Continent Airport, Wichita, Kansas 67209. The request should be forwarded through an appropriate FAA Maintenance Inspector, who may add comments and then

send it to the Manager, Wichita Aircraft Certification Office.

Note: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Wichita Aircraft Certification Office.

(f) All persons affected by this directive may obtain copies of the document referred to herein upon request to the Cessna Aircraft Company, P.O. Box 7704, Wichita, Kansas 67277; or may examine this document at the FAA, Central Region, Office of the Assistant Chief Counsel, room 1558, 601 E. 12th Street, Kansas City, Missouri 64106.

Issued in Kansas City, Missouri, on April 9, 1992.

Barry D. Clements,

Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 92-8656 Filed 4-14-92; 8:45 am]

BILLING CODE 4910-13-M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Part 101

[Docket No. RM88-22-000]

Accounting for Phase-In Plans

Issued: April 9, 1992.

AGENCY: Federal Energy Regulatory Commission.

ACTION: Termination order; notice of inquiry.

SUMMARY: The Federal Energy Regulatory Commission (Commission) is terminating a Notice of Inquiry docket that it instituted by Notice of Inquiry issued on June 27, 1988, in Docket No. RM88-22-000, 53 FR 24096 (June 27, 1988). The purpose of the Notice of Inquiry was principally to elicit discussions regarding Statement of Financial Accounting Standards No. 92, "Regulated Enterprises—Accounting for Phase-in Plans" (FASB No. 92) issued by the Financial Accounting Standards Board. FASB No. 92 sets forth certain criteria that a public utility must meet in order to capitalize in its publicly circulated financial statements costs associated with constructing a new plant when a regulatory commission has adopted a phase-in plan.

Given that the comments that the Commission received reflect neither a consensus favoring a rulemaking regarding the issues that FASB No. 92 raises, nor any clear indication of what direction the Commission should take in formulating proposed rules, the Commission has elected not to go forward with a rulemaking and to terminate the notice of inquiry.

DATES: This termination order was effective April 9, 1992.

FOR FURTHER INFORMATION CONTACT: Joseph C. Lynch, Federal Energy Regulatory Commission, Office of the General Counsel, 825 North Capitol Street, NE., Washington, DC 20426, (202) 208-2128.

SUPPLEMENTARY INFORMATION: In addition to publishing the full text of this document in the **Federal Register**, the Commission also provides all interested persons an opportunity to inspect or copy the contents of this document during normal business hours in room 3308, at the Commission's Headquarters, 941 North Capitol Street, NE., Washington, DC 20426. The Commission Issuance Posting System (CIPS), an electronic bulletin board service, provides access to the texts of formal documents issued by the Commission. CIPS is available at no charge to the user and may be assessed using a personal computer with a modem by dialing (202) 208-1397. To access CIPS, set your communications software to use 300, 1200 or 2400 baud, full duplex, no parity, 8 data bits and 1 stop bit. The full text of this termination order will be available on CIPS for 10 days from the date of issuance. The complete text on diskette in WordPerfect format may also be purchased from the Commission's copy contractor, La Dorn Systems Corporation, also located in room 3308, 941 North Capitol Street, NE., Washington, DC 20426.

Before Commissioners: Martin L. Allday, Chairman; Charles A. Trabandt, Elizabeth Anne Moler, Jerry J. Langdon and Branko Terzic.

I. Background

On June 21, 1988, the Federal Energy Regulatory Commission (Commission) issued a Notice of Inquiry into the interrelationship between the Commission's accounting authority over regulatory reports and the Securities and Exchange Commission's (SEC) authority over issuance of financial statements.[1] The Commission was concerned, in particular, with the Financial Accounting Standards Board's Statement of Financial Accounting Standards No. 92, "Regulated Enterprises—Accounting for Phase-In Plans" (FASB No. 92).[2] FASB No. 92 set forth criteria that a public utility must meet to capitalize [3] plant-related costs when recovery of those costs is deferred for ratemaking purposes to periods beyond the period that they would be charged to expense under Generally Accepted Accounting Principles (GAAP).[4]

FASB No. 92 provides for different accounting for plants that a public utility either substantially constructed or completed on or before January 1, 1988 and plants constructed subsequently. FASB No. 92 requires that, for older plants, where a regulatory body defers recovery of the costs of these plants, a utility must recover all deferred costs within ten years of the date that cost deferrals begin. FASB No. 92 also requires that rates may not increase disproportionately from year to year during the phase-in period. [5] FASB No.

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[1] Under section 301 of the Federal Power Act (FPA), 16 U.S.C. 825 (1988), the Commission has authority to prescribe the manner in which licensees and public utilities are to maintain their accounts and records for regulatory reporting purposes. The Commission's authority over the accounts of the companies under its jurisdiction extends to the entire business of these companies and promotes the uniform accounting that is essential to the Commission's regulation of the electric utility industry. See, *e.g.*, S. Rep. No. 621, 74th Cong., 1st Sess. 53 (1935); *accord, e.g.*, Accounting Release No. AR-14, 58 FERC ¶ 61,166 at _____ & n.32, *slip op.* at 9 & n.32 (1992); Unison Transformer Services, Inc., 48 FERC ¶ 61,327 at 62,076 n.6 (1989); Florida Power Corporation, 34 FERC ¶ 61,227 at 61,393-94 (1986); *cf. Schneidewind, et al.* v. *ANR Pipeline Co., et al.*, 485 U.S. 293, 304 (1988); see also 15 U.S.C. § 79t(b) (1988).

The SEC has statutory authority to establish financial accounting and reporting standards for publicly held companies under the Securities and Exchange Act of 1934. Since 1973, the SEC has recognized the Financial Accounting Standards Board (FASB) as the designated organization in the private sector responsible for establishing financial accounting and reporting standards. SEC Accounting Series Release No. 150 (December 20, 1973).

FASB's mission is to establish and improve standards of financial accounting and reporting for the guidance and education of the public, including issuers, auditors, and users of financial information. Those standards govern the preparation of financial reports. Both the SEC and the American Institute of Certified Public Accountants (in its Code of Professional Conduct, adopted January 12, 1988) recognize FASB's pronouncements as authoritative.

[2] Financial Accounting Standards Board, Statement of Financial Accounting Standards No. 92, Regulated Enterprises Accounting for Phase-in Plans, in Accounting Standards—Original Pronouncements (1991).

[3] "Capitalize" means that the utility would record the cost as an asset.

[4] GAAP is a technical term in financial accounting. GAAP encompasses the conventions, rules and procedures necessary to define accepted accounting practices at a particular time. GAAP incorporates the accounting profession's current consensus as to which economic resources and obligations a business enterprise should record as assets and liabilities, which changes in assets and liabilities it should record and when it should record them, how a business enterprise should measure assets and liabilities, when the enterprise should prepare financial statements and what information those statements should contain.

[5] *I.e.*, The percentage increase in rates scheduled under the phase-in plan for each future year can be no greater than the percentage increase in rates scheduled under the plan for each immediately preceding year.

92 provides that, unless a utility conforms to the criteria of FASB No. 92, the utility must reflect the deferred costs as a loss in the current year.

For newer construction, FASB No. 92 provides that, where substantial plant construction has not occurred before January 1, 1988, a utility may not reflect phase-in plant cost recovery for such plants in its financial reports regardless of the length of the phase-in.

In its Notice of Inquiry,[6] the Commission noted that phase-in plans are a way of allocating over time the cost of providing service in a manner consistent with regulatory objectives and with the public interest. A phase-in plan recognizes expenses differently in particular periods than would GAAP. A phase-in plan does not disallow rate recognition of costs; it merely provides for recovery of those costs in a later period. Where deferred cost recovery is probable, the deferred costs are regulatory-created assets that the utility should show on the balance sheets that it files with the Commission.

The Commission observed that the SEC and this Commission are in some instances viewing differently how utilities should prepare financial statements.[7] The SEC has decided to follow FASB No. 92. This Commission has determined that a utility's books and records should reflect the economic effects of regulation,[8] even if that means that the books and records that the utility files with the Commission do not always conform to FASB No. 92.

The Commission solicited comments on the proper recognition in utilities' financial statements and books of accounts of costs that would be treated differently by FASB and the SEC, on the one hand, and by this Commission, on the other hand—and particularly the costs associated with the construction of new plants.

The Notice of Inquiry was published in the **Federal Register**,[9] with comments originally due on or before August 22, 1988. Subsequently, the Commission extended the date for the filing of comments to August 31, 1988, and then to September 7, 1988.

[6] Accounting for Phase-In Plans—Notice of Inquiry, 53 FR 20496 (published June 27, 1988); IV FERC Statutes and Regulations ¶ 35,521 (issued June 21, 1988).

[7] Compare Arkansas Power & Light Company, 41 FERC ¶ 61,034 (1987) and Kansas Gas and Electric Company, 43 FERC ¶ 61,248 (1988) with IV FERC Statutes and Regulations at 35,669 & n.16 (citing letter from SEC to Arkansas Power and Light Company and Middle South Utilities, Inc., dated May 20, 1988).

[8] *E.G.*, 41 FERC at 61,084.

[9] 53 FR 20496 (1988).

II. Comments Received

The Commission received 70 comments. The comments reflect neither a clear consensus for a rulemaking nor any agreement on what rules the Commission should adopt if it elected to embark upon a rulemaking. Nor did the commentors agree in their answers to the questions that the Commission posed in its Notice of Inquiry. Rather, the commentors' responses to the questions reflected their view of whether or not the Commission should begin a rulemaking. For example, those who favored a rulemaking thought that FASB No. 92 would increase the cost of capital for regulated utilities while those who opposed a rulemaking perceived no effect on utilities' cost of capital.

Several commentors support a rulemaking that would reject FASB No. 92 for regulatory accounting or ratemaking purposes.[10] They argue that FASB No. 92 ignores the economics of the ratemaking process and fails to recognize the sudden rate effect of adding a major generating facility to rate base. These commentors also vigorously criticize FASB No. 92's 10-year limitation on the phase-in of deferred plant construction costs. Other commentors oppose a rulemaking. They submit that FASB's standards, although not perfect, generally reflect the economics of the ratemaking process and should remain the basis for utility external financial reporting.[11]

Still others who submitted comments, though clearly unhappy with FASB No. 92, do not, for a variety of reasons, think that the Commission should commence a rulemaking on the subject. Most of this latter group favor closer cooperation between the Commission and FASB to work out problems in general financial and regulatory reporting accounting.[12]

[10] Among those holding this view are Allegheny Electric Cooperative, Inc., Connecticut Municipal Electric Energy Cooperative, Florida Public Service Commission, North Carolina Utilities Commission, Ohio Public Utilities Commission (Ohio Commission), and Oklahoma Municipal Power Authority (OMPA). The Ohio Commission and OMPA propose that the Commission require utilities to reflect in their published financial statements those phase-in plans that do not comply with the requirements of FASB No. 92.

[11] Among those holding this view are American Gas Association, Arthur Anderson & Company, Columbia Gas System, Duke Power Company, Edison Electric Institute, General Accounting Office, Georgia Power Company, Rochester Gas & Electric Corporation and Virginia Electric and Power Company.

[12] Among those holding this view are Arkansas Power & Light Company, Florida Power and Light Company, Indiana Utility Regulatory Commission, New York State Electric & Gas Corporation, Philadelphia Electric Company, Technical Advisory Committee—G&T Managers Association, Commonwealth of Virginia and Washington Gas Light Company.

Other commentors, though critical of FASB No. 92 and supporting a rulemaking, have no recommendation on the content of the rules that the Commission might consider adopting.[13]

III. Conclusion

One of the principal purposes underlying the Notice of Inquiry was an effort to determine whether those involved with the industries subject to Commission regulation believed that a rulemaking was warranted, and what rules should be proposed. Our review of the comments received indicates that there is neither a consensus favoring a rulemaking concerning the issues that FASB No. 92 raises, nor any clear indication of what direction the Commission should take in formulating proposed rules. Moreover, the Commission had not determined whether to embark upon a rulemaking when it issued the Notice of Inquiry, and, based upon a review of the comments, presently sees no need to embark upon such a rulemaking. In addition, as Price Waterhouse has observed, regardless of FASB's requirements with respect to general purpose financial statements, the Commission has authority to obtain the data necessary to regulate public utilities.[14] In this regard, the Commission also notes that public utilities presently must still report to the Commission according to its Uniform System of Accounts, and that these reports are public documents. Accordingly, the Commission has decided not to go forward with a rulemaking and to terminate this Notice of Inquiry.

With respect to those commentors who urge the Commission to adopt FASB No. 92 or GAAP, we disagree. As Florida Power & Light Company notes, a utility that does not recognize an approved phase-in plan for general financial purposes would, if the Commission were to adopt FASB No. 92, appear to have an extraordinarily low return on investment in the early years of recovery under its plan and an extraordinarily high return on investment during the later years of the plan.[15] The failure to recognize an

[13] Among this group are Missouri Public Service Commission, National Association of Regulatory Utility Commissioners, and New Mexico Public Service Commission.

[14] Price Waterhouse Comments at 3.

[15] This is so because FASB No. 92 requires utilities to expense currently the costs of a capitalized phase-in plan that extends beyond ten years or otherwise fails to meet the FASB No. 92 criteria. When the utility recognizes this expense on its financial statement, it has no current matching

Continued

approved phase-in plan for general financial reporting purposes, if the Commission were to adopt FASB No. 92, could also, as the Indiana Utility Regulatory Commission notes, result in a utility showing an operating loss that has occurred and is not expected to occur.[16]

Moreover, FASB No. 92 requires disclosure in general financial statements of all phase-in plans, including those not qualifying for deferral of costs under FASB No. 92. The required disclosures for plans that do not qualify under FASB No. 92 include: (a) The terms of the plan; (b) the net amount deferred for ratemaking purposes at the balance sheet date; and (c) the net change in deferred amounts for ratemking purposes during the period.[17] Readers of utilities' general purpose financial statements thus will know of phase-in plans even if such plans do not qualify for balance sheet recognition. If they wish further information about these plans, beyond what is contained in these general purpose financial statements, they may consult the reports and other filings that the utilities file with the Commission.

California Federal (a holding company engaged in the savings and loan business), Edison Electric Institute, New England Power Company and several others who submitted comments also suggest that the Commission conform the Uniform System of Accounts to GAAP, as FASB interprets them. The Commission rejects this suggestion. In the Commission's view, as discussed above, FASB No. 92 does not reflect the economics of ratemaking.[18]

IV. Summary

As discussed above, the Commission has decided not to go forward with a rulemaking and to terminate this Notice of Inquiry. In addition, because FASB No. 92 does not reflect the economics of ratemaking, the Commission rejects the suggestion that it adopt GASB No 92 as part of the Uniform System of Accounts. Likewise, for similar reasons, the Commission rejects the suggestion that it conform the Uniform System of Accounts to GAAP in instances where GAAP does not permit proper recognition of the economic effects of ratemaking actions.

It is Ordered: Docket No. RM88–22–000 is hereby terminated.

By the Commission.

Lois D. Cashell,

Secretary.

[FR Doc. 92–8686 Filed 4–14–92; 8:45 am]

BILLING CODE 6717–01–M

revenue. The recognition of an expense when there is no current matching revenue results in a decrease in net income.

When the revenue accrues to the utility in later years, the utility has no off-setting expense. The recognition of revenue when there is no off-setting expense results in an increase in net income. See Florida Power and Light Company Comments at 1; see also Technical Advisory Committee—G&T Managers Association Comments at 2–3.

[16] Indiana Utility Regulatory Commission Comments at 5.

[17] FASB No. 92, ¶ 11 and ¶ 12; *see* Virginia Electric and Power Company Comments at 4; Georgia Power Company Comments at 4.

[18] See supra notes 15 and 16 and accompanying test.

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[FI–66–89]

RIN 1545–A014

Allocation and Accounting Rules on Tax Exempt Bonds for Arbitrage Rebate Purposes; Correction

AGENCY: Internal Revenue Service, Treasury.

ACTION: Correction to notice of proposed rulemaking.

SUMMARY: This document contains corrections to the notice of proposed rulemaking (FI–66–89), which was published on Thursday, January 30, 1992, (57 FR 3562). The proposed regulations relate to arbitrage rebate requirements applicable to tax exempt bonds issued by State and local governments.

FOR FURTHER INFORMATION CONTACT: William P. Cejudo, (202–566–3283, not a toll free call).

SUPPLEMENTARY INFORMATION:

Background

The notice of proposed rulemaking that is the subject of these corrections proposes to amend the Income Tax Regulations (26 CFR part 1) to provide general allocation and accounting rules for arbitrage rebate purposes.

Need for Correction

As published, the proposed regulations contain errors which may prove to be misleading and are in need of clarification.

Correction of Publication

Accordingly, the publication of the proposed regulations (FI–66–89), which was the subject of FR Doc. 92–1943, is corrected as follows:

§ 1.148–4 [Corrected]

Paragraph 1. On page 3568, column 3, under § 1.148–4(d)(3)(ii), the paragraph designation "(c)" is corrected to read "(C)".

Par. 2. On page 3570, column 2, under 1.484–4(e)(6)(ii), the paragraph designation "(c)" is corrected to reach "(C)".

Par. 3. On page 3570, column 3, under § 1.484–4(e)(7)(ii), line 8, the language "make allocations on each date that it" is corrected to read "make necessary allocations on each date that it".

Cynthia E. Grigsby,

Alternate Federal Register Liaison Officer, Assistant Chief Counsel (Corporate).

[FR Doc. 92–8568 Filed 4–14–92; 8:45 am]

BILLING CODE 4830–01–M

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26 CFR Part 1

[FI–90–91]

RIN 1545–AQ19

Transferred Proceeds Allocations and Other Arbitrage Restrictions on Refunding Issues; Correction

AGENCY: Internal Revenue Service, Treasury

ACTION: Correction to notice of proposed rulemaking.

SUMMARY: This document contains corrections to the notice of proposed rulemaking (FI–90–91), which was published on Wednesday, February 12, 1992, (57 FR 5101). The proposed regulations relate to arbitrage restrictions applicable to tax exempt bonds issued by State and local governments.

FOR FURTHER INFORMATION CONTACT: William P. Cejudo, (202–566–3283, not a toll free call).

SUPPLEMENTARY INFORMATION:

Background

The notice of proposed rulemaking that is the subject of these corrections proposes to amend the Income Tax Regulations (26 CFR part 1) to provide guidance on allocations of transferred proceeds and other restrictions on refunding issues for purposes of arbitrage yield restrictions under section 148, the arbitrage rebate requirement under section 148(f), and the advance refunding limitations under section 149(d) of the Internal Revenue Code.

Need for Correction

As published, the proposed regulations contain errors which may prove to be misleading and are in need of clarification.

Correction of Publication

Accordingly, the publication of the proposed regulations (FI–90–91), which was the subject of FR Doc. 92–3162, is corrected as follows:

Paragraph 1. On page 5101, column 3, in the preample, under the heading "2. 1989 Temporary Regulations", the first full paragraph, line 8, the language "Section 1.484–T(e) of the 1989" is corrected to read "Section 1.148–4T(e) of the 1989".

Par. 2. On page 5102, column 3, in the preamble, the heading "E. Other Special Allegation Rules for Refundings", is corrected to read "E. Other Special Allocation Rules for Refundings".

Par. 3. On page 5104, column 2, in the authority citation for part 1, line 3, the language "1.148–9 also issued under 26 U.S.C. 148(f) and" is corrected to read "1.148–9 also issued under 26 U.S.C. 148(f) and (b)".

§ 1.148–8 [Corrected]

Par. 4. On page 5105, column 2, in § 1.148–8(f)(2)(i), line 3, the language "as in § 2.148–11(b)(1)." is corrected to read "as in § 1.148–11(b)(1).".

§ 1.148–11 [Corrected]

Par. 5. On page 5106, column 3, in § 1.148–11(b)(3), line 1, the language "*Current refunding issue.* "Advance", is corrected to read "(3) *Current refunding issue.* "Current".

Par. 6. On page 5108, column 2, in § 1.148–11(e)(3), paragraph (ii), *Example,* line 11, the language "pay the 1995 issue at maturity. On January 1," is corrected to read "pay the 1985 issue at maturity. On January 1".

Par. 7. On page 5109, column 2, in § 1.148–11(j)(1), line 6, the language "purposes of the multipurpose issue." is corrected to read "purpose of an issue.".

Par. 8. On page 5110, column 2, in § 1.148–11(k)(2), line 6, the language "refunding purposes of a multipurpose" is corrected to read "refunding purposes of an".

Par. 9. On page 5110, column 2, in § 1.148–11(k)(2), line 20, the language "specified in § 1.148–8T(h)(i) (i) and (ii)." is corrected to read "specified in § 1.148–8T(h)(1)(i) and (ii).".

Cynthia E. Grigsby

Alternate Federal Register Liaison Officer Assistant Chief Counsel (Corporate).

[FR Doc. 92–8570 Filed 4–14–92; 8:45 am]

BILLING CODE 4830–01–M

26 CFR Parts 40 and 49

[PS–27–91]

RIN 1545–AQ04

Special Rules for Use of Government Depositaries Under Chapter 33; Hearing Cancellation

AGENCY: Internal Revenue Service, Treasury.

ACTION: Cancellation of notice of public hearing on proposed regulatons.

SUMMARY: This document provides notice of cancellation of a public hearing on proposed Income Tax Regulations relating to deposits of excise taxes imposed on communications services and air transportation.

DATES: The public hearing originally scheduled for Tuesday, April 28, 1992, beginning at 10 a.m. is cancelled.

FOR FURTHER INFORMATION CONTACT: Bob Boyer of the Regulations Unit, Assistant Chief Counsel (Corporate), 202–377–9231, (not a toll-free number).

SUPPLEMENTARY INFORMATION: The subject of the public hearing is proposed regulations that amend temporary and proposed regulations (T.D. 8328) relating to requirements for returns, payments, and deposits of tax for excise taxes currently reportable on Form 720. The proposed regulations amend the proposed regulations by adding special deposit rules for chapter 33 taxes. A notice appearing in the **Federal Register** for Friday, January 31, 1992 (57 FR 3734), announced that the public hearing on the proposed regulations would be held on Tuesday, April 28, 1992, beginning at 10 a.m. in the IRS Commissioner's Conference Room, room 3313, Internal Revenue Building, 1111 Constitution Avenue, NW., Washington, DC.

The public hearing scheduled for Tuesday, April 28, 1992, has been cancelled.

By direction of the Commissioner of Internal Revenue.

Cynthia E. Grigsby,

Alternate Federal Register Liaison Officer, Assistant Chief Counsel (Corporate).

[FR Doc. 92–8712 Filed 4–14–92; 8:45 am]

BILLING CODE 4830–01–M

PANAMA CANAL COMMISSION

35 CFR Part 133

RIN 3207–AA32

Tolls for Use of Canal

AGENCY: Panama Canal Commission.

ACTION: Advance notice of proposed rulemaking; request for comments; notice of hearing.

SUMMARY: The Panama Canal Commission proposes an increase of approximately 9.9% in the rates of tolls to become effective October 1, 1992. The basis for the toll increase is that the Commission anticipates that in fiscal years 1992 and 1993, it will experience, in the aggregate, a significant deficit created by a trend of nominal traffic and revenue growth inadequate to absorb cost increases due to inflation. The proposed increase is necessary to comply with the requirement that tolls be set to produce revenues sufficient to cover all costs of maintenance and operation of the Panama Canal, including capital for plant replacement, expansion and improvements and working capital.

This advance notice of proposed rulemaking announces the availability from the Commission of an analysis showing the basis and justification for the proposed change, solicits written data, views, or arguments from interested parties, and sets the time and place for the public hearing.

DATES: Written comments and requests to present oral testimony must be received on or before May 20, 1992; a public hearing will be held on June 4, 1992, Washington, DC at 9:30 a.m.

ADDRESSES: Comments and requests to testify at the hearing may be mailed to: Michael Rhode, Jr., Assistant to the Chairman and Secretary, Panama Canal Commission, 2000 L Street NW., suite 550, Washington, DC 20036–4996, (Telephone: (202) 634–6441); copies of the Commission's analysis showing the basis and justification for the proposed changes are available from the Commission (at the above address) or from the Office of Financial Management, Panama Canal Commission, Balboa Heights, Republic of Panama (Telephone: 011–507–52–3194).

The hearing will be held at The Grand Hotel, 2350 M Street, NW., Washington, DC 20037. Oral presentations should be limited to 20 minutes. Regulations governing the content of the notice of appearance or intention to present supplementary data at the hearing appear in 35 CFR 70.8 and 70.10.

FOR FURTHER INFORMATION CONTACT: Michael Rhode, Jr. at the above address, (telephone: (202) 634–6441).

SUPPLEMENTARY INFORMATION: Section 1602 (b) of the Panama Canal Act of 1979, as amended, 22 U.S.C. 3792(b), requires that Canal tolls be prescribed

at rates calculated to produce revenues to cover, as nearly as practicable, all costs of maintaining and operating the Panama Canal and the facilities and appurtenances related thereto, as well as to provide capital for plant replacement, expansion, and improvements and working capital. The rates of tolls for use of the Panama Canal were last increased on October 1, 1989 by 9.8%. The rates placed in effect at that time have proven adequate to provide, in the aggregate, sufficient revenues to cover all operating and capital costs of the Canal through 1991, but the Commission anticipates significant deficits in the aggregate during the next two fiscal years.

These deficits are the result of the continuing trend of traffic growth revenues inadequate to absorb cost increases due to inflation. Commission projections indicate that total operating expenses in fiscal year 1992 will exceed revenues by $4.2 million. In fiscal year 1993, at present toll rates, a cumulative deficiency of $37.6 million is projected. This growing imbalance between inflation and traffic growth underlies the clear need for placing a toll rate increase of 9.9%. The new rates will replace existing rates on October 1, 1992.

Section 1604 of the Panama Canal Act of 1979, as amended, 22 U.S.C. 3794, establishes the procedures that the Panama Canal Commission must follow in proposing a toll rate increase. Those procedures have been supplemented by regulations in 35 CFR part 70, which in addition, provide interested parties with instructions for participating in the process governing changes in the rates of tolls. The statute and regulations require this advance notice of proposed rulemaking in order for the Commission to announce the proposed change and afford interested parties an opportunity to submit written data, views or arguments and participate in the public hearing on June 4, 1992. A written analysis is also made available to the public showing the basis and justification for the change.

All pertinent data, views or arguments presented in writing, or orally at the hearing, will be considered, along with other relevant information, before the Commission publishes a notice of proposed rulemaking in the **Federal Register** and forwards a complete record and its final recommendation to the President of the United States. In considering the proposal, the President has the authority to approve, disapprove, or modify any recommendation of the Commission. The final rule, approved and published by the President, shall be effective no earlier than 30 days from the date of publication in the **Federal Register**.

This advance notice of proposed rulemaking does not constitute a "major rule" as defined in section 1(b) of Executive Order 12291, dated February 17, 1981. Analysis of the proposed toll increase indicates that it will not (1) Have an annual effect on the economy of $100 million or more; (2) cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions, or (3) have a significant adverse effect on competition, employment, investment, productivity, innovation, or on the ability of the United States-based enterprises to compete with foreign based enterprises in domestic or export markets.

A review of the environmental effect of the proposed increase in the rates of tolls concludes that the proposal is not a major federal action which will have a significant effect on the quality of the environment of a foreign nation; therefore, pursuant to Executive Order 12114, dated January 4, 1979, an environmental analysis is not required.

The Assistant to the Chairman and Secretary of the Panama Canal Commission has certified to the Office of Management and Budget that these proposed changes in regulations meet the applicable standards provided in sections 2(a) and (b)(2) of Executive Order No. 12778.

Finally, the Regulatory Flexibility Act is inapplicable, since this regulation is one relating to "rates" or "practices relating" thereto (5 U.S.C. 601 (2)).

List of Subjects in 35 CFR Part 133

Panama Canal, Vessels.

Accordingly, it is proposed that 35 CFR part 133 be amended as follows:

PART 133—TOLLS FOR USE OF CANAL

1. The authority citation for part 133 continues to read as follows:

Authority: Issued under authority of the President by 22 U.S.C. 3791; E.O. 12215, 45 FR 36043.

2. Section 133.1 is revised to read as follows:

§ 133.1 Rates of toll.

The following rates of toll shall be paid by vessels using the Panama Canal:

(a) On merchant vessels, yachts, army and navy transports, colliers, hospital ships, and supply ships, when carrying passengers or cargo, $2.21 per net vessel ton of 100 cubic feet each of actual earning capacity—that is, the net tonnage determined in accordance with part 135 of this chapter.

(b) On vessels in ballast without passengers or cargo, $1.76 per net vessel ton.

(c) On other floating craft including warships, other than transports, colliers, hospital ships, and supply ships, $1.23 per ton of displacement.

Dated: April 9, 1992.

Michael Rhode, Jr.,

Assistant to the Chairman and Secretary.

[FR Doc. 92-8690 Filed 4-14-92; 8:45 am]

BILLING CODE 3640-04-M

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 36

RIN 2900-AF67

Loan Guaranty: Lender Participation Fees-Lender Appraisal Processing Program

AGENCY: Department of Veterans Affairs.

ACTION: Proposed regulatory amendment.

SUMMARY: The Department of Veterans Affairs (VA) is proposing to amend its loan guaranty regulations (38 CFR part 36) by requiring lenders to pay a fee to participate in VA's Lender Appraisal Processing Program.

DATES: Comments must be received on or before May 15, 1992. Comments will be available for public inspection until May 26, 1992. VA proposes to make these regulations effective 30 days after publication of the final regulations.

ADDRESSES: Interested persons are invited to submit written comments, suggestions or objections regarding this proposal to the Secretary of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420. All written comments will be available for public inspection in room 170, Veterans Service Unit, at the above address between the hours of 8 a.m. and 4:30 p.m., Monday through Friday (except holidays) until May 26, 1992.

FOR FURTHER INFORMATION CONTACT: Ms. Judith Caden, Assistant Director for Loan Policy (264), Loan Guaranty Service, Veterans Benefits Administration, Department of Veterans Affairs, Washington, DC 20420, (202) 233-3024.

SUPPLEMENTARY INFORMATION: On May 22, 1990, VA published in the **Federal Register** (55 FR 21015) final regulations at 38 CFR 36.4344 implementing a Lender Appraisal Processing Program

(LAPP) and authorizing the Secretary to require the payment of fees by lenders participating in the program. LAPP allows lenders who have automatic processing authority under VA's Automatic Lending Program to also have a staff appraisal reviewer determine the reasonable value of properties to be purchased with VA-guaranteed loans. The qualifications of prospective staff appraisal reviewers must first be reviewed by, and found acceptable to, VA. To partially defray the expenses incurred in administering the Lender Appraisal Processing Program, VA is proposing to amend 38 CFR 36.4225 and 36.4348 to require the payment by participating lenders of a $100 fee for the approval of each staff appraisal reviewer.

The Secretary hereby certifies that the proposed regulatory amendments will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601–612. The fee VA will charge lenders is not a large amount and should have a minimal impact on small entities.

The Secretary has also determined that the proposed amendments are not a "major rule" within the meaning of Executive Order 12291, Federal Regulation. They will not have an annual effect on the economy of $100 million or more, and will not cause a major increase in costs or prices for consumers or individual industries, nor will they have other significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

The Catalog of Federal Domestic Assistance Program numbers are 64.114 and 64.119.

List of Subjects in 38 CFR Part 36

Condominiums, Handicapped, Housing Loan programs—housing and community development, Manufactured homes, Veterans.

This amendment is proposed under the authority granted the Secretary by sections 501(a), 3703(c)(1), and 3712(g) of title 38, United States Code.

Approved: February 20, 1992.

Edward J. Derwinski,

Secretary of Veterans Affairs.

For the reasons set out in the preamble, VA proposes to amend 38 CFR part 36 as set forth below:

PART 36—LOAN GUARANTY

1. The authority citation for part 36, §§ 36.4201 through 36.4287 continues to read as follows:

Authority: Sections 36.4201 through 36.4287 issued under 72 Stat. 1114, 84 Stat. 1110 (38 U.S.C. 501(a), 3712).

2. In § 36.4225, paragraph (f) is added to read as follows:

§ 36.4225 Authority to close manufactured home loans on automatic basis.

* * * * *

(f) Lenders participating in VA's Lender Appraisal Processing Program shall pay a fee of $100 for approval of each staff appraisal reviewer.

3. The authority citation for part 36, §§ 36.4300 through 36.4375 continues to read as follows:

Authority: Sections 36.4300 through 36.4375 issued under 72 Stat. 1114 (38 U.S.C. 501(a)).

4. In § 36.4348, paragraph (f) is added to read as follows:

§ 36.4348 Authority to close loans on the automatic basis.

* * * * *

(f) Lenders participating in VA's Lender Appraisal Processing Program shall pay a fee of $100 for approval of each staff appraisal reviewer.

[FR Doc. 92–8658 Filed 4–14–92; 8:45 am]
BILLING CODE 8320–01–M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300248; FRL–4055–4]

RIN 2070 AC–18

N,N-Bis 2-(Omega-Hdroxypolyoxyethylene/ Polyoxypropylene) Ethyl Alkylamine; Tolerance Exemption

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: This document proposes that an exemption from the requirement of a tolerance be established for residues of N,N-bis 2-(omega-hydroxypolyoxyethylene/ polyoxypropylene) ethyl alkylamine when used as an inert ingredient (surfactant) in pesticide formulations applied to growing crops only. This proposed regulation was requested by Akzo Chemicals, Inc.

DATES: Comments, identified by the document control number [OPP–36600248], must be received on or before May 15, 1992.

ADDRESSES: By mail, submit written comments to: Public Response and Program Resources Branch, Field Operations Division (H7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person deliver comments to: Rm. 1128, CM #2, 1921 Jefferson Davis Highway, Arlington, VA 22202. Information submitted as a comment concerning this document may be claimed confidential by marking any part of all of that information as "Confidential Business Information" (CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential will be included in the public docket by the EPA without prior notice. The public docket is available for public inspection in rm. 1128 at the address given above, from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: By mail: Connie Welch, Registration Support Branch, Registration Division (H7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 711I, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202, (703)-305-7252.

SUPPLEMENTARY INFORMATION: At the request of Akzo Chemicals, Inc., 300 South Riverside Plaza, Chicago, IL 60606, the Administrator, pursuant to section 408(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a(e)), proposes to amend 40 CFR 180.1001(d) by establishing an exemption from the requirement of a tolerance for residues of N,N-bis 2-(omega-hydroxypolyoxyethylene/ polyoxypropylene) ethyl alkylamine when used as an inert ingredient (surfactant) in pesticide formulations applied to growing crops only.

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol

dispensers; microencapsulating agents; and emulsifiers. The term "inert" is not intended to imply nontoxicity; the ingredient may or may not be chemically active.

The data submitted in the petition and other relevant material have been evaluated. As part of the EPA policy statement on inert ingredients published in the Federal Register of April 22, 1987 (52 FR 13305), the Agency established data requirements which will be used to evaluate the risks posed by the presence of an inert ingredient in a pesticide formulation. Exemptions from some or all of the requirements may be granted if it can be determined that the inert ingredient will present minimal or no risk. The Agency has decided that the data normally required to support the proposed tolerance exemption for N,N-bis 2-(omega-hydroxypolyoxyethylene/ polyoxypropylene) ethyl alkylamine will not need to be submitted. The rationale for this decision is described below.

1. This chemical is structurally similar to the following chemicals that are already exempt from the requirement of a tolerance when used in accordance with good agricultural practices as inert (or occasionally active) ingredients in pesticide formulations applied to growing crops only under 40 CFR 180.1001(d):

a. N,N-bis 2-(omega-hydroxypolyoxyethlene) ethyl alkylamine; the reaction product of 1 mole of N,N-bis(2-hydroxyethyl) alkylamine and 3 to 60 moles of ethylene oxide, where the alkyl group (C_8-C_{18}) is derived from coconut, cottonseed, soya, or tallow acids.

b. Alpha-alkyl (C_{12}-C_{18})-omega-hydroxypoly(oxyethylene) copolymers with poly(oxypropylene); polyoxyethylene content averages 3 to 12 moles, and polyoxypropylene content averages 2 to 9 moles.

c. Primary n-alkylamines, where the alkyl group (C_8-C_{18}) is derived from coconut, cottonseed, soya, or tallow acids.

2. This chemical is structurally similar to the chemical N,N-bis (2-hydroxyethyl alkylamine, where the alkyl groups (C_{14}-C_{18}) are derived from tallow, which is already cleared for use by the Food and Drug Administration as an antistatic agent in food packaging materials, subject to the provisions as specified in 21 CFR 178.3130.

3. No nitrosamines are present in N,N-bis 2-(omega-hydroxypolyoxyethylene/ polyoxypropylene) ethyl alkylamine at the analytical detection limit of 10 parts per billion.

4. The residual content of the monomers ethylene oxide and propylene oxide in N,N-bis 2-(omega-hydroxypolyoxyethylene/ polyoxypropylene) ethyl alkylamine is less than 1 part per million.

5. No additional ethylene oxide is formed upon degradation of N,N-bis 2-(omega-hydroxypolyoxyethylene/ polyoxypropylene) ethyl alkylamine.

Based upon the above information and review of its use, EPA has found that, when used in accordance with good agricultural practice, this ingredient is useful and does not pose a risk to human health or the environment. Therefore, EPA proposes that the exemption from the requirement of a tolerance be established as set forth below.

Any person who has registered or submitted an application for registration of a pesticide, under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as amended, which contains any of the ingredients listed herein, may request within 30 days after publication of this document in the Federal Register that this rulemaking proposal be referred to an Advisory Committee in accordance with section 408(e) of the Federal Food, Drug, and Cosmetic Act.

Interested persons are invited to submit written comments on the proposed regulation. Comments must bear a notation indicating the document control number, [OPP-300248]. All written comments filed in response to this petition will be available in the Public Response and Program Resources Branch, at the address given above from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays.

The Office of Management and Budget has exempted this rule from the requirements of section 3 of Executive Order 12291.

Pursuant to the requirements of the Regulatory Flexibility Act (Pub. L. 96-354, 94 Stat. 1164, 5 U.S.C. 601-612), the Administrator has determined that regulations establishing new tolerances or raising tolerance levels or establishing exemptions from tolerance requirements do not have a significant economic impact on a substantial number of small entities. A certification statement to this effect was published in the Federal Register of May 4, 1981 (46 FR 24950).

List of Subjects in 40 CFR Part 180

Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Recording and recordkeeping requirements.

Dated: March 30, 1992.

Anne E. Lindsay,

Director, Registration Division, Office of Pesticide Programs.

Therefore, it is proposed that 40 CFR part 180 be amended as follows:

PART 180—[AMENDED]

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

Authority: 21 U.S.C. 346a and 371.

2. In § 180.1001, paragraph (d) is amended in the table therein by adding and alphabetically inserting the inert ingredient, to read as follows:

§ 180.1001 Exemptions from the requirements of a tolerance.

* * * * *

(d) * * *

Inert ingredients	Limits	Uses
* *	* *	*
N,N-Bis 2-(omega-hydroxy polyoxyethylene/ polyoxypropylene ethyl alkylamine; the reaction product of 1 mole of N,N-bis(2-hydroxyethyl) alkylamine and 3-60 moles of ethylene oxide and propylene oxide, where the alkyl group (C_8-C_{18}) is derived from coconut, cottonseed, soya, or tallow acids.	Not more than 0.5% of pesticide formulation.	Surfactant
* *	* *	*

* * * * *

[FR Doc. 92-8734 Filed 4-14-92; 8:45 am]
BILLING CODE 6560-50-F

40 CFR Part 180

[PP7E3489/P503; FRL-3689-6]

RIN 2070-AC18

Pesticide Tolerance for 4-(Dichloroacetyl)-3,4-Dihydro-3-Methyl-2H-1,4-Benzoxazine

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: This document proposes that a tolerance be established for residues of 4-(dichloroacetyl)-3,4-dihydro-3-methyl-2H-1,4-benzoxazine when used as an inert ingredient (safener) in pesticide formulations containing metolachlor in or on the raw agricultural commodities for which tolerances have been established for metolachlor. The proposed regulation to establish a maximum permissible level for residues of the inert ingredient in or on the commodities was requested by the Ciba-Geigy Corp. This time-limited tolerance expires on December 1, 1996.

DATES: Written comments, identified by the document control number [PP 7E3489/P503], must be received on or before May 15, 1992.

ADDRESSES: By mail submit comments to: Public Response and Program Resources Branch, Field Operations Division (H7506), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, deliver comments to: Rm. 1128, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202.

Information submitted as a comment concerning this document may be claimed confidential by marking any part or all of that information as "Confidential Business Information" (CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice to the submitter. All written comments will be available for public inspection in rm. 246 at the address given above from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: By mail: Kerry Leifer, Registration Support Branch, Registration Division (H-7505C), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 711L, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202, 703-305-5180.

SUPPLEMENTARY INFORMATION:

I. Background

EPA is charged with administration of section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. Section 408 authorizes the Agency to establish tolerance levels and exemptions from the requirements of a tolerance for residues of pesticide chemicals in raw agricultural commodities. Historically, finite tolerances were limited to the active as opposed to the inert ingredients in pesticide formulations, whereas exemptions from the requirement of a tolerance were routinely established for inert ingredients. This proposed rule represents the first instance in which a tolerance would be established for an inert ingredient in raw agricultural commodities under section 408 of FFDCA.

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 162.3(c), and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): solvents such as alcohols and hydrocarbons surfactants such as polyoxyelthylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting and spreading agents; propellants in aerosol dispensers; and emulsifiers. The term "inert" is not intended to imply nontoxicity; the ingredient may or may not be chemically active.

A policy statement on inert ingredients published in the **Federal Register** of April 22, 1987 (52 FR 13305), included data requirements which were to be used to evaluate the risks posed by the presence of an inert ingredient in a pesticide formulation. The minimal ("base set") data requirements for inert ingredients were listed in that policy statement. It was also noted that, based upon the results of the "base set" studies, the Agency may elect to require additional data such as would be required under 40 CFR part 158 for an active ingredient. Included among these additional requirements are residue chemistry data which would support the establishment of a finite tolerance for the residues of an inert ingredient in raw agricultural commodities and/or processed foods.

In those cases where the toxicity of an inert ingredient is such that exposure to the inert ingredient must be restricted to assure that the use of the inert ingredient in a pesticide formulation does protect the public health, EPA will propose to establish a tolerance for residues of the inert ingredient on raw agricultural commodities.

II. Provisions of Proposed Rule

The Ciba-Geigy Corp., Agricultural Division, P.O. Box 18300, Greensboro, NC 27419, has submitted pesticide petition (PP) 7E3489 to EPA.

This petition requested that the Administrator, pursuant to section 408(e) of the FFDCA, propose the establishment of a tolerance for residues of 4-(dichloroacetyl)-3,4-dihydro-3-methyl-2H-1,4-benzoxazine (when used as an inert ingredient (safener) in formulations of the active ingredient metolachlor) at 0.01 part per million (ppm) in or on the raw agricultural commodities for which tolerances for metolachlor have been established. A safener is a herbicidal antidote that protects desirous crops while allowing the herbicide to act on the intended weed targets.

The data submitted in the petition and other relevant material have been evaluated. This inert ingredient is considered useful for the purpose for which the tolerance is sought. The toxicological, ecological, and environmental fate data considered in support of the proposed tolerance include:

1. A 90-day rat oral toxicity study with a no-observed-effect level (NOEL) of 100 ppm or 5.0 milligrams (mg)/kilogram (kg)/day. The lowest effect level (LEL) was 300 ppm, with a finding of increased histopathologic incidences of nephrosis in the kidneys of male rats.

2. A 90-day dog oral toxicity study with a NOEL of 200 ppm or 5.0 mg/kg/day. An increased mean liver/gallbladder to terminal body weight ratio was noted at the LEL of 50 mg/kg/day.

3. A 21-day rabbit dermal toxicity study with no irritation noted at 5.0 mg/kg/day.

4. A rat developmental effects study with a NOEL for maternal and developmental toxicity of 100 mg/kg/day.

5. Mutagenicity studies including the micronucleus test (Chinese hamster), DNA repair studies (rat hepatocytes and human fibroblasts), and Salmonella/mammalian activation gene mutation (Ames) assay were negative with and without metabolic activation.

6. An acute mallard duck oral toxicity study with an LD_{50} of 2,150 mg/kg or greater.

7. An acute bobwhite quail oral toxicity study with an LD_{50} of 2,000 mg/kg or greater.

8. A 96-hour rainbow trout static acute toxicity study with an LC_{50} of 3.54 mg/liter (L).

9. A 48-hour *daphnia magna* flow-through acute toxicity study with an EC_{50} of 4.78 mg/L.

10. Environmental fate studies including hydrolysis, photolysis, aerobic soil metabolism, and soil adsorption/desorption.

The reference dose (RfD), based on the 90-day rat oral toxicity study NOEL of 100 ppm (5.0 mg/kg/day) and the 90-day dog oral toxicity study NOEL of 5.0 mg/kg/day, using a 1,000-fold

uncertainty factor, is calculated by the Office of Pesticide Programs to be 0.0050 mg/kg body weight (bw)/day.

The theoretical maximum residue contribution (TMRC) from the proposed tolerance for a 1.5-kg daily diet is estimated to be 0.000187 mg/kg-bw/day for the overall U.S. population which represents 3.7 percent of the RfD. None of the TMRC exposure estimates for the most highly exposed population subgroups exceed 16.2 percent of the RfD.

The Agency does not expect exposure to 4-(dichloroacetyl)-3,4-dihydro-3-methyl-2H-1,4-benzoxazine under this tolerance to pose a significant risk to the public health due to:

(1) The lack of demonstrated mutagenicity. 4-(Dichloroacetyl)-3,4-dihydro-3-methyl-2H-1,4-benzoxazine was established to be nonmutagenic in four separate tests of genetic toxicity.

(2) The large uncertainty factor used in the dietary exposure estimates and establishment of the RfD. The 1,000-fold uncertainty factor is used in the risk assessment process whenever chronic data are not available; it incorporates a factor of 10 that is routinely used when extrapolations of NOELs from subchronic to chronic studies are made. Incorporation of this large uncertainty factor notwithstanding, the TMRC represents only 3.7 percent of the RfD.

(3) Actual residues being significantly less than the 0.01 ppm tolerance value. The 0.01 ppm tolerance for residues of 4-(dichloroacetyl)-3,4-dihydro-3-methyl-2H-1,4-benzoxazine was established by utilizing the level of sensitivity of the residue analytical method rather than a measurement of the true concentrations of residues, which could reasonably be expected to be less than the tolerance value.

This tolerance is being established as a time-limited tolerance because the Agency does not have data from two chronic feeding/oncogenicity studies which are part of the toxicology data typically required to be submitted in support of a tolerance request. In addition, EPA is requiring these studies for this inert ingredient because a structure-activity relationship analysis of 4-(dichloroacetyl)-3,4-dihydro-3-methyl-2H-1,4-benzoxazine indicated that the chemical has some similarities to the chemicals which have shown carcinogenic potential. The above studies will be required to be submitted to the Agency by April 1, 1996. When the Agency receives these chronic feeding/oncogenicity studies it will reassess this tolerance. However, based upon data considered in support of the tolerance and the restriction on exposure offered by a time limitation on the tolerance, the Agency does not believe that this proposed tolerance poses significant risks.

Additionally, a theoretical cancer risk assessment was conducted using a reasonable worst-case carcinogenic potency factor and the TMRC exposure estimate. The risk assessment indicated that a theoretical upper-bound estimate of lifetime dietary risk would be in the negligible range. However, this theoretical cancer risk assessment has not been subject to a formal peer-review process, and does not, at this time, consititute suitable grounds for waiving the oncogenicity data requirements.

This tolerance will expire on December 1, 1996. Residues not in excess of these tolerances will not be considered actionable if a pesticide containing this inert ingredient is legally applied during the term of a conditional registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, and in accordance with the acceptable labeling under a conditional registration. This tolerance will be revoked if any data indicate such revocation is necessary to protect the public health.

The nature of the residue is adequately understood, and an adequate analytical method, capillary column gas-liquid chromatography using an alkali flame ionization detector, will be made available in the Pesticide Analytical Manual, Vol. II (PAM II), for enforcement purposes. In the interim, the method will be available at the address given below: By mail: Calvin Furlow, Public Response and Program Resources Branch, Field Operations Division (H7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 1128C, CM #2, 1921 Jefferson Davis Highway, Arlington, VA 22202, (703)-557-4432.

Based upon the above information considered by the Agency, the tolerance established by 40 CFR 180.1096 would protect the public health. Therefore, it is proposed that the tolerance be established as set forth below.

Any person who has registered or submitted an application for registration of a pesticide under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, which contains any of the ingredients listed herein, may request within 30 days after publication of this document in the **Federal Register** that this rulemaking proposal be referred to an Advisory Committee in accordance with section 408(e) of the Federal Food, Drug, and Cosmetic Act.

Interested persons are invited to submit written comments on the proposed regulation. Comments must bear a notation indicating both the subject and the petition and document control number, [PP 7E3489/P503]. All written comments filed in response to this proposal will be available for inspection in the Registration Support Branch, at the address given above from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays. A public docket containing the data and information considered by the Agency in support of this proposed regulation has been established and is also available for public inspection at the same address.

The Office of Management and Budget has exempted this rule from the requirements of section 3 of Executive Order 12291.

Pursuant to the requirements of the Regulatory Flexibility Act (Pub. L. 96-354, 94 Stat. 1164, 5 U.S.C. 601-612), the Administrator has determined that regulations establishing new tolerances or raising tolerance levels or establishing exemptions from tolerance requirements do not have a significant economic impact on a substantial number of small entities. A certification statement to this effect was published in the **Federal Register** of May 4, 1981 (46 FR 24950).

List of Subjects in 40 CFR Part 180

Administrative practice and procedure, Agricultural commodities, Pesticides and pests.

Dated: March 30, 1992.

Anne E. Lindsay,

Director, Registration Division, Office of Pesticide Programs.

Therefore, it is proposed that 40 CFR part 180 be amended as follows:

PART 180—[AMENDED]

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

Authority: 21 U.S.C. 346a and 371.

2. By adding new § 180.460, to read as follows:

§ 180.460 4-(Dichloroacetyl)-3,4-dihydro-3-methyl-2H-1,4-benzoxazine; tolerances for residues.

Tolerances, to expire on December 1, 1996, are established at 0.01 part per million (ppm) for residues of 4-(dichloroacetyl)-3,4-dihydro-3-methyl-2H-1,4-benzoxazine when used as an inert ingredient (safener) in pesticide formulations containing metolachlor in or on the raw agricultural commodities for which a tolerance has been

established for metolachlor. Metolachlor tolerances are established under § 180.368.

[FR Doc. 92-8735 Filed 4-14-92; 8:45 am]
BILLING CODE 6560-50-F

40 CFR Part 180

[PP 2E4050/P562; FRL-4057-6]

RIN 2070-AC18

Exemption From the Requirement for a Pesticide Tolerance for 3-Carbamyl-2,4,5-Trichlorobenzoic Acid

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: This document proposes that an exemption from the requirement of a tolerance be established for the residues of the soil metabolite 3-carbamyl-2,4,5-trichlorobenzoic acid in or on all raw agricultural commodities which occur from the direct application of the fungicide chlorothalonil to certain crops and/or as inadvertent residues resulting from the soil metabolism of chlorothalonil when applied to certain crops, and subsequent uptake by rotated crops when used according to approved agricultural practices. This proposal to establish the exemption from the requirement for tolerance for residues of the soil metabolite was requested by ISK Biotech Corp.

DATES: Comments, identified by the document control number, [PP 2E4050/P562], must be received on or before May 15, 1992.

ADDRESSES: Written objections may be submitted to: Public Response and Program Resources Branch, Field Operations Division (H7506C), Office of Pesticide Programs, 401 M St., SW., Washington, DC 20460. In person, bring comments to: Rm. 1128, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202.

Information submitted as a comment concerning this document may be claimed confidential by marking any part or all of that information "Confidential Business Information" (CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice. All written comments will be available for public inspection in rm. 1128 at the address given above, from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: By mail: Cynthia Giles-Parker, Product Manager (PM) 22, Registration Division (H7505C), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 229, CM #2, 1921 Jefferson Davis Highway, Arlington, VA 22202, (703)-305-5540.

SUPPLEMENTARY INFORMATION: The ISK Biotech Corp., P.O. Box 8000, Mentor, OH 44061-8000, has submitted pesticide petition (PP) 2E4050 to EPA. The petition requested that the Administrator, pursuant to section 408(e) of the Federal Food, Drug, and Cosmetic Act (FFDCA) (21 U.S.C. 346a(e)), establish an exemption from the requirement of a tolerance for the residues of 3-carbamyl-2,4,5-trichlorobenzoic acid and 4-hydroxy-2,5,6-trichloroisophthalonitrile in rotated crops.

ISK Biotech Corp. amended the petition to request that EPA establish an exemption from the requirement of a tolerance as follows: An exemption from the requirement for a tolerance is proposed for the residues of 3-carbamyl-2,4,5-trichlorobenzoic acid in or on all raw agricultural commodities which occur from the direct application of chlorothalonil to crops in § 180.275(a) and (b) and/or as inadvertent residues resulting from the soil metabolism of chlorothalonil when applied to crops in § 180.275(a) and (b), and subsequent uptake by crops when used according to approved agricultural practices. The purpose of this exemption from the requirement of a tolerance would be to allow the rotation to crops for which there are no chlorothalonil tolerances in fields where preceding crops were treated with chlorothalonil. Residues studies show that the soil metabolite, 3-carbamyl-2,4,5-trichlorobenzoic acid, is the only residue of chlorothalonil which may be detected in the rotated crops. The data submitted in the petition and other relevant material have been evaluated. The toxicological data considered in support of the proposed exemption from the requirement of a tolerance for 3-carbamyl-2,4,5-trichlorobenzoic acid include:

1. No evidence of developmental toxicity in rats (no observed effect level [NOEL] > 2,000 milligrams [mg]/kilogram [kg]/day) or rabbits (NOEL > 1,000 mg/kg/day).

2. A reproductive NOEL = 750 mg/kg/day and a lowest observed effect level [LOEL] = 2,000 mg/kg/day based on reduced pup weights in rats.

3. Increased liver weights were observed in rats and dogs given 750 and 50 mg/kg/day of the metabolite, respectively, for 90 days.

4. No evidence of mutagenicity was observed in assays conducted in accordance with Pesticide Guideline Reference Numbers 84-2a, 84-2b or 84-4.

5. In a supplementary 90-day mouse feeding study no treatment-related effects were observed in males or females at doses of 0, 250, 500, 1,000, 5,000 and 10,000 parts per million (ppm) in feed.

6. In a supplementary mouse 90-day feeding study at doses of 0, 250, 750, 2,200 and 7,500 ppm no treatment-related effects were observed. However, no clinical chemistry or ophthalmological examinations were performed.

7. In a supplementary rat metabolism study more than 90 percent of the radiolabel was excreted in urine and feces during the first 72 hours. No significant accumulation in tissue was reported. However, there was no identification of metabolites and only one treatment regimen was used.

8. In a supplemental Interim Report of a combined chronic feeding and carcinogenicity study in rats at doses of 0, 80, 200, 500 and 1,000 mg/kg/day no treatment related effects in males or females were observed.

Since the soil metabolite 3-carbamyl-2,4,5-trichlorobenzoic acid is not of toxicological concern and based on the low levels detected only in certain rotated crops (1.2 ppm highest level found), the Agency can conclude that there are no toxicology concerns without calculating a Reference Dose (RfD) based on systemic toxicity.

The nature of the residues is adequately understood for the soil metabolite from the use of chlorothalonil on the raw agricultural commodities listed in §§ 180.275(a) and (b). Since an exemption from the requirement of a tolerance is being established an adequate analytical method is not required for enforcement purposes. Because the metabolite is not of toxicological concern at the levels which will occur in the rotated crops, there is no concern for secondary residues in milk, eggs, meat, and meat byproducts.

Based on the above information considered by the Agency, the exemption from the requirement of a tolerance established by amending 40 CFR part 180 would protect the public health. Therefore, it is proposed that the exemption be established as set forth below.

Any person who has registered or submitted an application for registration of a pesticide, under FIFRA, as amended, which contains any of the

ingredients listed herein, may request within 30 days after publication of this document in the **Federal Register** that this rulemaking proposal be referred to an Advisory Committee in accordance with FFDCA section 408(e).

Interested persons are invited to submit written comments on the proposed regulation. Comments must bear a notation indicating the document control number, [PP 2E4050/P542]. All written comments filed in response to this petition will be available in the Public Docket and Freedom of Information Section, at the address given above from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays.

The Office of Management and Budget has exempted this rule from the requirements of section 3 of Executive Order 12291.

Pursuant to the requirements of the Regulatory Flexibility Act (Pub. L. 96-354, 94 Stat. 1164, 5 U.S.C. 601-612), the Administrator has determined that regulations establishing new tolerances or raising tolerance levels or establishing exemptions from tolerance requirements do not have a significant economic impact on a substantial number of small entities. A certification statement to this effect was published in the **Federal Register** of May 4, 1981 (46 FR 24950).

List of Subjects in 40 CFR Part 180

Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Recording and recordkeeping requirements

Dated: March 30, 1992.

Anne E. Lindsay,

Director, Registration Division, Office of Pesticide Programs.

Therefore, it is proposed that 40 CFR part 180 be amended as follows:

PART 180—[AMENDED]

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

Authority: 21 U.S.C. 346a and 371.

2. In subpart D, by adding a new § 180.1110, to read as follows:

§ 180.1110 3-Carbamyl-2,4,5-trichlorobenzoic acid; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for the residues of 3-carbamyl-2,4,5-trichlorobenzoic acid in or on all raw agricultural commodities which occur from the direct application of chlorothalonil to crops in § 180.275(a) and (b) and/or as inadvertent residues resulting from the soil metabolism of chlorothalonil when applied to crops in § 180.275(a) and (b), and subsequent uptake by rotated crops when used according to approved agricultural practices.

[FR Doc. 92-8732 Filed 4-14-92; 8:45 am]

BILLING CODE 6560-50-F

Notices

Federal Register
Vol. 57, No. 73
Wednesday, April 15, 1992

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.

ADMINISTRATIVE CONFERENCE OF THE UNITED STATES

Committee on Rulemaking; Public Meeting

Pursuant to the Federal Advisory Committee Act (Pub. L. 92–463), notice is hereby given of the meeting of the Committee on Rulemaking of the Administrative Conference of the United States.

Committee on Rulemaking

Date: Monday, April 20, 1992.
Time: 4 p.m.
Location: Administrative Conference of the United States, 2120 L Street, NW., suite 500, Washington, DC 20037 (Library, 5th Floor).
Agenda: The Committee will meet to discuss: (1) Professor Robert Anthony's study of non-rule rulemaking.
Contact: Kevin L. Jessar, 202–254–7020.

Attendance at the committee meeting is open to the interested public, but limited to the space available. Persons wishing to attend should notify the Office of the Chairman at least one day in advance. The committee chairman, if he deems it appropriate, may permit members of the public to present oral statements at the meeting. Any member of the public may file a written statement with the committee before, during, or after the meeting. Minutes of the meeting will be available on request. The contact person's mailing address is: Administrative Conference of the United States, 2120 L Street, NW., suite 500, Washington, DC 20037. Telephone 202–254–7020.

Dated: April 13, 1992.
Jeffrey L. Lubbers,
Research Director.

[FR Doc. 92–8780 Filed 4–13–92; 10:20 am]
BILLING CODE 6110–01–M

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

Welfare Simplification and Coordination Advisory Committee; Meeting

AGENCY: Food and Nutrition Service, USDA.

ACTION: Pursuant to the Federal Advisory Committee Act (Public Law 92–463), notice is hereby given of a meeting of the Advisory Committee on Welfare Simplification and Coordination.

DATE AND TIME: April 30, 1992, 1:30 p.m. and May 1, 1992, 8:30 a.m.

ADDRESSES: Holiday Inn Arlington at Ballston, 4610 North Fairfax Drive, Arlington, Virginia, 22203.

PURPOSE OF MEETING: Section 1778 of the Mickey Leland Memorial Domestic Hunger Relief Act (title XVII of Pub. L. 101–624) requires the Secretary of Agriculture to appoint, after consultation with federal, state, and local officials as well as recipient representatives, an Advisory Committee on Welfare Simplification and Coordination (Committee). The purpose of the Committee is to examine the different policies implemented in the Food Stamp Program, cash and medical assistance programs under the Social Security Act, and housing assistance programs, to determine the major reasons for the differing policies and the degree to which such differences hinder receipt of multiple program benefits and to recommend common or simplified policies to reduce difficulty in gaining access to more than one type of assistance. The Committee is to prepare and submit a final report to specified congressional committees no later than July 1, 1993. The primary purpose of this Committee meeting is the review and discussion of welfare conformity issues.

Meetings of the Committee are open to the public. Members of the public may participate, as time permits. Members of the public may file written statements with the Committee before or after the meeting.

Persons wishing to file written statements or to obtain additional information about this meeting should contact Ellen Henigan, Supervisor, Work Program Section, Food Stamp Program, Food and Nutrition Service, USDA, 3101 Park Center Drive, room 718, Alexandria, Virginia 22302, (703) 305–2762.

Dated: April 10, 1992.
George A. Braley,
Acting Administrator.

[FR Doc. 92–8719 Filed 4–14–92; 8:45 am]
BILLING CODE 3420–30–M

DEPARTMENT OF COMMERCE

International Trade Administration

[A–588–819]

Notice of Antidumping Duty Order: Aspheric Ophthalmoscopy Lenses From Japan

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

EFFECTIVE DATE: April 15, 1992.

FOR FURTHER INFORMATION CONTACT: Stefanie Amadeo, Office of Antidumping Investigations, Import Administration, International Trade Administration, Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230, at (202) 377–1174.

ORDER:

Scope of Order

The products covered by this investigation are aspheric ophthalmoscopy lenses (lenses), which are single element, non-contact ophthalmoscopy lenses, whether mounted or unmounted, framed or unframed, of which one or both surfaces are aspherical in shape. The subject merchandise is currently classifiable under subheading 9018.50.00 of the *Harmonized Tariff Schedule (HTS).* Although the HTS number is provided for convenience and customs purposes, our written description of the scope of this proceeding is dispositive.

Antidumping Duty Order

In accordance with section 735(a) of the Tariff Act of 1930, as amended, (the Act) (19 U.S.C. 1673d(a)), on February 21, 1992, the Department of Commerce (the Department) made its final determination that lenses from Japan are being sold at less than fair value (57 FR 6703, February 27, 1992). On April 6, 1992, in accordance with section 735(d) of the Act, the International Trade Administration (ITC) notified the

Department that an industry in the United States is threatened with material injury by reason of such imports. The ITC did not determine, pursuant to section 735(b)(4)(B) of the Act that, but for the suspension of liquidation of entries of lenses from Japan, the domestic industry would have been materially injured.

When the ITC finds threat of material injury, and makes a negative "but for" finding, the "Special Rule" provision of section 736(b)(2) applies. Therefore, all unliquidated entries or warehouse withdrawals, for consumption of lenses of Japan made on or after April 15, 1992, the date on which the ITC will publish its final affirmative determination of threat of material injury in the **Federal Register** will be liable for the assessement of antidumping duties. The Department will direct U.S. Customs officers to terminate the suspension of liquidation for entries entered, or withdrawn from warehouse, for consumption before April 15, 1992, the date the ITC will publish in the **Federal Register** its final determination of threat of material injury, and to release any bond or other security, and refund any cash deposit, posted to secure the payment of estimated antidumping duties with respect to these entries.

The Department will direct U.S. Customs officers to assess, upon further advice by the administering authority pursuant to section 736(a)(1) of the Act, antidumping duties equal to the amount by which the foreign market value of the merchandise exceeds the United States price for all entries of lenses from Japan. These antidumping duties will be assessed on all entries of lenses from Japan, entered or withdrawn from warehouse, for consumption on or after the date of publication of this antidumping duty order in the **Federal Register**. Customs officers must require, at the same time as importers would normally deposit estimated duties, the following cash deposits for the subject merchandise:

Producer/manufacturer/exporter	Deposit rate (percent)
Nikon Corp. and Nikon Inc.	158.00
All Others	158.00

This notice constitutes the antidumping duty order with respect to lenses from Japan, pursuant to section 736(a) of the Act. Interested parties may contact the Central Records Unit, room B-099 of the Main Commerce Building, for copies of an updated list of antidumping duty orders currently in effect.

This order is published in accordance with section 736(a) of the Act and 19 CFR 353.21.

Dated: April 10, 1992.

Marjorie A. Chorlins,

Acting Assistant Secretary for Import Administration.

[FR Doc. 92-8828 Filed 4-13-92; 12:13 am]

BILLING CODE 3510-DS-M

Foreign-Trade Zones Board

[Docket 30-90]

Foreign-Trade Zone 24—Wilkes-Barre/Scranton, PA; Withdrawal of Application for Subzone Status for Jewelcor, Inc.

Notice is hereby given of the withdrawal of the application submitted by the Eastern Distribution Center, Inc., grantee of FTZ 24, requesting authority for subzone status for the watch distribution and assembly facility of Jewelcor, Inc., in Exeter, Pennsylvania. The application was filed on July 2, 1990 (55 FR 31413, 8/2/90).

The withdrawal is requested by the applicant because of changed circumstances, and the case has been closed without prejudice.

Dated: April 8, 1992.

John J. Da Ponte, Jr.,

Executive Secretary.

[FR Doc. 92-8717 Filed 4-14-92; 8:45 am]

BILLING CODE 3510-02-M

International Trade Administration

[A-588-087]

Portable Electric Typewriters From Japan; Final Results of Antidumping Duty Administrative Review

AGENCY: Import Administration/International Trade Administration, Department of Commerce.

ACTION: Notice of final results of antidumping duty administrative review.

SUMMARY: On October 19, 1988, the Department of Commerce published in the **Federal Register** (53 FR 40926) the final results of its administrative review of the antidumping duty order on portable electric typewriters from Japan. The final results for Ricoh Corp. for the periods May 1, 1981 through April 30, 1986, and for Sharp Electronics Corp. for the period May 1, 1985 through April 30, 1986, were inadvertently excluded from the October 19, 1988 final results notice. We are publishing the final results for these two firms.

EFFECTIVE DATE: April 14, 1992.

FOR FURTHER INFORMATION CONTACT: Thomas Prosser or Robert Marenick, Office of Antidumping Compliance, International Trade Administration, U.S. Department of Commerce, Washington, DC 20230; telephone: (202) 377-5255.

SUPPLEMENTARY INFORMATION:

Background

On October 19, 1988, the Department of Commerce (the Department) published in the **Federal Register** (53 FR 40926) the final results of its administrative review of the antidumping duty order on portable electric typewriters from Japan. The review covered eleven manufacturers/exporters of this merchandise to the United States, and various periods from May 1, 1981 through April 30, 1986. The final results for Ricoh Corp. (Ricoh) for the periods May 1, 1981 through April 30, 1986, and for Sharp Electronics Corp. (Sharp) for the period May 1, 1985 through April 30, 1986, were inadvertently excluded from the October 19, 1988 final results notice. We have now completed this administrative review of Ricoh and Sharp, and we are publishing the final results for these two firms in accordance with section 751(a)(1) of the Tariff Act of 1930 (19 U.S.C. 1675(a)(1)) (the Tariff Act) and 19 CFR 353.22(c).

Scope of the Review

Imports covered by the review are shipments of non-automatic PETs from Japan that do not incorporate a calculating mechanism. The merchandise is currently classified under Harmonized Tariff System (HTS) item numbers 8469.21.00 and 8469.29.00. During the review period this merchandise was classifiable under Tariff Schedules of the United States Annotated (TSUSA) item number 676.0510 and, in some cases, under TSUSA item number 676.0540. HTS and TSUSA numbers are provided for convenience and Customs purposes. The written description remains dispositive.

This review covers two manufacturers/exporters of Japanese PETs to the United States: Ricoh for the periods May 1, 1981 through April 30, 1986, and Sharp for the period May 1, 1985 through April 30, 1986.

Analysis of Comments Received

We invited interested parties to comment on the preliminary results. We received comments from Ricoh but, as the comments were received after the close of the comment period, we have not considered them for these final results. We received no comments from Sharp.

Final Results of the Review

Ricoh did not respond to the Department's request for information and Sharp did not respond adequately to the Department's request for information. Consequently, for these firms we have used the best information available (BIA) for assessment and estimated antidumping duty cash deposit purposes. BIA is the highest rate for a responding firm during each review period, or the highest prior rate for the non-responding firm, whichever is higher. See Portable Electric Typewriters from Japan, Final Results of Antidumping Duty Administrative Review (53 FR 40926, October 19, 1988). We have determined the final margins to be:

Manufacturer	Period of review	Margin (percent)
Ricoh	5/1/81–4/30/82	4.92
	5/1/82–4/30/83	4.92
	5/1/83–4/30/84	4.92
	5/1/84–4/30/85	5.20
	5/1/85–4/30/86	8.85
Sharp	5/1/85–4/30/86	8.85

The Department will instruct the Customs Service to assess antidumping duties on all appropriate entries. The Department will issue appraisement instructions directly to the Customs Service.

Furthermore, the following deposit requirements will be effective upon publication of this notice of final results of administrative review for all shipments of the subject merchandise, entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided by section 751(a)(1) of the Tariff Act: (1) The cash deposit rate for the reviewed companies will be as outlined above; (2) for previously reviewed or investigated companies not listed above, the cash deposit rate will continue to be the company-specific rate published for the most recent period; (3) if the exporter is not a firm covered in these, prior reviews, or the original less-than-fair-value investigation, but the manufacturer is, the cash deposit rate will be the rate established for the most recent period for the manufacturer of the merchandise; and (4) the cash deposit rate for all other manufacturers or exporters will be 3.87%. This rate represents the highest rate for any firm with shipments in the administrative review, other than those firms receiving a rate based entirely on best information available. (See Portable Electric Typewriters from Japan, Final Results of Antidumping Duty Administrative Review, 56 FR 56393, November 4, 1991). The rate for Sharp in this review supersedes the rates established in the 1988–1990 review period since those rates were based on the belief that Sharp had not been previously reviewed.

These deposit requirements, when imposed, shall remain in effect until publication of the final results of the next administrative review.

This notice also serves as a final reminder to importers of their responsibility under 19 CFR 353.26 to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

This administrative review and notice are in accordance with section 751(1)(1) of the Tariff Act (19 U.S.C. 1675(a)(1)) and 19 CFR 353.22.

Dated: April 7, 1992.

Marjorie A. Chorlins,

Acting Assistant Secretary for Import Administration.

[FR Doc. 92–8718 Filed 4–14–92; 8:45 am]

BILLING CODE 3510–DS–M

Announcement of the Postponement of the Hearing and Extension of the Briefing Schedule in the Countervailing Duty Investigation of Certain Softwood Lumber Products From Canada

AGENCY: Import Adminstration, International Trade Administration, Department of Commerce.

EFFECTIVE DATE: April 14, 1992.

SUMMARY: At the request of the Government of Canada, the Governments of Alberta, British Columbia, Ontario, and Quebec, and the Canadian Forest Industries Council and affiliated companies, who are interested parties in this investigation, we have postponed the hearing and extended the briefing schedule for this investigation. The hearing date has been changed from April 24, 1992, to April 29, 1992. The hearing will held at 10 a.m. in room 4832. Accordingly, the case briefs are now due by 5 p.m. on April 21, 1992, and the rebuttal briefs are now due by 10 a.m. on April 27, 1992.

FOR FURTHER INFORMATION CONTACT: Bernard Carreau or Kelly Parkhill, Office of Countervailing Compliance, Import Administration, U.S. Department of Commerce, room B099, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone (202) 377–2787.

This announcement is published pursuant to § 355.38 of the Department's regulations.

Dated: April 10, 1992.

Alan M. Dunn,

Assistant Secretary for Import Administration.

[FR Doc. 92–8723 Filed 4–14–92; 8:45 am]

BILLING CODE 3510–DS–M

National Institute of Standards and Technology

[Docket No. 92036–2065]

Opportunity To Join a Cooperative Research and Development Consortium for the Casting of Aerospace Alloys

AGENCY: National Institute of Standards and Technology, Commerce.

ACTION: Notice.

SUMMARY: The National Institute of Standards and Technology (NIST) seeks indutrial parties interested in entering into a cooperative industrial/NIST research consortium on the development of new technology to monitor and control the process of casting metal alloys commonly used in aerospace applications. The program will be undertaken within the scope and confines of The Federal Technology Transfer Act of 1986 (15 U.S.C. 3710a), which provides federal laboratories including NIST, with the authority to enter into cooperative research agreements with qualified parties. Under this law, NIST may contribute personnel, equipment and facilities—but not funds—to the cooperative research program. For this consortium, it is currently expected that participants will be required to contribute $10,000 annually for the program. Members will be expected to make significant additional contributions to the consortium's efforts in the form of materials, equipment, personnel and/or funds. The firsth phase of the research program is expected to last three to five years. This is not a grant program.

DATE: Interested parties should contact NIST at the address or telephone number shown below but not later than May 15, 1992.

ADDRESS: Dr. H. Thomas Yolken, Office of Intelligent Processing of Materials, National Institute of Standards and Technology, Gaithersburg, MD 20899.

FOR FURTHER INFORMATION CONTACT: Dr. H. Thomas Yolken, (301) 975–5727.

SUPPLEMENTARY INFORMATION: NIST seeks qualified industrial parties interested in entering into a cooperative consortium research program on the development of precision casting technology for metal alloys with aerospace applications. Currently, it is contemplated that the research will concentrate on the following areas: (1) Micromodeling of the casting process including a study of nucleation; (2) combination of micromodels with macromodels; (3) validation of the models developed; (4) the development of thermophysical and related properties data for certain alloys and materials used in the casting process; and (5) development of process sensors to obtain data on the casting process and ultimately provide real time control.

NIST would like to enter into a cooperative consortium research and development program with industrial companies in order to develop technology to model, monitor and control the casting of metal alloys commonly used in the aerospace industry. NIST would like to work with metal casting companies, users of alloy cast parts and instrumentation companies that have significant expertise in the casting of alloys and/or in the measurement of materials processing. Companies should be prepared to invest adequate resources in the collaboration and be finally committed to the goal of developing new casting technology.

This program is being undertaken within the scope and confines of the Federal Technology Transfer Act of 1986 (Pub. L. 99–502, 15 U.S.C. 3710a), which authorizes government owned and operated federal laboratories, including NIST, to enter into cooperative research and development agreements (CRDAs) with qualified parties. Under the law, a CRDA may provide for contributions from the federal laboratory of personnel, facilities and equipment, but not direct funding. Participants will be required to contribute $10,000 per year for the program. NIST intends to conduct a planning meeting in April 1992 for interested parties.

Dated: April 10, 1992.

John W. Lyons,

Director.

[FR Doc. 92–8713 Filed 4–14–92; 8:45 am]

BILLING CODE 3510–13–M

National Oceanic and Atmospheric Administration

Progress on Emergency Striped Bass Research Study

AGENCY: National Marine Fisheries Service (NMFS), NOAA, Commerce.

ACTION: Notice of public meeting.

SUMMARY: NMFS and the U.S. Fish and Wildlife Service will hold a joint meeting to discuss progress on the Emergency Striped Bass Research Study, as authorized by the amended Anadromous Fish Conservation Act (Pub. L. 96–118).

DATES: The meeting will convene on Thursday, May 21, 1992, at 10 a.m., and will ajourn at approximately 3 p.m. The meeting is open to the public.

ADDRESSES: Department of Commerce, NOAA, Main Lobby Conference Room, Silver Spring Metro Center #1, 1335 East-West Highway, Silver Spring, MD 20910.

FOR FURTHER INFORMATION CONTACT: David G. Deuel, Office of Fisheries Conservation and Management, NMFS, 1335 East-West Highway, Silver Spring, MD 20910. Telephone: (301) 713–2347.

Dated: April 9, 1992.

David S. Crestin,

Acting Director, Office of Fisheries Conservation and Management, National Marine Fisheries Service.

[FR Doc. 92–8641 Filed 4–14–92; 8:45 am]

BILLING CODE 3510–22–M

North Pacific and Gulf of Mexico Fishery Management Councils; Statements of Organization, Practices and Procedures

AGENCY: National Marine Fisheries Service (NMFS), NOAA, Commerce.

ACTION: Notice of revision to statements of organizations, practices and procedures.

SUMMARY: Pursuant to section 302(f)(6) of the Magnuson Fishery Conservation and Management Act (Magnuson Act), 16 U.S.C. 1801 *et seq.*, each Regional Fishery Management Council (Council) is responsible for carrying out its functions under the Magnuson Act, in accordance with such uniform standards as are prescribed by the Secretary of Commerce (Secretary). Further, each Council must make available to the public a statement of its organization, practices and procedures (SOPP).

On January 6, 1992, NOAA published in the **Federal Register** (57 FR 375) a final rule that revised the regulations (50 CFR parts 601 and 605) and guidelines concerning the operations of the Councils under the Magnuson Act. The final rule, effective February 5, 1992, implemented parts of sections 108 and 109 of Public Law 101–627, the Fishery Conservation Amendments of 1990, which amended and reauthorized the Magnuson Act through September 30, 1993.

In accordance with the above-mentioned final rule, the North Pacific Fishery Management Council (North Pacific Council) has revised its SOPPs, which were orginally published March 1, 1977 (42 FR 11858), and the Gulf of Mexico Fishery Management Council (Gulf Council) has revised its SOPPs, which were originally published September 13, 1977 (42 FR 177). Interested parties may obtain a copy of the North Pacific's or Gulf Council's revised SOPPs by contacting either Clarence G. Pautzke, Executive Director, North Pacific Fishery Management Council, P.O. Box 103136, 605 W. 4th Avenue, Anchorage, AK 99501; telephone: (907) 271–2817; or Wayne E. Swingle, Executive Director, Gulf of Mexico Fishery Management Council, Lincoln Center, Suite 331, 5401 W. Kennedy Boulevard, Tampa, FL 33609; telephone: (813) 228–2815.

Dated: April 9, 1992.

Samuel W. McKeen,

Acting Assistant Administrator for Fisheries, National Marine Fisheries Service.

[FR Doc. 92–8640 Filed 4–14–92; 8:45 am]

BILLING CODE 3510–22–M

DELAWARE RIVER BASIN COMMISSION

Notice of Commission Meeting and Public Hearings

Notice is hereby given that the Delaware River Basin Commission will hold a public heading on Wednesday, April 22, 1992. The hearing will be part of the Commission's regular business meeting which is open to the public and scheduled to begin at 9:30 a.m. in the University of Delaware's Goodstay Center, 2600 Pennsylvania Avenue, Wilmington, Delaware.

The Commission's hearing on the following subjects will begin at 1:30 p.m.:

Applications for Approval of the Following Projects Pursuant to Article 10.3, Article 11 and/or Section 3.8 of the Compact

1. *Cressona Aluminum Company D–82–5 RENEWAL–2.* An application for the renewal of a ground water

withdrawal project to supply up to 21.6 mg/30 days of water to the applicant's industrial facility from Well Nos. 1 and 2. Commission approval on April 29, 1986 was limited to six years and will expire unless renewed. The applicant requests that the total withdrawal from all wells remain limited to 21.6 mg/30 days. The project is located in Cressona Borough, Schuylkill County, Pennsylvania.

2. *Sybron Chemicals, Inc. D–85–5 RENEWAL.* An application for the renewal of a ground water withdrawal project to supply up to 77 mg/30 days of water to the applicant's industrial facility from Well Nos. 2, 4, 5 and EQ106. Commission approval on May 1, 1985 was limited to four years. The total withdrawal limit from all wells is reduced from 80 to 77 mg/30 days. The project is located in Pemberton Township, Burlington County, New Jersey.

3. *AT&T Microelectronics D–86–79 RENEWAL.* An application for the renewal of a ground water withdrawal project to supply to 22.3 mg/30 days of water to the applicant's industrial facility from Well No. 1. Commission approval on March 25, 1987 was limited to five years. The applicant requests that the total withdrawal from all wells remain limited to 22.3 mg/30 days. The project is located in Muhlenberg Township, Berks County, Pennsylvania.

4. *Town of Newton D–88–13 CP.* An application to upgrade and expand a 1.0 million gallons per day (mgd) sewage treatment plant to provide advanced secondary treatment of wastewater from residents of the Town of Newton, Sussex County, New Jersey, through the year 2010. A design average flow of 1.4 mgd of treatment plant effluent will be discharged to Moore's Brook through the existing outfall located just above the confluence with Paulins Kill.

5. *Vic Mead Hunt Club D–90–34.* A surface water withdrawal project for purposes of golf course irrigation. The applicant will withdraw a combined total of up to 0.45 mgd from Pond Nos. 1 and 2 with the average 30-day withdrawal not to exceed 0.33 mgd. The water will be applied to a 37-acre portion of the golf course and restricted to seasonal use between March 1st and November 1st only. The total yearly withdrawal will be 20.1 mg. The project ponds are located on an unnamed tributary to Wilson Run (a tributary of Brandywine Creek), just east of Adams Dam Road near Centerville, New Castle County, Delaware.

6. *Mobil Oil Corporation D–90–40.* An application for approval of a ground water withdrawal project to take up to 110 mg/30 days of water from the applicant's ground water decontamination system from new recovery Well Nos. RW–19, RW–20 and RW–21; and new process Well Nos. PW–48 and PW–49; and to limit the withdrawal from all wells to 150 mg/30 days. The project is located in Greenwich Township, Gloucester County, New Jersey.

7. *Bradywine Country Club D–90–65.* A surface water withdrawal project to provide water from a golf course pond for irrigation of approximately 25 acres of the applicant's golf course. A well is also used to augment pond storage and can withdraw water at up to 2.0 mg/30 days (0.067 mgd). Water will be withdrawn from the pond at up to 7.0 mg/30 days (0.233 mgd) for seasonal irrigation. The project site is located just east of the Concord Pike (Route 202) and north of Talleyville in New Castle County, Delaware.

8. *West Pikeland Township D–91–45.* A sewage treatment plant (STP) expansion project that will increase the average design capacity of the applicant's existing 0.048 mgd STP to 0.074 mgd and continue to provide secondary biological treatment as well as tertiary filtration. The proposed STP will continue to serve the residential development of Twin Hills of Chester Springs in the Townships of West Pikeland and Upper Uwchlan, Chester County, Pennsylvania. Discharge will continue to be to the ground water via existing and proposed additional seepage beds located near Pickering Creek (a tributary of the Schuylkill River) near the southwest corner of West Pikeland Township.

9. *Walnutport Authority D–91–50 CP.* A surface water withdrawal project that consists of a combined total withdrawal of 0.35 mgd from Fisher Springs 1 and 2, or Oplinger Springs 1 and 2, or Heimbach Quarry, for emergency use in the applicant's water distribution system which serves Walnutport Borough and a portion of Lehigh Township. The sources are all located approximately 0.25 miles to 2.0 miles north of Walnutport Borough in Lehigh Township, Northampton County, Pennsylvania.

10. *Womelsdorf-Robesonia Joint Authority D–91–97 CP.* An application for approval of a ground water withdrawal project to supply up to 12.9 mg/30 days of water to the applicant's distribution system from new Well No. 3, and to increase the existing withdrawal limit from all wells of 15 mg/30 days to 28 mg/30 days. The project is located in Heidelberg Township, Berks County, Pennyslvania.

Documents relating to these items may be examined at the Commission's offices. Preliminary dockets are available in single copies upon request. Please contact George C. Elias concerning docket-related questions. Persons wishing to testify at this hearing are requested to register with the Secretary prior to the hearing.

Additional Hearing Scheduled

By earlier notice, the Commission announced its schedule of public hearings on proposed amendments to its Comprehensive Plan, Water Code, Water Quality Regulations and Rules of Practice and Procedure relating to water quality standards and policies to protect existing water quality in certain waters of the Basin. The proposal would also classify the Upper Delaware Scenic and Recreational River, the Delaware Water Gap National Recreation Area and the Delaware River from Millrift, Pennsylvania to the northern boundary of the Delaware Water Gap National Recreation Area as Special Protection Waters. At this time, the Commission is scheduling an additional hearing on the same proposal.

Hearing Dates: The public hearings are scheduled as follows:

May 5, 1992 from 2 to 5 p.m., resuming at 7 p.m.

May 6, 1992 from 2 to 5 p.m., resuming at 7 p.m.

May 15, 1992 at 1 p.m.

ADDRESSES: The May 5, 1992 hearing will be held in the Ballroom of the Inn at Hunt's Landing, 900 Routes 6 & 209, Matamoras, Pennsylvania. The May 6, 1992 hearing will be held in the Tusten Theater on Bridge Street (Route 52) in Narrowsburg, New York. The May 15, 1992 hearing will be held in the New Castle County Council Chambers, First Floor of the City/County Building, 800 French Street, Wilmington, Delaware.

FOR FURTHER INFORMATION CONTACT: Copies of the full text of the proposed amendments, the Water Code, the Water Quality Regulations and the Rules of Practice and Procedure may be obtained by contacting Susan M. Weisman, Commission Secretary, Delaware River Basin Commission, Telephone (609) 883–9500.

Persons wishing to testify are requested to notify the Secretary in advance. Written comments on the proposed amendments should also be submitted to the Secretary at the Delaware River Basin Commission, P.O. Box 7360, West Trenton, New Jersey 08628.

Dated: April 7, 1992.

Susan M. Weisman,

Secretary.

[FR Doc. 92-8619 Filed 4-14-92; 8:45 am]

BILLING CODE 6360-01-M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project Nos. 1417-001 and 1835-013]

Central Nebraska Public Power and Irrigation District and Nebraska Public Power District; Extension of Time to Comment on Draft Environmental Impact Statement

April 9, 1992.

On March 30, 1992, the Commission received a request from Governor Nelson of Nebraska for an extension of the comment period for the draft environmental impact statement (EIS) for relicensing the Kingsley Dam Project No. 1417 and the North Platte/Keystone Diversion Dam Project No. 1835. The two hydropower projects are located on the North Platte, South Platte, and Platte River in Nebraska.

By notice dated March 13, 1992, the Commission extended the comment period for the draft EIS to April 30, 1992. In his March 25, 1992 letter, Governor Nelson states that he is seeking to use the state comment process as a vehicle for achieving consensus among the Nebraska parties, and urges that the comment period be extended until June 15, 1992, to permit this effort to go forward.

The March 13, 1992 notice anticipated that a further extension of the comment period might be warranted in view of the forthcoming staff report. In addition, the consolidated review process contemplated by Governor Nelson may assist the Commission in its evaluation of the issues presented. Accordingly, the extension is granted to all persons who wish to comment on the draft EIS. Comments that were due on April 30, 1992, are now due no later than June 15, 1992.

For further information, please contact S. Ronald McKitrick at (202) 219-2783.

Lois D. Cashell,

Secretary.

[FR Doc. 92-8642 Filed 4-14-92; 8:45 am]

BILLING CODE 6717-01-M

[P-10552-002]

Application Filed With the Commission; Contractors Power Group, Inc.

April 9, 1992.

Take notice that the following hydroelectric application has been filed with the Federal Energy Regulatory Commission and is available for public inspection.

a. Type of application: Minor License.

b. Project no.: 10552-002.

c. Date filed: May 13, 1991.

d. Applicant: Contractors Power Group, Inc.

e. Name of project: Mile 28 Water Power Project.

f. Location: On the Bureau of Reclamation's Milner-Gooding Canal, off Snake River, in Jerome County, Idaho. Section 7, T8S, R20E, Boise Meridian.

g. Filed pursuant to: Federal Power Act, 16 U.S.C. 791(a)-825(r).

h. Applicant contact: Mr. John J. Straubhar, P.E., P.O. Box 820, Twin Falls, ID 83303, (208) 788-0484.

i. FERC contact: Mr. Surender M. Yepuri, P.E. (202) 219-2847.

j. Deadline date: See attached paragraph D9.

k. Status of environmental analysis: This application is ready for environmental analysis at this time—see attached paragraph D9.

l. Description of project: The proposed project, within the canal with the exception of the transmission line, would consist of: (1) A 240-foot-long concrete diversion/overflow spillway; (2) a 34-foot-wide, 55-foot-long powerhouse containing two Kaplan turbine/generator units with a total rated capacity of 1.5 MW; (3) a 1200-foot-long tailrace channel; (4) a 150-foot-long, 35-kV transmission line connecting a local distribution line; and (4) appurtenant facilities.

The project would have an estimated annual output of 5.8 GWh and would cost $1,700,000 in 1991 dollars to construct.

m. Purpose of project: Power generated would be sold to a local utility.

n. This notice also consists of the following standard paragraphs: A4 and D9.

o. Available locations of application: A copy of the application, as amended and supplemented, is available for inspection and reproduction at the Commission's Public Reference and Files Maintenance Branch, located at 941 North Capitol Street, NE., room 3104, Washington, DC 20426, or by calling (202) 208-1371. A copy is also available for inspection and reproduction at (1) J. Straubhar, 1061 Blue Lakes North, suite 204, Twin Falls, ID 83303; Telephone (208) 734-8633; and (2) Jerome Public Library, Jerome, ID.

A4. Development Application—Public notice of the filing of the initial development application, which has already been given, established the due date for filing competing applications or notices of intent. Under the Commission's regulations, any competing development application must be filed in response to and in compliance with the public notice of the initial development application. No competing applications or notice of intent may be filed in response to this notice.

D9. Filing and Service of Responsive Documents—The application is ready for environmental analysis at this time, and the Commission is requesting comments, reply comments, recommendations, terms and conditions, and prescriptions.

The Commission directs, pursuant to § 4.34(b) of the regulations (see Order No. 533 issued May 8, 1991, 56 FR 23108 (May 20, 1991)), that all comments, recommendations, terms and conditions and prescriptions concerning the application be filed with the Commission within 60 days from the issuance date of this notice. All reply comments must be filed with the Commission within 105 days from the date of this notice.

Anyone may obtain an extension of time for these deadlines from the Commission only upon a showing of good cause or extraordinary circumstances in accordance with 18 CFR 385.2008.

All filings must: (1) Bear in all capital letters the title "COMMENTS," "REPLY COMMENTS," "RECOMMENDATIONS," "TERMS AND CONDITIONS," or "PRESCRIPTIONS;" (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address and telephone number of the person submitting the filing; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, recommendations, terms and conditions or prescriptions must set forth their evidentiary basis and otherwise comply with the requirements of 18 CFR 4.34(b). Any of these documents must be filed by providing the original and the number of copies required by the Commission's regulations to: Secretary, Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426. An additional copy must be sent

to: Director, Division of Project Review, Office of Hydropower Licensing, Federal Energy Regulatory Commission, room 1027, at the above address. Each filing must be accompanied by proof of service on all persons listed on the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 4.34(b), 385.2010.

Lois D. Cashell,

Secretary.

[FR Doc. 92–8632 Filed 4–14–92; 8:45 am]

BILLING CODE 6717–01–M

[P–10893–001]

Application Filed With the Commission; Hy Power Energy Co.

April 9, 1992.

Take notice that the following hydroelectric application has been filed with the Federal Energy Regulatory Commission and is available for public inspection.

a. *Type of application:* Major License.

b. *Project no.:* 10893–001.

c. *Date filed:* March 19, 1992.

d. *Applicant:* Hy Power Energy Company.

e. *Name of project:* Inglis Lock By-Pass Dam.

f. *Location:* On the Inglis By-Pass Channel in Levy County, Florida.

g. *Filed pursuant to:* Federal Power Act 16 U.S.C. §§ 791(a)–825(r).

h. *Applicant contact:* Mr. Robert Karow, 7008 Southwest 30th Way, Gainesville, FL 32601, (904) 336–4727.

i. *FERC contact:* Charles T. Raabe (dt) (202) 219–2811.

j. *Comment date:* With 60 days of the date filed shown in paragraph (c).

k. *Description of project:* The proposed project would utilize the existing U.S. Army Corps of Engineers' Inglis Lock By-Pass Channel and would consist of: (1) A log boom; (2) a 45-foot-wide concrete intake channel; (3) a trash rack; (4) a 28-foot-wide 115-foot-long powerhouse containing one 3,200-kW generating unit operated at a 22.5-foot head; (5) a tailrace; (6) a substation; (7) a 2-mile-long, 12.47-kV transmission line; and (8) appurtenant facilities.

The application was filed during the term of applicant's preliminary permit. Applicant estimates that the average annual generation would be 16.2 GWH. Project power would be sold to Florida Power Corporation.

l. Pursuant to § 4.32(b)(7) of 18 CFR of the Commission's regulations, if any resource agency, Indian Tribe, or person believes that an additional scientific study should be conducted in order to form an adequate factual basis for a complete analysis of the application on its merit, the resource agency, Indian Tribe, or person must file a request for a study with the Commission not later than 60 days from the issuance date of the notice and serve a copy of the request on the applicant.

Lois D. Cashell,

Secretary.

[FR Doc. 92–8630 Filed 4–14–92; 8:45 am]

BILLING CODE 6717–01–M

[P–10668–002]

Application Filed With the Commission; Barbara K. Londergan

April 9, 1992.

Take notice that the following hydroelectric application has been filed with the Federal Energy Regulatory Commission and is available for public inspection.

a. *Type of application:* Major License.

b. *Project No.:* 10668–002.

c. *Date filed:* March 19, 1992.

d. *Applicant:* Barbara K. Londergan.

e. *Name of project:* Vulcan Project.

f. *Location:* On the Fax River, near Appleton, Outagamie County, Wisconsin.

g. *Filed pursuant to:* Federal Power Act 16 U.S.C. 791(a)—825(r)

h. *Applicant contact:* Mrs. Barbara K. Londergan, 1206 Shipley Road, Wilmington, DE 19803, (302) 762–2967.

i. *FERC contact:* Mary Golato (202) 219–2804.

j. *Comment date:* Within 60 days of the date filed shown in paragraph (c).

k. *Description of project:* Vulcan Project is an existing site that is at the end of a 600-foot power canal that is attached to the Department of the Army, Corps of Engineer's Upper dam in Appleton on the Fox River. The proposed project would consist of the following facilities: (1) An existing dam; (2) an existing reservoir with a surface area of 1,430 acres and a gross storage capacity of 6,980 acre-feet; (3) existing powerhouse containing six new turbine-generator units having a total capacity of 1,800 kilowatts; (4) an existing transmission line; and (5) appurtenant facilities. The applicant estimates that the cost of the project is $1,670,028. The average annual generation will be approximately 6.2 gigawatthours.

1. Pursuant to § 4.32(b)(7) of 18 CFR of the Commission's regulations, if any resource agency, Indian Tribe, or person believes that an additional scientific study should be conducted in order to form an adequate factual basis for a complete analysis of the application on its merit, the resource agency, Indian Tribe, or person must file a request for a study with the Commission not later than 60 days from the issuance date of this notice and serve a copy of the request on the application.

Lois D. Cashell,

Secretary.

[FR Doc. 92–8631 Filed 4–14–92; 8:45 am]

BILLING CODE 6717–01–M

[P–10873–002]

Application Filed With the Commission; Michael P. O'Brien and Robert A. Davis, III

February 28, 1992.

Take notice that the following hydroelectric application has been filed with the Federal Energy Regulatory Commission and is available for public inspection.

a. *Type of application:* Minor Lecense.

b. *Project No.:* 10873–002.

c. Date filed: January 7, 1992.

d. *Applicant:* Michael P. O'Brien and Robert A. Davis, III

e. *Name of project:* Cullasaja River Project.

f. *Location:* On the Cullasaja River, Macon County, North Carolina.

g. *Filed pursuant to:* Federal Power Act 16 U.S.C. 791 (a)–825(r).

h. *Applicant contact:* Robert A. Davis, III, 390 Timber Laurel Lane, Lawrenceville, GA 30243, (404) 995–0891.

i. *FERC contact:* Mary Golato (202) 219–2804

j. *Comment date:* 60 days from the issuance date of this notice.

k. *Description of Project:* The proposed project would consist of the following facilities: (1) An existing dam 208 feet long and 23 feet high; (2) an existing dam 208 feet surface area of 67 acres at a spillway crest elevation of 3,606 feet mean sea level and a gross storage capacity of 462 acre-feet; (3) a new penstock 36 inches in diameter; (4) an existing powerhouse containing a new turbine-generator unit with a proposed capacity of 900 kilowatts; (5) a 150-foot-long, 2.3-kilovolt transmission line; and (6) appurtenant facilities. The applicant estimates that the cost of the project is $457,000. The average annual generation will be approximately 3,100,000 kilowatthours.

1. Pursuant to § 4.32(b)(7) of 18 CFR of the Commission's regulations, if any resource agency, Indian Tribe, or person believes that an additional scientific study should be conducted in order to form an adequate factual basis for a complete analysis of the application on its merit, the resource agency, Indian Tribe, or person must file a request for a study with the Commission not later than 60 days from the issuance date of

this notice and serve a copoy of the request on the applicant.

Lois D. Cashell,

Secretary.

[FP Doc. 92-8643 Filed 4-14-92; 8:45 am]

BILLING CODE 6717-01-M

[Project Nos. 2187-002, et al.]

Hydroelectric Applications (Public Service Co. of Colorado, et al); Applications

Take notice that the following hydroelectric applications have been filed with the Commission and are available for public inspection:

1 *a. Type of application:* Subsequent License.

b. Project No.: 2187-002.

c. Date filed: December 30, 1991.

d. Applicant: Public Service Company of Colorado.

e. Name of project: Georgetown Hydroelectric.

f. Location: On South Clear Creek in Clear Creek County, Colorado, partially within Arapaho National Forest and on U.S. lands administered by the Bureau of Land Management.

g. Filed pursuant to: Federal Power Act 16 USC 791(a)-825(r)

h. Applicant contact: Mr. Timothy J. Flanagan, Kelly, Stansfield & O'Donnell, 1225-17th Street, Suite 2500, Denver, CO 80202-5533, (303) 825-3534.

i. FERC contact: James Hunter at (202) 219-2839

j. Deadline date: June 12, 1992.

k. Status of environmental analysis: This application is not ready for environmental analysis at this time—see attached paragraph El.

l. Description of project: The project as proposed for licensing consists of: (1) The 19-foot-high, 150-foot-long Clear Lake Dam impounding the 26-acre Clear Lake Reservoir; (2) a 1.3-mile-long reach of South Clear Creek; (3) the 26-foot-high, 115-foot-long Georgetown Forebay Dam impounding the 3-acre Forebay Reservoir; (4) a 26 to 34-inch-diameter, 5,410-foot-long steel penstock; (5) a powerhouse containing two 720-kW generating units; and (6) a substation connecting directly to the applicant's distribution system. The average annual generation is 5.91 GWh. The applicant is not proposing any changes to the existing project works. Subsequent licenses are defined in 18 CFR 16.2(e).

m. Purpose of project: Power generated at the project is delivered to customers within the applicant's service area.

n. This notice also consists of the following standard paragraphs: B1 and E1.

2. *a. Type of application:* New Major License.

b. Project no.: 2533-006.

c. Date filed: December 26, 1991.

d. Applicant: Potlatch Corporation.

e. Name of project: Brainerd Hydroelectric Project.

f. Location: On the Mississippi River in the city of Brainerd in Crow Wing County, Minnesota.

g. Filed pursuant to: Federal Power Act, 16 U.S.C. § 791(a)-825(r).

h. Applicant contact. Mr. Glenn R. Koepp, Mead & Hunt, Inc., 6501 Watts Road, Suite 101, Madison, Wisconsin 53719, (608) 273-6380.

i. FERC contact: Mr. Michael Strzelecki, (202) 219-2827.

j. Comment date: June 12, 1992.

k. Status of environmental analysis: This application is not ready for environmental analysis at this time—see attached paragraph E.

l. Description of project: The run-of-river project consists of: (1) A 25-foot-high L-shaped-dam; (2) a 2,500-acre impoundment; (3) a powerhouse containing five generating units with a total installed capacity of 3,342 kW; (4) a three 500-kVA, 2,400/480-volt step-down transformers; and (5) appurtenant facilities.

The applicant is not proposing any changes to the existing project works as licensed. The Applicant estimates the average annual generation from this project to be 18,291 MWh.

m. Purpose of project: All project energy generated would be utilized by the Applicant.

n. This notice also consists of the following standard paragraphs: B1 and E.

o. Available locations of application: A copy of the application, as amended and supplemented, is available for inspection and reproduction at the Commission's Public Reference and Files Maintenance Branch, located at 941 North Capitol Street, NE., room 3104, Washington, DC 20426, or by calling (202) 208-1371. A copy is also available for inspection and reproduction at the Potlatch Corporation, located at 207 Avenue C, Cloquet, Minnesota 55720, or by calling Mr. Charles Pottenger at (218) 879-1055.

3 *a. Type of application:* Subsequent License.

b. Project no.: 2275-001.

c. Date filed: December 30, 1991.

d. Applicant: Public Service Company of Colorado.

e. Name of project: Salida Hydroelectric.

f. Location: On the South Fork Arkansas River in Chaffee County, Colorado, partially within San Isabel National Forest.

g. Filed pursuant to: Federal Power Act 16 USC §§ 791(a)-825(r).

h. Applicant contact: Mr. Timothy J. Flanagan, Kelly, Stansfield & O'Donnell, 1225-17th Street, Suite 2500 Denver, CO, 80202-5533 (303) 825-3534.

i. FERC contact: James Hunter at (202) 219-2839.

j. Deadline date: May 27, 1992.

k. Status of environmental analysis: This application is not ready for environmental analysis at this time—see attached paragraph E1.

l. Description of project: The project consists of two developments, Salida No. 1, consisting of: (1) a 10-foot-high, 50-foot-long dam impounding the 3-acre-foot Garfield Reservoir; (2) a 26 to 24-inch-diameter, 4,806-foot-long gravity pipeline; (3) a 29-foot-high, 200-foot-long dam impounding the 13-acre-foot Fooses Reservoir; (4) a 30 to 26-inch-diameter, 8,080-foot-long penstock; and (5) Powerhouse No. 1 containing a 750-kW generating unit; and Salida No. 2, consisting of: (1) a 16-foot-high dam impounding the 10-acre-foot Forebay No. 2; (2) a 34 to 26-inch-diameter, 11,668-foot-long penstock; and (3) Powerhouse No. 2 containing a 560-kW generating unit. The project also includes a 25-kV, 2-mile-long transmission line and appurtenant facilities. The average annual generation is 7.67 GWh. The applicant is not proposing any changes to the existing project works.

m. Purpose of project: Power generated at the project is delivered to customers within the applicant's service area.

n. This notice also consists of the following standard paragraphs: B1 and E1.

4 *a. Type of application:* New Major License.

b. Project nos.: 2357-003.

c. Date filed: October 21, 1991.

d. Applicant: Wisconsin Electric Power Company.

e. Name of project: White Rapids Project.

f. Location: On the Menominee River in Menominee County, Michigan and Marinette County, Wisconsin.

g. Filed purusant to: Federal Power Act, 16 U.S.C. 791(a)-825(r).

h. Applicant contact: Mr. Richard G. Fuller, Wisconsin Electric Power Company, 1401 South Carpenter Avenue, Iron Mountain, MI 49802, (906) 779-2484.

i. FERC contact: Robert Bell (dt) (202) 219-2806.

j. Comment date: May 13, 1992.

k. Status of environmental analysis: This application is not ready for

environmental analysis at this time—see attached standard paragraph El.

l. Description of project: The project as licensed consists of the following: The existing project consists of: (1) A 240 foot long earth dike, located at the left end of the dam when facing downstream, with a crest elevation of 722.8 feet NGVD and a minimum crest width of 16 feet, constructed of clay and gravel fill with a concrete core approximately 75 feet long; (2) a 480 foot long earth dike, located at the right end of the dam when facing downstream, with a crest 12 feet wide and an elevation of 723.4 feet NGVD, constructed of clay and gravel fill with a sheet pile cutoff wall driven to bedrock, a tile drainage system, and a concrete corewall; (3) a reservoir with a surface area of 435 acres and a total volume of 5,155 acre-feet at the normal maximum elevation of 716.5 feet NGVD; (4) a reinforced concrete spillway on bedrock with a crest elevation of 701.4 feet NGVD containing (a) Nine 15.5 foot high by 24 foot wide Tainter gates, operated by two mobile electric hoists, (b) a 6 foot wide fish sluice, located on the right end of the spillway, non operational since 1949, and (c) a stilling pool and flexible apron located downstream from the spillway; (5) a powerhouse with a reinforced concrete substructure on bedrock, 133 feet long by 72 feet wide, and a steel frame brick superstructure, 36 feet high, containing (a) 35-ton crane, running overhead on rails, (b) a restroom with holding tank for waste water (c) three S. Morgan Smith, vertical-shaft, Francis type turbines rated at 4,385 hp and 3,100 hp and (d) three General Electric 2,300 V three phase, 60 cycle generators rated at 3,000 kW, 3,000 kW and 2,000 kW; (6) a transmission system containing (a) One 3 phase, 10,500 kVA, 60 cycle, oil filled transformer (b) switch gears, along with associated metering and protection equipment (c) a 0.28 mile, 138 kV, transmission line consisting of one 3 phase circuit of 4/0 ACSR conductors. No changes are being proposed for this new license. The applicant estimates the average annual generation for this project would be 41,461 MWH. The dam and existing project facilities are owned by the applicant.

m. Purpose of project: Project power would be utilized by the applicant for sale to its customers.

n. This notice also consists of the following standard paragraphs: B1 and E1.

o. Available location of application: A copy of the application, as amended and supplemented, is available for inspection and reproduction at the Commission's Public Reference and Files Maintenance Branch, located at 941 North Capitol Street NE., room 3104, Washington, DC 20426, or by calling (202) 208–1371. A copy is also available for inspection and reproduction at Wisconsin Electric Power Company 1401 South Carpenter Avenue Iron Mountain, MI 49802 (906) 779–2484.

5 *a. Type of application:* New Major License.

b. Project no.: 2362–002.

c. Date filed: December 30, 1991.

d. Applicant: Blandin Paper Company.

e. Name of project: Blandin Hydroelectric Project.

f. Location: On the Mississippi River in the city of Grand Rapids in Itasca County, Minnesota..

g. Filed purusant to: Federal Power Act, 16 U.S.C. 791(a)–825(r).

h. Applicant contact: Mr. Joseph Maher, Manager of Engineering, Blandin Paper Company, 115 First Street SW., Grand Rapids, Minnesota 55744, (218) 327–6398.

i. FERC contact: Mr. Michael Strzelecki, (202) 219–2827.

j. Comment date: June 1, 1992.

k. Status of environmental analysis: This application is not ready for environmental analysis at this time—see attached standard paragraph E.

l. Description of project: The run-of-river project as licensed consists of: (1) A 25-foot-high dam on the Mississippi River; (2) a 465-acre impoundment; (3) a powerhouse containing two generating units having a total installed capacity of 2.1 MW; (4) a short transmission line extending from the powerhouse to the Blandin mill; and (5) appurtenant facilities.

The Applicant is not proposing any changes to the existing project works as licensed. The Applicant estimates the average annual generation from this project to be 10,565 MWh.

m. Purpose of project: All project energy generated would be utilized by the Applicant..

n. This notice also consists of the following standard paragraphs: B1 and E.

o. Available locations of application: A copy of the application, as amended and supplemented, is available for inspection and reproduction at the Commission's Public Reference and Files Maintenance Branch, located at 941 North Capitol Street NE., room 3104, Washington, DC 20426, or by calling (202) 208–1371. A copy is also available for inspection and reproduction at the Blandin Paper Company referenced above.

6 *a. Type of application:* Minor License.

b. Project no.: 10895–000.

c. Date filed: September 10, 1991.

d. Applicant: Michiana Hydro-electric Power Corporation.

e. Name of project: Mishawaka Project.

f. Location: On the St. Joseph River, the City of Mishawaka, St. Joseph County, Indiana.

g. File pursuant to: Federal Power Act 16 U.S.C. 791 (a)–825(r).

h. Applicant contact: John E. Fisher, P.E., Partner, Lawson-Fisher Associates, 525 West Washington Street, South Bend, IN 46601, (219) 234–3167.

i. FERC contact: Mary Golato (202) 219–2804.

j. Deadline date: May 29, 1992.

k. Status of environmental analysis: This application is not ready for environmental analysis at this time—see attached paragraph E.

l. Description of project: The project structures to be licensed consist of: (1) An existing timber crib grouted rock gravity dam about 327 feet long and 10 feet high; (2) a proposed concrete and brick powerhouse at the north embankment, about 80 feet long and 60 feet wide, equipped with two vertical, adjustable blade turbines with a total capacity of 1,480 kilowatts; (3) a proposed forebay channel for the powerhouse, about 180 feet long and 60 feet wide, and a tailrace channel of about 40 feet long and 50 feet wide; (4) a reservoir with a surface area of 115 acres at the normal surface elevation 694 feet mean sea level; (5) a proposed fish ladder and bypass facilities; and (6) appurtenant facilities.

m. Purpose of project: All project energy generated would be utilized by the applicant for sale to its customers.

n. This notice also consists of the following standard paragraphs: A2, B1 and E.

o. Available locations of application: A copy of the application, as amended and supplemented, is available for inspection and reproduction at the Commission's Public Reference and Files Maintenance Branch, located at 941 North Capitol Street NE., room 3104, Washington, DC 20426, or by calling (202) 219–1371. A copy is also available for inspection and reproduction at Mr. John E. Fisher, Lawson Fisher Associates, 525 West Washington Street, South Bend, Indiana 46601, (219) 234–3167.

a. Type of application: Preliminary Permit.

b. Project no.: 11038–000.

c. Date filed: November 1, 1990.

d. Applicant: County of Arapahoe and Town of Parker, Colorado.

e. Name of project: Upper Gunnison Basin Project

f. Location: Partially within the Gunnison National Forest, San Isabel National Forest, and the Pike National Forest on the Taylor River, the Slate River, the East River, Lottis Creek, Willow Creek, Copper Creek, Dead Man Gulch, West Brush Creek, Cement Creek, Texas Creek, East Brush Creek, and Middle Brush Creek in Gunnison, Chaffee, and Park Counties, Colorado. Sixth Meridian in T12S, R76W; T12S, R77W; T13S, R77W; T13S, R82W; T13S, R84W; T13S, R85W; T13S, R86W; T14S, R78W; T14S, R79W; T14S, R80W; T14S, R82W; T14S, R83W; T14S, R84W; T15S, R80W; T15S, R81W; T15S, R82W; T15S, R84W; T15S, R85W; and T15S, R86W. New Mexico Meridian in T49N, R4E; T50N, R1E; T50N, R4E; T50N, R5E; T50N, R1W; T51N, R1E; T51N, R4E; and T51N, R1W.

g. Filed pursuant to: Federal Power Act, 16 U.S.C. 791(a)–825(r).

h. Applicant contact:

Ms. Jeannie Jolly, Chairman, Board of County Commissioners, Arapahoe County Building, 5334 South Prince Street, Littleton, Colorado 80166, (303) 795–4563.

Mr. Frank P. Jaeger, Public Works Director, Town of Parker, P.O. Box 667, Parker, Colorado 80134, (303) 795–4563.

i. FERC Contact: Mr. Michael Strzelecki, (202) 219–2827.

j. Comment date: May 27, 1992.

k. Description of project: The proposed power and water supply project would utilize the existing Bureau of Reclamation's Taylor Park Reservoir as a lower reservoir for two pumped storage developments and would consist of two power generating developments and three water conveyance developments. The Taylor Park Reservoir is also part of the proposed Rocky Point Pumped Storage Project No. 7802 whose license application is presently being processed by the Commission.

The first pumped storage development would consist of: (1) A 450-foot-high dam creating a 4,340-acre upper reservoir on Lottis Creek at the head of Union Canyon; (2) an 8,000-foot-long, 11-foot-diameter power tunnel connecting the upper reservior with a powerhouse; (3) the powerhouse with a total installed capacity of 60 MW; (4) a 2,000-foot-long, 11-foot-diameter tailrace returning water to the lower reservoir; (5) a 25-mile-long transmission line of undetermined location; and (6) appurtenant facilities.

The second pumped storage development would consist of: (1) A 194-foot-high dam creating a 980-acre upper reservoir on the Taylor River; (2) a 4,000-foot-long power tunnel connecting the upper reservoir with a powerhouse; (3) the powerhouse with an undetermined generating capacity; (4) a tailrace returning water to the lower reservoir; (5) a short transmission line interconnecting with the proposed transmission line of the first development; and (6) appurtenant facilities.

The first proposed water conveyance development would consist of: (1) A series of short diversion structures on the following creeks: East River, Cooper Creek, West Brush Creek, Middle Brush Creek, East Brush Creek, Cement Creek, Deadman Gulch, Spring Creek, Taylor River, Texas Creek, and Willow Creek; and (2) a 36-mile-long system of pipes collecting the water from these diversions and conveying it to the proposed upper reservoir of the first development.

The second proposed water conveyance development would consist of: (1) An intake on Willow Creek; and (2) an 11,400-foot-long, 8-foot-diameter tunnel conveying water to the proposed upper reservoir of the first development.

The third proposed water conveyance development would consist of a 42-mile-long aqueduct conveying water from the proposed power tunnel of the first development to the existing Denver Water Development's Antero Reservoir for water supply purposes.

No new roads will be needed to conduct the studies. The approximate cost of the studies would be $4,700,000.

l. This notice also consists of the following standard paragraphs: A5, A7, A9, A10, B, C, and D2.

8 *a. Type of application:* Amended Application for Preliminary Permit.

b. Project no. 11092–000.

c. Date filed: February 21, 1991; Amended March 12, 1992.

d. Applicant: Sacramento Municipal Utility District (SMUD) & El Dorado County Water Agency (EL Dorado).

e. Name of project: Upper American River Project Expansion

f. Location: Partially within El Dorado National Forest, on South Fork American River, Silver Fork American River, and Silver Creek, a tributary of the South Fork American River; in El Dorado County, California. Sections 33 & 34, T12N, R14E; Sections 1, 2, 3, 10 & 11, T11N, R14E; Sections 3, 4, 17, 21, 22, & 24–28, T10 & 11N, R16E; Section 9, 10, 15—18, 22–24, T11N, R15&16E; Sections 19 & 30, T11N, R12E.

g. Filed pursuant to: Federal Power Act, 16 USC 791(a)-825(r).

h. Applicant contact: Mr. S. David Freeman, Sacramento Municipal District, 6201 S Street, P.O. Box 15830, Sacramento, CA 95819, (916) 452–3211.

i. FERC contact: Mr. Surender M. Yepuri, P.E., (202) 219–2847.

j. Comment date: May 6, 1992.

k. Description of project: The proposed multipurpose project, consisting of the four inter related components, would collectively enhance SMUD's licensed Upper American River Project No. 2101—expand the water supply, operational flexibility, power regulation capabilities, and load following capabilities.

(i) Jones Fork Hydroelectric Power Plant—This component of the proposed project would use applicant's existing Union Valley dam and reservoir and Ice House dam and reservoir and would include: (1) a 10,000-foot-long water conductor system; (2) a powerhouse containing one turbine/generator unit with a rated capacity of 35 MW; and (3) appurtenant structures.

(ii) Lower Ice House Reservoir Addition—This component of the proposed project would include: (1) a 138-foot-high concrete-faced rockfill main dam at elevation 5,328 feet msl; (2) a 30,000 acre-foot reservoir at elevation 5,320 feet msl; and (5) appurtenant structures.

(iii) South Fork Diversion—This component of the proposed project, diverting water from the South Fork of American River and its tributaries and conveying it into the Ice House Reservoir would include: (1) A diversion dam (Forni Diversion) on South Fork American River at elevation 5,490 feet msl; (2) a 12-foot-diameter, 8.5-mile-long South Fork Tunnel conveying water from the Forni Diversion to the existing Ice House Reservoir; (3) Forni Creek Diversion structures and connections conveying water into the South Fork Tunnel; and (4) appurtenant structures.

(iv) Iowa Hill Pumped Storage Facility—This component of the proposed project would use the existing Slab Creek reservoir and would include: (1) An earthfill ring dike at elevation 3,077 feet msl, with a spillway section; (2) a 4,200-foot-long water conductor system; (3) an underground powerhouse containing two generator/motor units with a total rated capacity of 250 MW; (4) a 7,000-foot-long, 230-kV transmission line connecting to the applicant's existing line and the Iowa Canyon Switchyard; and (5) appurtenant structures.

The applicant estimates (1) An increase of 448 GWh in the average annual generation from the Jones Fork Hydroelectric Power Plant, the South Fork Diversion, and the Iowa Hill Pumped Storage Facility and (2) the cost of the work to be performed under the permit to be $5,000,000.

l. This notice also consists of the following standard paragraphs: A8, A10, B, C, and D2.

m. Refiling of comments or motions to intervene in this docket is not necessary. This notice supplements the notice issued January 2, 1992, for SMUD's Project No. 11092 in light of (1) The joint Amended Application filed on March 12, 1992, adding El Dorado as co-applicant for Project No. 11092; and (2) El Dorado's motion to withdraw its competing October 3, 1991, application for a preliminary permit for Project No. 11017.

9 *a. Type of application:* Minor License.

b. Project no.: 11219–000.

c. Date filed: December 30, 1991.

d. Applicant: Mayo Hydro.

e. Name of project: Mayo Dam Hydro Project.

f. Location: On the Mayo River, near Mayodan, Rockingham County, North Carolina.

g. Filed pursuant to: Federal Power Act 16 U.S.C. 791(a)—825(r).

h. Applicant contact: Mr. Charles C. Wood, Jr., Mayo Hydro, 1240 Springwood Church Road, Gibsonville, NC 27249, (919) 449–5054.

i. FERC contact: Mary Golato (202) 219–2804.

j. Deadline date: May 29, 1992.

k. Status of environmental analysis: This application is not ready for an environmental analysis at this time—see attached paragraph E.

1. Description of Project: The proposed project would consist of: (1) An existing concrete, stone masonry dam 590.5 feet long and 13.5 feet high, (2) an existing reservoir with a surface area of about 11 acres, a normal water surface elevation of 586.4 feet mean sea level, and storage capacity of 85 acre-feet; (3) an existing 24.5-foot-long abutment section; (4) an existing power canal about 1,600 feet long, 30 to 40 feet wide; (5) an existing 10-foot-diameter penstock approximately 85 feet long; (6) two proposed powerhouses containing a total of three Francis turbine-generator units with a total installed capacity of 1,104 kilowatts; (7) two tailraces, one approximately 50 feet long by 30 feet wide and the other approximately 85 feet long by 40 feet wide; (8) a proposed 100-foot-long, 12.4-kilovolt transmission line; and (9) appurtenant facilities. The average annual generation would be 3,840,000 kilowatthours. The dam is owned by the applicant.

m. Purpose of project: Power generated would be sold to a local utility.

n. This notice also consists of the following standard paragraphs: A2, B1, and E

o. *Avaiable location of application:* A copy of the application, as amended and supplemented, is available for inspection and reproduction at the Commission's Public Reference and Files Maintenance Branch, located at 941 North Capitol Street, NE., room 3104, Washington, DC 20426, or by calling (202) 208–1371. A copy is also available for inspection and reproduction at the address of Mr. Charles C. Wood, Jr., 1240 Springwood Church Road, Gibsonville, NC 27429, and at the Mayodan Library, 101 North 10th Avenue, Mayodan, NC 27027, (919) 548–6951.

10 *a. Type of application:* Preliminary Permit.

b. Project no.: 11226–000.

c. Date filed: January 13, 1992.

d. Applicant: Hammond Hydroelectric Company.

e. Name of project: Challis Creek Hydro Site No. 2 Project.

f. Location: On Challis and Mill Creeks in Custer County, Idaho, near the town of Challis. T.14N., R18E., sections 2, 11, and 12 Boise Meridian.

g. Filed pursuant to: Federal Power Act, section 30 16 U.S.C. 791(a)–825(r).

h. Applicant contact: Jack S. Hammond, P.E., P.O. Box 460, Troy, ID 83871–0460, (208) 835–8443.

i. FERC contact: Ms. Deborah Frazier-Stutely (202) 219–2842.

j. Comment date: June 1, 1992.

k. Description of project: The proposed project would consist of (1) A diversion dam on Challis Creek at elevation 5,390 feet; (2) a 42-inch-diameter, 11,000-foot-long steel pipe; (3) a diversion dam on Mill Creek at elevation 5,390 feet; (4) a 24-inch-diameter, 6,000-foot-long steel pipe; (5) a 51-inch-diameter, 100-foot-long penstock directing flows from the two diversions to; (6) a powerhouse containing one generating unit with an installed capacity of 900 kW, producing an estimated annual energy output of 4.5 million kWh; (7) a 60-inch-diameter, 200-foot-long tailrace discharging project flows at the junction of Challis and Mill Creeks; and (8) a 1-mile-long transmission line tying into an existing line.

The applicant estimates the cost of the studies to be conducted under the preliminary permit would be $20,000. No new roads will be needed for the purpose of conducting these studies.

l. Purpose of project: Project power would be sold to a local utility.

m. This notice also consists of the following standard paragraphs: A5, A7, A9, A10, B, C, D2.

11 *a. Type of application:* Preliminary Permit.

b. Project no.: 11240–000.

c. Date filed: January 21, 1992.

d. Applicant: Swanton Village, Vermont.

e. Name of project: West Rutland Pumped Storage.

f. Location: Near the Castleton River in the Town of West Rutland, Rutland County, Vermont.

g. Filed pursuant to: Federal Power Act U.S.C. 791(a)–825(r).

h. Applicant contact: Mr. George H. Lague, 120 First Street, Swanton, Vermont 05488, (802) 868–3397.

i. FERC contact: Charles T. Raabe (202) 219–2811.

j. Comment date: May 13, 1992.

k. Competing Application: Project No. 11241–000.

Date filed: January 21, 1992.

Due date: April 30, 1992.

l. Description of Project: Applicant proposes to study two closed-loop alternatives. Alternative 1 would consist of: (1) An upper reservoir having 1,240 acre-foot useable storate capacity of water surface elevation 1400 feet msl; (2) a 13-foot-diameter, 1,170-foot-deep vertical shaft; (3) a 15-foot-diameter, 6,500-foot-long tunnel; (4) an underground powerhouse containing two turbine/pump units each rated at 80–MW at a 1.210-foot-maximum head; (5) existing quarries utilized as a lower reservoir having water surface elevation 500 feet msl; (6) a 13.8/115–kV switchyard; (7) a 1.8-mile-long, 115–kV transmission line; and (8) appurtenant facilities. Alternative 2 would consist of: (1) an upper reservoir having 1,500 acre-foot useable storage capacity at water surface elevation 1460 feet msl; (2) a 13-foot-diameter, 200-foot-deep vertical shaft; (3) a 13-foot-diameter, 8,700-foot-long tunnel; (4) an underground powerhouse containing two turbine/pump units each rated at 100–MW at a 1,270-foot-maximum head; (5) existing quarries utilized as a lower reservoir having water surface elevation 500 feet msl; (6) a 13.8/115–kV switchyard; (7) a 1.8-mile-long, 115–kV transmission line; and (8) appurtenant facilities.

The project would be interconnected to the existing West Rutland Substation. Applicant estimated that the cost of the studies under the permit would be $350,000. Project energy would be sold to/purchased from one or more electric utilities. The existing quarries are owned by Gawet Marble & Granite, Inc.

m. This notice also consists of the following standard paragraphs: A8, A10, B, C and D2.

12 *a. Type of application:* Preliminary Permit.

b. Project no.: 11243–000.

c. Date filed: January 23, 1992.

d. Applicant: Whitewater Engineering Corporation.

e. Name of project: Power Creek Hydroelectric Project.

f. Location: Partially within the Chugach National Forest on Power Creek near the city of Cordova in Alaska. Sections 4, 5, 6, 7, 8, and 9 in T15S, R2W; sections 12, 13, 23, 24, 26, and 27 in T15S, R3W.

g. Filed pursuant to: Federal Power Act, 16 U.S.C. 791(a)–825(r).

h. Applicant contact: Thom A. Fischer, President, Whitewater Engineering Corporation, 1050 Larrabee Avenue, suite 104–707, Bellingham, WA 98225, (206) 733–3008.

i. FERC contact: Mr. Michael Strzelecki, (202) 219–2827.

j. Comment date: May 27, 1992.

k. Description of project: The proposed project would consist of: (1) A 20-foot-high diversion structure on Power Creek; (2) an 8,000-foot-long, 96-inch-diameter penstock; (3) a powerhouse with a total installed capacity of 5.0 MW; (4) a tailrace returning the water to Power Creek; (5) a 7-mile-long transmission line interconnecting with an existing transmission line at the Eyak Substation; and (7) appurtenant facilities.

No new roads will be needed to conduct the studies. The approximate cost of the studies would be $217,000.

l. This notice also consists of the following standard paragraphs: A5, A7, A9, A10, B, C, and D2.

13 *a. Type of application:* Preliminary Permit.

*b. Project no.:*11244–000.

c. Date filed: January 29, 1992.

d. Applicant: Whitewater Engineering Corporation.

e. Name of Project: Silver Lake Hydroelectric Project.

f. Location: Partially within the Chugach National Forest on Silver Lake and the Duck River near the city of Valdez in Alaska. Sections 1, 2, 11, and 12 in T11S, R8W; section 36 in T10S, R8W; sections 3, 4, 5, 6, 7, 8, 9, 10, 11, 14, and 15 in T11S, R7W; and sections 31, 32, 33 in T10S, R7W.

g. Filed pursuant to: Federal Power Act, 16 U.S.C. 791(a)–825(r).

h. Applicant contact: Thom A. Fischer, President, Whitewater Engineering Corporation, 1050 Larrabee Avenue, suite 104–707, Bellingham, WA 98225, (206) 733–3009.

i. FERC contact: Mr. Michael Strzelecki, (202) 219–2827.

j. Comment date: May 27, 1992.

k. Description of project: The proposed project would consist of: (1) A 100-foot-high dam at the mouth of the U.S. Forest Service's existing Silver Lake raising the existing water elevation by 90 feet and creating a 1,670-acre impoundment; (2) a 6,000-foot-long, 8-foot-diameter penstock; (3) a powerhouse with a total installed capacity of 15.0 MW; (4) a tailrace returning the water to the Duck River; (5) an 18-mile-long transmission line interconnecting with an existing Copper Valley Electric Association, Inc. transmission line near Valdez; and (7) appurtenant facilities.

No new roads will be needed to conduct the studies. The approximate cost of the studies would be $250,000.

l. This notice also consists of the following standard paragraphs: A5, A7, A9, A10, B, C, and D2.

14. *a. Type of application:* Preliminary Permit.

b. Project no.: 11252–00.

c. Date filed: February 7, 1992.

d. Applicant: J. V. Coan & Associates.

e. Name of project: Grand Mesa Hydropower Project.

f. Location: Partially on lands adminstered by the Bureau of Land Management and the National Forest Service utilizing the applicant's existing Doughspoon/Dirty George Aqueduct system near the city of Delta in Delta County, Colorado. Section 36 in T12S, R96W; sections 30 and 31 in T12S, R95W; sections 6 and 7 in T13S, R95W; sections 1, 12, 13, 14, 15, 22, 23, 24, 25, 26, 27, 28, 30, and 36 in T13S, R96W; sections 6, 18, and 19 in T14S, R95W; and sections 1, 12, 13, 24, and 25 in T14S, R96W.

g. Filed pursuant to: Federal Power Act, 16 U.S.C. 791(a)–825(r).

h. Applicant contact: Mr. Jim Coan, J. V. Coan & Associates, 1723 East 3rd Street, Delta, Colorado 99508, (303) 874–7734.

i. FERC contact: Mr. Michael Strzelecki, (202) 219–2827.

j. Comment date: May 13, 1992.

k. Description of project: The proposed project would include three developments. The first development would consist of : (1) The applicant's existing diversion structure on Dirty George Creek; (2) approximately 5 miles of the existing Dirty George Aqueduct from the diversion structure to a powerhouse; (3) a proposed 4,260-foot-long, 10-inch-diameter pipeline from the applicant's existing Porter Reservoir #4 to the applicant's existing Dugger Reservoir; (4) replacement of an existing pipeline with a 5,500-foot-long, 12-inch-diameter Dugger pipeline from the Dugger Reservoir to its interconnection with the Doughspoon pipeline; (5) replacement of an existing pipeline with a 7,200-foot-long, 10-inch-diameter Doughspoon pipeline from the applicant's existing Doughspoon Reservoir to its interconnection with the Dugger pipeline; (6) replacement of an existing pipline with a 5,460-foot-long, 16-inch-diameter pipeline from the interconnection of the Dugger and Doughspoon pipelines to a powerhouse; (7) a proposed powerhouse with a total installed capacity of 1,000 kW; (8) a proposed 2.6-mile-long extension of an existing 7.2/12.4 kV transmission line interconnecting with the proposed transmission line of the first development; and (9) appurtenant facilities.

The second development would consist of: (1) Replacement of an existing pipeline with a 13,600-foot-long, 24-inch-diameter pipeline from the powerhouse of the first development to a second powerhouse on the north bank of Doughspoon Creek; (2) the proposed second powerhouse with a total installed capacity of 2,500 kW; (3) a proposed 2.5-mile-long transmission line interconnecting with an existing transmission line near the applicant's existing Delta Reservoir; and (4) appurtenant facilities.

The third development would consist of: (1) Replacement of an existing pipeline with a 13,200-foot-long, 20-inch-diameter pipeline from the second powerhouse to a third powerhouse near the applicant's existing Delta Reservoir; (2) the proposed third powerhouse with an installed capacity of 500 kW; (3) a proposed tailrace returning water to the Delta Reservoir; and (4) appurtenant facilities.

No new roads will be needed to conduct the studies. The approximate cost of the studies would be $75,000.

1. This notice also consists of the following standard paragraphs: A5, A7, A9, A10, B, C, and D2.

15 *a. Type of application:* Preliminary Permit.

b. Project No.: 11261–000.

c. Date filed: February 28, 1992.

d. Applicant: City of Anaheim et al.

e. Name of project: Lake Elsinore.

f. Location: In Cleveland National Forest, at Lake Elsinore, supplied by the San Jacinto River, in Riverside County, California, Township 6 S, Range 5 W, and Section 23.

g. Filed pursuant to: Federal Power Act 16 USC 791(a)–825(r).

h. Applicant contact: Mr. Edward K. Aghjayan, Public Utility Department, City of Anaheim, 222 S. Harbor Blvd., Anaheim, CA 92805, (714) 254–5100.

i. FERC contact: Michael Spencer at (202) 219–2846.

j. Comment date: June 8, 1992.

k. Description of project: The proposed pumped storage project would consist of: (1) A 120-foot-high rockfill

upper dam; (2) a 100-foot-high rockfill dike at the other end of the upper reservoir with intake facilities; (3) an upper reservoir with a surface area of 95 acres, and a storage capacity of 2,000 acre-feet; (4) Lake Elsinore would be used as the lower reservoir; (5) a 12-foot-diameter, 10,900-foot-long-tunnel; (6) a powerhouse/pump station with a generating capacity of 240 MW; and (7) a 3-mile-long transmission line. The project would have an estimated average annual generation of 1,920 MWh.

A new access road approximately 2-miles-long will be needed to conduct the studies under the permit. The applicant estimates that the cost of the studies to be conducted under the preliminary permit would be $200,000.

l. Purpose of project: Project power would be used by the cities.

m. This notice also consists of the following standard paragraphs: A5, A7, A9, A10, B, C, and D2.

16 *a. Type of application:* Preliminary Permit.

b. Project No.: 11262–000.

c. Date filed: March 6, 1992.

d. Applicant: Continental Energy Company, NA.

e. Name of project: Mesa Creek Hydroelectric Project.

f. Location: Partially within the Grand Mesa National Forest on Mesa Creek near the town of Mesa in Mesa County, Colorado. Sections 16, 17, 21, 22, and 27 in T11S, R96W.

g. Filed pursuant to: Federal Power Act, 16 U.S.C. 791(a)–825(r).

h. Applicant contact: Mr. Arlan W. Feil, Continental Energy Company, NA, P.O. Box 60251, Grand Junction, Colorado 81506, (303) 243–1425.

i. FERC contact: Mr. Michael Strzelecki, (202) 219–2827.

j. Comment date: June 1, 1992

k. Description of project: The proposed project would consist of: (1) a 3-foot-high diversion structure on Mesa Creek; (2) a 13,100-foot-long, 20-inch-diameter penstock; (3) a powerhouse with a total installed capacity of 1.5 MW; (4) a tailrace returning the water to Mesa Creek; (5) a short transmission line interconnecting with an existing Grand Valley Rural Power Association transmission line located adjacent to the powerhouse; and (7) appurtenant facilities.

No new roads will be needed to conduct the studies. The approximate cost of the studies would be $76,000.

m. This notice also consists of the following standard paragraphs: A5, A7, A9, A10, B, C, and D2.

17 *a. Type of application:* Preliminary Permit.

b. Project no.: 11266–000.

c. Date filed: March 9, 1992.

d. Applicant: Elsinore Valley Municipal Water District.

e. Name of project: Lake Elsinore.

f. Location: In Cleveland National Forest, at Lake Elsinore, supplied by the San Jacinto River, in Riverside County, California, Township 6 S, Range 5 W, and Section 23.

g. Filed pursuant to: Federal Power Act 16 U.S.C. 791(a)–825(r).

h. Applicant contact: Mr. D. James Laughlin, Elsinore Valley Municipal Water District, 31315 Chancy Street, Lake Elsinore CA 92530, (714) 674–3146.

i. FERC contact: Michael Spencer at (202) 219–2846.

j. Comment date: June 12, 1992.

k. Competing application: Project No. 11261–000 filed February 28, 1992.

l. Description of project: The proposed storage project would consist of: (1) An upper reservoir with a surface area of 80 acres, and a storage capacity of 2,000 acre-feet formed by a 120-foot-high rockfill dam at one end and a 50-foot-high rockfill dike at the other end with intake facilities; (2) the existing Lake Elsinore with a surface area of approximately 3,412 acres would be used as the lower reservoir; (3) a 12-foot-diameter, 10,900-foot-long tunnel; (4) a powerhouse/punp station with a generating capacity of 240 MW; and (5) a 3-mile-long transmission line. The project would have an estimated average annual generation of 520,000 MWh.

No new access road will be needed to conduct the studies. The applicant estimates that the cost of the studies to be conducted under the preliminary permit would be $500,000.

m. Purpose of project: Project power would be sold.

n. This notice also consists of the following standard paragraphs: A8, A10, B, C, and D2.

18 *a. Type of application:* Preliminary Permit.

b. Project no.: 11270–000.

c. Date filed: March 23, 1992.

d. Applicant: Coralville Reservoir Hydro Associates.

e. Name of project: Coralville Hydroelectric Project.

f. Location: On the Iowa River, near Iowa City, Johnson County, Iowa.

g. Filed pursuant to: Federal Power Act 16 U.S.C. 791(a)–825(r).

h. Applicant contact: Mr. David K. Iverson, Synergics, Inc., 191 Main Street, Annapolis, MD 21401, (410) 268–8820.

i. FERC contact: Ed Lee (dt) (202) 219–2809.

j. Comment date: June 11, 1992

k. Description of project: The proposed project would utilize the existing U.S. Army Corps of Engineers Coralville Dam and Lake and would consist of: (1) A proposed diversion tunnel to a new powerhouse containing two 6–MW generating units for a total installed capacity of 12 megawatts; (2) a new tailrace; (3) a proposed ½-mile, 13.8–kV transmission line; and (4) appurtenant facilities. The project would have an average annual generation of 52.56 MWh. The applicant estimates that the cost of the studies will be aproximately $100,000. The applicant intends to sell the project generation to a local utility or power company.

1. This notice also consists of the following standard paragraphs: A5, A7, A10, B, C, and D2.

19 *a. Type of application:* Preliminary Permit.

b. Project no.: 11265–000.

c. Date filed: March 9, 1992.

d. Applicant: Portland General Electric Company.

e. Name of project: Clackamas Creeks.

f. Location: In Mount Hood National Forest, on tributaries to the Clackamas river, in Clackamas County, Oregon. Township 5 S Range 6 E Sections 15, 16, 22, 23, 27, 28, and 35—Range 8 E Sections 27, 28, 32 and 33—Township 6 S Range 8 E Sections 5 and 6—Range 7E Sections 1–4.

g. Filed pursuant to: Federal Power Act 16 U.S.C. 791(a)—825(r).

h. Applicant contact: Mr. Gary W. Hackett, Portland General Electric Company, 121 SW Salmon Street, Portland, OR 97204, (503) 464–8005.

i. FERC contact: Michael Spencer at (202) 219–2846.

j. Comment date: June 12, 1992.

k. Description of project: The proposed multi-site project, consisting of the three interrelated components, would collectively enchance the applicant's licensed Oak Grove Project No. 135.

The Three Lynx and Frog Lake developments would consist of: (1) A 10-foot-high diversion dam on each of the following Creeks: Dinner, Deer, Three Lynx, Cripple, and South Fork Cripple, Bull, Pint, and Half Pint; and (2) pipelines with diameters varying between 10 and 30 inches to convey the water to the Oak Grove Project No. 135 flow line.

The Timothy lake development would consist of adding a second powerhouse to the existing Oak Grove powerhouse at Timothy Lake. The new powerhouse would contain a generating unit with a capacity of 1,300 kW.

The proposed developments will increase the estimated average annual generation of Project No. 135 by 17,600 MWh.

No new access road will be needed to conduct the studies. The applicant estimates that the cost of the studies to be conducted under the preliminary permit would be $1,050,000.

l. Purpose of project: Project power would be used by the applicant.

m. This notice also consists of the following standard paragraphs: A5, A7, A9, A10, B, C, and D2.

20. *a. Type of application:* Minor License.

b. Project no.: 10661-000.

c. Date filed: September 24, 1988.

d. Applicant: Michigan Power Company.

e. Name of project: Constantine Hydroelectric Project.

f. Location: On the St. Joseph River near Constantine, St. Joseph County, Michigan.

g. Filed pursuant to: Federal Power Act, 16 U.S.C. 791(a)-825(r).

h. Applicant contact: Mr. R.W. Harmon, American Electric Power Service Corp., 1 Riverside Plaza, Columbus, OH 43215, (614) 223-1638.

i. FERC contact: Michael Dees (202) 219-2807.

j. Deadline date: May 18, 1992.

k. Status of environmental analysis: This application is ready for environmental analysis at this time—see attached standard paragraph D10.

l. Description of project: The existing project consists of the following: (1) An existing dam; (2) a 525 acre reservoir; (3) a headrace cannel; (4) a powerhouse containing four 300-kW generating units; and (5) appurtenant facilities.

m. Purpose of project: All project energy generated would be sold.

n. This notice also consists of the following standard paragraphs: A4 and D10.

o. Available location of application: A copy of the application, as amended and supplemented, is available for inspection and reproduction at the Commission's Public Reference and Files Maintenance Branch, located at 941 North Capitol Street NE., room 3104, Washington, DC, 20426, or by calling (202) 208-1371.

21 *a. Type of application:* Minor License.

b. Project no.: 10836-000.

c. Date filed: October 16, 1989.

d. Applicant: Friends of Keeseville, Inc.

e. Name of project: Ausable.

f. Location: On the Ausable River in the Village of Keeseville, Towns of AuSable and Chesterfield, Counties of Clinton and Essex, New York.

g. Filed pursuant to: Federal Power Act 16 U.S.C. 791(a)—825(r).

h. Applicant contact: Ms. Ann Ruzow Holland, P.O. Box 446, Keeseville, NY 12944, (518) 834-9606.

i. FERC contact: Charles T. Raabe (tag) (202) 219-2811.

j. Deadline date: May 18, 1992.

k. Status of Environmental Analysis: This application is ready for environmental analysis at this time—see attached paragraph D10.

l. Description of project: The proposed run-of-river project would consist of: (1) A rehabilitated 8-foot-high, 160-foot-long timber-crib overflow-type dam; (2) a new reinforced concrete intake structure 35 feet wide and 45 feet long with trash racks angled 45 degrees to the direction of flow and an adjacent fish passage sluice about 12 feet wide; (3) a reservoir having a surface area of about 4.3 acres and a storage capacity of about 17 acre-feet at dam crest elevation 403.2 feet USGS; (4) a new wood penstock 9 feet in diameter and about 250 feet long with a bifurcation at the powerhouse entrance; (5) a new reinforced-concrete powerhouse, 53 feet long, 40 feet wide and about 30 feet high, containing two new 400-kW turbine-generator units; (6) a 4.8-kV underground transmission line 80 feet long; and (7) appurtenant facilities.

Applicant estimates that the average annual generation would be 4,000,000 kWh. Project power would be sold to a public utility. The dam is owned by the Village of Keeseville, New York.

m. This notice also consists of the following standard paragraph: A4 and D10.

n. Available locations of application: A copy of the application, as amended and supplemented, is available for inspection and reproduction at the Commission's Public Reference and Files Maintenance Branch, located at 941 North Capitol Street, NE., room 3104, Washington, DC 20426, or by calling (202) 208-1371. A copy is also available for inspection and reproduction at Friends of Keeseville, Inc., 1 A Mill Street, Keeseville, N.Y. 12944, (518) 834-9606.

Standard Paragraphs

A2. Development application—Any qualified applicant desiring to file a competing application must submit to the Commission, on or before the specified deadline date for the particular application, a competing development application, or a notice of intent to file such an application. Submission of a timely notice of intent allows an interested person to file the competing development application no later than 120 days after the specified deadline date for the particular application. Applications for preliminary permits will not be accepted in response to this notice.

A4. Development application.—Public notice of the filing of the initial development application, which has already been given, established the due date for filing competing applications or notices of intent. Under the Commission's regulations, any competing development application must be filed in response to and in compliance with public notice of the initial development application. No competing applications or notices of intent may be filed in response to this notice.

A5. Preliminary Permit—Anyone desiring to file a competing application for preliminary permit for a proposed project must submit the competing application itself, or a notice of intent to file such an application, to the Commission on or before the specified comment date for the particular application (see 18 CFR 4.36). Submission of a timely notice of intent allows an interested person to file the competing preliminary permit application no later than 30 days after the specified comment date for the particular application. A competing preliminary permit application must conform with 18 CFR 4.30(b)(1) and (9) and 4.36.

A7. Preliminary permit—Any qualified development applicant desiring to file a competing development application must submit to the Commission, on or before the specified comment date for the particular application, either a competing development application or a notice of intent to file such an application. Submission of a timely notice of intent to file a development application allows an interested person to file the competing application no later than 120 days after the specified comment date for the particular application. A competing license application must conform with 18 CFR 4.30(b)(1) and (9) and 4.36.

A8. Preliminary permit—Public notice of the filing of the initial preliminary permit application, which has already been given, established the due date for filing competing preliminary permit applications or notices of intent. Any competing preliminary permit or development application or notice of intent to file a competing preliminary permit or development application must be filed in response to and in compliance with the public notice of the initial preliminary permit application. Initial preliminary permit application. No competing applications or notices of intent to file competing applications may

be filed in response to this notice. A competing license application must conform with 18 CFR 4.30 (b)(1) and (9) and 4.36.

A9. Notice of intent—A notice of intent must specify the exact name, business address, and telephone number of the prospective applicant, include an unequivocal statement of intent to submit, if such an application may be filed, either (1) A preliminary permit application or (2) a development application (specify which type of application), and be served on the applicant(s) named in this public notice.

A10. Proposed scope of studies under permit—A preliminary permit, if issued, does not authorize construction. The term of the proposed preliminary permit would be 36 months. The work proposed under the preliminary permit would include economic analysis, preparation of preliminary engineering plans, and a study of environmental impacts. Based on the results of these studies, the Applicant would decide whether to proceed with the preparation of a development application to construct and operate the project.

B. Comments, Protests, or motions to intervene—Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of the 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 Commission's Rules may become a party to the proceeeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

B1. Protests or motions to intervene—Anyone may submit a protest or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, 385.211, and 385.214. In determining the appropriate action to take, the Commission will consider all protests filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any protests or motions to intervene must be received on or before the specified deadline date for the particular application.

C. Filing and service of responsive documents—Any filings must bear in all capital letters the title "COMMENTS", NOTICE OF INTENT TO FILE COMPETING APPLICATION", "COMPETING APPLICATION", "PROTEST", "MOTION TO INTERVENE", as applicable, and the Project Number of the particular application to which the filing refers. Any of the above-named documents must be filed by providing the original and the number of copies provided by the Commission's regulations to: The Secretary, Federal Energy Regulatory Commission, 825 North Capitol Street NE., Washington, DC 20426. An additional copy must be sent to Director, Division of Project Review, Federal Energy Regulatory Commission, room 1027, at the above-mentioned address. A copy of any notice of intent, competing application or motion to intervene must also be served upon each representative of the Applicant specified in the particular application.

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.

D10. Filing and service of responsive documents—The application is ready for environmental analysis at this time, and the Commission is requesting comments, reply comments, recommendations, terms and conditions, and prescriptions.

The Commission directs, pursuant to § 4.34(b) of the regulations (see Order No. 533 issued May 8, 1991, 56 FR 23108, May 20, 1991) that all comments recommendations, terms and conditions and prescriptions concerning the application be filed with the Commission within 60 days from the issuance date of this notice (May 18, 1992 for Project Nos. 10661–000 and 10836–000). All reply comments must be filed with the Commission within 105 days from the date of this notice (July 1, 1992 for the above two projects).

Anyone may obtain an extension of time for these deadlines from the Commission only upon a showing of good cause or extraordinary circumstances in accordance with 18 CFR 385.2008.

All filings must (1) Bear in all capital letters the title "COMMENTS", "REPLY COMMENTS", "RECOMMENDATIONS," "TERMS AND CONDITIONS," or "PRESCRIPTIONS;" (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds: (3) furnish the name, address, and telephone number of the person submitting the filing; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, recommendations, terms and conditions or prescriptions must set forth their evidentiary basis and otherwise comply with the requirements of 18 CFR 4.34(b). Agencies may obtain copies of the application directly from the applicant. Any of these documents must be filed by providing the original and the number of copies required by the Commission's regulations to: The Secretary, Federal Energy Regulatory Commission, 825 North Capitol Street NE., Washington, DC 20426. An additional copy must be sent to Director, Division of Project Review, Office of Hydropower Licensing, Federal Energy Regulatory Commission, Room 1027, at the above address. Each filing must be accompanied by proof of service on all persons listed on the service list prepared by the Commission in this proceeding, in accordance with 28 CFR 4.34(b), and 385.2010.

E. Filing and service of responsive documents—The application is not ready for environmental analysis at this time; therefore, the Commission is not now requesting comments, recommendations, terms and conditions or prescriptions.

When the application is ready for environmental analysis, the Commission will notify all persons on the service list and affected resource agencies and Indian tribes. If any person wishes to be placed on the service list, a motion to intervene must be filed by the specified deadline data here in for such motions. All resource agencies and Indian tribes that have official responsibilities that may be affected by the issues addressed in this proceeding, and persons on the service list will be able to file comments, terms and conditions, and prescriptions within 60 days of the date the Commission issues a notification letter that the application is ready for an environmental analysis. All reply comments must be filed with the Commission within 105 days from the date of that letter.

All filings must (1) Bear in all capital letters the title "PROTEST" or "MOTION TO INTERVENE;" (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. Any of these documents must be filed by providing the original and the number of copies required by the Commission's regulations to: The Secretary, Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426. An additional copy must be

sent to Director, Division of Project Review, Office of Hydropower Licensing, Federal Energy Regulatory Commission, Room 1027, at the above address. A copy of any protest or motion to intervene must be served upon each representative of the applicant specified in the particular application.

E1. Filing and Service of Responsive Documents—The application is not ready for environmental analysis at this time; therefore, the Commission is not now requesting comments, recommendations, terms and conditions, or prescriptions.

When the application is ready for environmental analysis, the Commission will issue a public notice requesting comments, recommendations, terms and conditions, or prescriptions.

All filings must (1) Bear in all capital letters the title "PROTEST" or "MOTION TO INTERVENE;" (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. Agencies may obtain copies of the application directly from the applicant. Any of these documents must be filed by providing the original and the number of copies required by the Commission's regulations to: The Secretary, Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426. An additional copy must be sent to Director, Division of Project Review, Office of Hydropower Licensing, Federal Energy Regulatory Commission, room 1027, at the above address. A copy of any protest or motion to intervene must be served upon each representative of the applicant specified in the particular application.

Dated: April 9, 1992, Washington, DC.

Lois D. Cashell,

Secretary.

[FR Doc. 92-8633 Filed 4-14-92; 8:45 am]

BILLING CODE 8710-01-M

[Docket No. GP92-9-000]

Arkansas Oil and Gas Commission, Tight Formation Determination Arkansas-2, Docket No. JD92-01180T; Preliminary Finding

April 9, 1992

On November 12, 1991, the Arkansas Oil and Gas Commission (Arkansas) notified the Commission that it determined that the Mansfield Sand in the Mansfield Gas Field, in portions of Sebastian and Scott Counties, Arkansas, qualifies as a tight formation under section 107(b) of the Natural Gas Policy Act of 1978.

For the reasons discussed below, the Commission issues this preliminary finding that Arkansas' determination is not supported by substantial evidence.

Arkansas' Determination

Arkansas determined that the Mansfield Sand in the Mansfield Gas Field, in portions of Sebastian and Scott Counties, Arkansas, qualifies as a tight formation.[1] The recommended area contains approximately 30,000 acres.[2] M&P Exploration Co. and Grubbs Energy Co. requested Arkansas to designate the Mansfield Sand as a tight formation.

Arkansas' determination was based on permeability data from one well and production rate data from six wells. The notice indicates that, except for wells that encounter a fracture system, most of the wells completed in the Mansfield Sand would not achieve a production rate in excess of the applicable guidelines, prior to stimulation.

On February 24, 1992, in response to a tolling letter sent under section 275.202 of the regulations, Arkansas reaffirmed its determination.[3] Arkansas' response included a backpressure test on a previously unreported gas well (the Godwin #4 well); the test showed that the well produced only 44 Mcfd prior to stimulation and 48 Mcfd after frac. Arkansas also provided an analysis of two drill cutting samples that suggest low permeability characteristics were encountered.

Discussion

The Mansfield Sand within the recommended area is folded. The fold is known as the Hartford anticline (an anticline is a fold of rock strata that inclines downward on both sides from a median line or axis). Arkansas states that the Hartford anticline is fractured and that the fractures appear to control production.[4] Arkansas notes that wells are placed near suspected fractures since gas can usually be produced from such wells, even with low matrix porosity and permeability, without the use of artificial stimulation. However, sands without fractures must be stimulated (fractured artificially) to achieve commercial production.

The record indicates that there are 54 wills that currently produce from the Mansfield Sand in the recommended area. Twenty-nine (29) of these wells produced without stimulation due to natural fractures. The remaining 25 wells are stimulated before production (fractured artificially). All of the unstimulated wells are concentrated along the crest of the Hartford anticline and a small portion of its northern flank.[5] In contrast, most of the producing stimulated wells are located along the eastern, western, and southern flanks of the Hartford anticline and surround the unstimulated wells.

Thus, the record shows that there are two distinct permeability systems at work within the recommended area—one that has been substantially developed without stimulation because of natural fractures and one that needs to be stimulated to obtain production since there are no natural fractures.

The permeability and flow rate data in the record comes from stimulated wells located on the eastern, western and southern flanks of the Hartford anticline only and show that these areas meet the Commission's guidelines. The record contains no permeability and flow rate data for the unstimulated wells located along the crest and nothern flank of the Hartford anticline, however.

Under the Commission's tight formation guidelines, permeability resulting from natural fractures must be considered when determining whether a formation meets the Commission's *in situ* permeability guideline.[6] Additionally, the Commission has stated

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[1] Arkansas defines the Mansfield Sand as those sources of supply which are stratigraphically equivalent to the interval between the subsurface depths of 1,500 feet and 2,056 feet as measured from the electric log on the Diamond Shamrock Corporation No. 1 Chumley well, which is located in Sebastian County.

[2] The recommended area includes Section 6 in T4N, R29W; Section 1–12 in T4N, R30W; Sections 1–5 in T4N, R31W; Sections 8–12 in T4N, R31W; Sections 31 and 32 in T5N, R29W; Sections 31–36 in T5N, R30W; and Sections 33–36 in T5N, R31W.

[3] The December 24, 1991 letter requested Arkansas to explain its use of permeability and production rate data from only those wells that required stimulation to produce and the presence of a separate cluster of unstimulated open hole completions. Under § 275.202(b) of the regulations, the 45-day period begins on the date Arkansas' response was received.

[4] The notice states that wells in the Mansfield Gas Field have long producing histories and that current pressures are the same as those reported 90 years ago, which suggests that gas continuously migrates into the Mansfield Sand along fault and fracture zones. The notice also indicated that the initial production rate was 550 Mcfd.

[5] The location of this cluster is consistent with normal geological expectations for anticlinal structures, where natural fractures are most likely to occur at or near the crest of the upward fold.

[6] The Interim Rule issued February 20, 1980, in Docket No. RM79-76, states that matrix permeability (i.e., permeability of the rock), by itself, "will not be sufficient to qualify a formation, because formations with very low matrix permeabilities may be economic to develop if fractures have developed naturally. Therefore, to fulfill the guideline containing the specific

Continued

that its objectives in establishing the tight formation program were to identify and include tight formations that could not be commercially developed absent application of enhance production techniques, and to exclude "the types of development activities that could occur under the otherwise applicable maximum lawful prices." [7]

Therefore, without any data for the unstimulated wells, the Commission is unable to conclude that these wells have the same low *in situ* permeability and flow rate characteristics as the stimulated wells since the unstimulated wells, which are located along fractures, are in a small area that was commercially developed without application of enhanced production techniques.

Based on the above, the Commission hereby makes a preliminary finding, under § 275.202(a) of the regulations, that the determination is not supported by substantial evidence in the record upon which it was made. Arkansas or the applicants may, within 30 days from the date of this preliminary finding, submit written comments and request an informal conference with the Commission pursuant to § 275.202(f) of the regulations. A final Commission order will be issued within 120 days after the issuance of this preliminary finding.

By direction of the Commission.

Lois D. Cashell,

Secretary.

[FR Doc. 92-8687 Filed 4-14-92; 8:45 am]

BILLING CODE 6717-01-M

[Docket Nos. CP92-433-000, et al.]

Tarpon Transmission Co., et al.; Natural Gas Certificate Filings

Take notice that the following filings have been made with the Commission:

1. Tarpon Transmission Co.

[Docket No. CP92-433-000]

April 6, 1992.

Take notice that on March 24, 1992, Tarpon Transmission Company (Tarpon), 300 Crescent Court, suite 1320, Dallas, Texas 75201, filed in Docket No. CP92-433-000, a request pursuant to section 7(b) of the Natural Gas Act and part 157 of the Commission's Regulations for permission and approval to abandon firm gas transportation service to Trunkline Gas Company (Trunkline) under Rate Schedule No. 1 of Tarpon's FERC Gas Tariff, all as more fully set forth in the application which is on file with the Commission and open to public inspection.

Tarpon states that on February 15, 1977, it entered into a service agreement with Trunkline providing for the transportation of "all gas" which Trunkline delivered or caused to be delivered to Tarpon. Tarpon further states that the Commission authorized such service for Trunkline by order issued on August 4, 1977 in Docket No. CP77-315. Tarpon indicates that on December 16, 1981, the Commission authorized Tarpon to transport additional production purchased by Trunkline in Docket No. CP82-6. Tarpon states that by letter dated December 6, 1990, Trunkline provided written notice to Tarpon that it was terminating the transportation agreement of February 15, 1977, effective July 1, 1991. Tarpon requests that such abandonment be effective as of the date of a Commission order in this proceeding.

Comment date: April 27, 1992, in accordance with Standard Paragraph F at the end of this notice.

2. Questar Pipeline Co.

[Docket No. CP92-431-000]

April 7, 1992

Take notice that on March 24, 1992, Questar Pipeline Company (Questar), 79 South State Street, Salt Lake City, Utah 84111, filed in Docket No. CP92-431-000 a request pursuant to §§ 157.205 and 157.208 of the Commission's Regulations and Questar's blanket certificate issued in Docket No. CP82-491-000 pursuant to section 7 of the Natural Gas Act for authorization to convert the jurisdictional status of its existing Skull Creek interconnect facilities, located in Moffat County, Colorado, and Sweetwater County, Wyoming, from NGPA section 311 facilities to NGA section 7(c) facilities consistent with the Commission's Order No. 537 issued September 20, 1991, all as more fully set forth in the request that is on file with the Commission and open to public inspection.

Questar states that the Skull Creek interconnect facilities consists of (1) Approximately 4.47 miles of 16-inch O.D. pipeline, (2) approximately 21.49 miles of 12 3/4-inch O.D. pipeline, (3) one compressor station, comprising two 1,301 horsepower (site rated) compressors, (4) one meter and regulating station consisting primarily of one 10-inch meter run, valving and associated yard and station piping and (5) a 40 MMcf per day, skid-mounted refrigeration dew-point plant. The pipeline, compressor station, meter and regulating facilities were placed in service on May 1, 1991. The dew-point plant was placed in service on July 1, 1991. These facilities were constructed to provide the intermediate transportation of natural gas between the interstate transmission systems of two open-access pipeline companies, Questar and Williams Natural Gas Company, on behalf of contracting shippers, including producers, pipeline companies, marketers and end users. Questar states that the Skull Creek interconnect has a marketable peak-day capacity of 45 MMcf per day. The total cost of the Skull Creek interconnect facilities is $9,791,926. Questar states that it proposes no new rates for the utilization of its Skull Creek interconnect facilities. Questar is presently charging firm and interruptible transportation rates between the Part 284 maximum and minimum levels set forth in Questar's Original Volume No. 1-A of its currently effective FERC Gas Tariff.

Comment Date: May 22, 1992, in accordance with Standard Paragraph G at the end of this notice.

3. Williston Basin Interstate Pipeline Co.

[Docket No. CP92-442-000]

April 8, 1992.

Take notice that on April 3, 1992, Williston Basin Interstate Pipeline Company (Williston Basin), suite 300, 200 North Third Street, Bismarck, North Dakota 58501, filed in Docket No. CP92-442-000 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 a natural gas sales tap and appurtenant facilities under Williston Basin's blanket certificate issued in Docket No. CP83-1-000 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.

Williston Basin proposes to abandon the Yellowstone County, Montana, sales tap and appurtenant facilities located on its Elk Basin-Billings Transmission Line, by which it serves Montana-Dakota Utilities Co., a Division of MDU Resources Group, Inc. (Montana-Dakota), described as Station 2782+86. It is stated that Montana-Dakota has advised that the sales tap is no longer needed since the end-user customer would henceforth receive service through Montana-Dakota's distribution line extensions. Williston Basin advises that the tap facilities have no "plant value" since the cost of the tap was

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permeability limit, the formation's average effective or *in situ* permeability throughout the pay section must be expected to be 0.1 millidarcy, or less."

[7] Interim Rule issued February 20, 1980, in Docket No. RM79-76.

borne by Montana-Dakota. It is estimated that the cost of removal of the tap would be $150.

Comment date: May 26, 1992, in accordance with Standard Paragraph G at the end of this notice.

4. Pennzoil Co.

[Docket No. CI92-35-000]

April 8, 1992.

Take notice that on March 18, 1992, as supplemented on March 30, 1992, Pennzoil Company (Pennzoil) of P. O. Box 2967, Houston, Texas 77252-2967, filed an application pursuant to section 7 of the Natural Gas Act and the Federal Energy Regulatory Commission's (Commission) regulations thereunder for a blanket certificate authorizing sales of natural gas from properties it has acquired or may acquire as a successor-in-interest prior to January 1, 1993, the effective date of total decontrol under the Natural Gas Wellhead Decontrol Act of 1989, all as more fully set forth in the application which is on file with the Commission and open for public inspection. Pennzoil also requests waiver of the Commission's regulations which would require Pennzoil to file and maintain rate schedules.

Comment date: May 1, 1992, in accordance with Standard Paragraph J at the end of the notice.

Standard Paragraphs

F. Any person desiring to be heard or make any protest with reference to said filing should on or before the comment date file with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, DC 20426, a motion to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214) and the Regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a motion to intervene in accordance with the Commission's Rules.

Take further notice that, pursuant to the authority contained in and subject to jurisdiction conferred upon the Federal Energy Regulatory Commission by sections 7 and 15 of the Natural Gas Act and the Commission's Rules of Practice and Procedure, a hearing will be held without further notice before the Commission or its designee on this filing if no motion to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that a grant of the certificate is required by the public convenience and necessity. If a motion for leave to intervene is timely filed, or if the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for the applicant to appear or be represented at the hearing.

G. Any person or Commission's staff may, within 45 days after the 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 § 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 therefore, 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.

Standard Paragraph

J. Any person desiring to be heard or make any protest with reference to said filings should on or before the comment date file with the Federal Energy Regulatory Commission, 825 North Capitol Street NE., Washington, DC 20426 a motion to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.211, .214). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party in any proceeding herein must file a petition to intervene in accordance with the Commission's rules.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for the applicant to appear or be represented at the hearing.

Lois D. Cashell,

Secretary.

[FR Doc. 92-8645 Filed 4-14-92; 8:45 am]

BILLING CODE 6717-01-M

Public Access to Commission Systems

April 9, 1992.

Take notice that on May 11, 1992, the Federal Energy Regulatory Commission (FERC) will start a pilot program to allow remote public access to the Commission Issuance System (CIS) and the Automated Docket Sheet System (ADSS). The CIS contains the official service list for each proceeding before FERC; the ADSS contains the docket sheet listing all filings made and documents issued for each proceeding before FERC. Remote access will allow the public to access these two systems using a personal computer with a modem and read or print information from their own offices.

The FERC would like 50 participants for this pilot project. Anyone wishing to participate should submit a request and one copy to Office of the Secretary, room 3110, 825 North Capitol Street, Washington, DC 20426 during business hours between April 15, 1992 and April 22, 1992. The original will be time stamped and retained; the copy will be time stamped and returned to the filer. The request should include the entity's name, address, phone number and a contact person.

The 50 participants in the pilot project will be selected based on the order (first received) in which their request was received by the Office of the Secretary. Starting May 11, 1992, 20 participants will be given remote logon access to these two systems. Ten more participants will be given access each month through August. At the end of the pilot project period, access will be available to any entity requesting it.

The 50 participants selected will be notified of their selection and be given additional information by May 1, 1992.

Lois D. Cashell,

Secretary.

[FR Doc. 92-8688 Filed 4-14-92; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. RP91-143-000]

Great Lakes Gas Transmission Limited Partnership; Informal Settlement Conference

April 8, 1992.

Take notice that an informal settlement conference will be convened in this proceeding on Wednesday, May 6, 1992, at 10 a.m. The conference will be held at the offices of the Federal Energy Regulatory Commission, 810 First Stret, NE., Washington, DC for the purpose of exploring the possible settlement of all issues raised in the above-referenced docket.

Any party, as defined by 18 CFR 385.102(c), or any participant as defined by 18 CFR 385.102(b), is invited to attend. Persons wishing to become a

party must move to intervene and receive intervenor status pursuant to the Commission's regulations (18 CFR 385.214).

For additional information, contact J. Carmen Gastilo at (202) 208–2182 or John P. Roddy at (202) 208–1176.

Lois D. Cashell,

Secretary.

[FR Doc. 92–8629 Filed 4–14–92; 8:45 am]

BILLING CODE 6717–01–M

[P–8864–007 and P–9025–005]

Application Filed With the Commission

February 28, 1992.

Take notice that the following hydroelectric application has been filed with the Federal Energy Regulatory Commission and is available for public inspection.

a. Type of applications: Major License.

b. Project Nos.: (1) 8864–007 and (2) 9025–005.

c. Dates filed: (1) June 10, 1991, and (2) March 27, 1991.

d. Applicant: Weyerhaeuser Company.

e. Name of Projects: (1) Calligan Creek Hydroelectric and (2) Hancock Creek Hydroelectric.

f. Locations: (1) On Calligan Creek, in King County, Washington; Sections 31 and 32, Township 25 North, Range 9 East, Willamette Meridian.

(2) On Hancock Creed, in King County, Washington; Sections 7 and 8, Township 24 North, Range 9 East, Willamette Meridian.

g. Filed Pursuant to: Federal Power Act, 16 U.S.C. 791(a)–825(r).

h. Applicant Contact: Mr. Michael S. Wright, Permit/Engineering Inc., 1300—114th Avenue, SE., suite 220, Bellevue, WA 98004, (206) 451–7371.

i. FERC Contact: Mr. Surender M. Yepuri, P.E. (202) 219–2847.

j. Deadline Date: See attached paragraph D9.

k. Status of Environmental Analysis: These applications are ready for environmental analysis at this time—see attached paragraph D9.

l. Description of project:

Calligan Creek Hydroelectric

The proposed project would consist of: (1) A 8-foot-high, 60-foot-long diversion dam with crest elevation at 2,221.0 feet; (2) a 23-foot-wide, 48-foot-long intake structure with fish screens; (3) a 42-inch-diameter, 1,400-foot-long steel siphon which is filled with water at start-up times by an 18-inch-diameter, 1400-foot-long force main; (4) a 40-inch-diameter, 4,925-foot-long steel penstock; (5) a 42-foot-wide by 44-foot-long powerhouse containing a generating unit with a rated capacity of 5.4 MW; (6) a 148-foot-long tailrace returning the discharge into the creek; (7) a 4.25 mile long, 35-kV transmission line tying into the substation of the Black Creek Project No. 6221; and (8) related facilities.

The project would have an estimated annual output of 21.68 Gwh and would cost $8,997,600 in 1990 dollars to construct.

Hancock Creek Hydroelectric

The proposed project would consist of: (1) A 7-foot-high, 62-foot-long diversion dam with crest elevation at 2,171.0 feet; (2) a 20-foot-wide, 12-foot-high, and 53-foot-long intake structure with fish screens; (3) a 45-inch-diameter, 2,460-foot-long steel siphon which is filled with water at start-up times by an 18-inch-diameter, 2,460-foot-long force main; (4) a 40-inch-diameter, 5,060-foot-long steel penstock; (5) a 38-foot-wide by 40-foot-long powerhouse containing a generating unit with a rated capacity of 6.3 MW; (6) a 125-foot-long tailrace returning the discharge into the creek; (7) a 2.0 mile long, 35-kV transmission line tying into the substation of the Black Creek Project No. 6221; and (8) related facilities.

The project would have an estimated annual output of 22.91 GWh and would cost $10,438,000 in 1990 dollars to construct.

m. Purpose of Projects: Power generated would be sold to a local utility.

n. This notice also consists of the following standard paragraphs: A4 and D9.

o. Available Locations of Applications: A copy of the applications, as amended and supplemented, is available for inspection and reproduction at the Commission's Public Reference and Files Maintenance Branch, located at 941 North Capitol Street, NE., room 3104, Washington, DC 20426, or by calling (202) 208–1371. A copy is also available for inspection and reproduction at (1) Weyerhaeuser Company, Tacoma, Washington 98477; telephone no. (206) 924–2932; and (2) King County Public Library, 126 East Fourth, North Bend, WA 98045.

A4. Development Application—Public notice of the filing of the initial development application, which has already been given, established the due date for filing competing applications or notices of intent. Under the Commission's regulations, any competing development application must be filed in response to and in compliance with the public notice of the initial development application. No competing applications or notices of intent may be filed in response to this notice.

D9. Filing and Service and Responsive Documents—The application is ready for environmental analysis at this time, and the Commission is requesting comments, reply comments, recommendations, terms and conditions, and prescriptions.

The Commission directs, pursuant to section 4.34(b) of the regulations (see Order No. 533 issued May 8, 1991, 56 Fed. Reg. 23108 (May 20, 1991)), that all comments, recommendations, terms and conditions and prescriptions concerning the application be filed with the Commission within 60 days from the issuance date of this notice. All reply comments must be filed with the Commission within 105 days from the date of this notice.

Anyone may obtain an extension of time for these deadlines from the Commission only upon a showing of good cause or extraordinary circumstances in accordance with 18 CFR 385.2008.

All filings must: (1) Bear in all capital letters the title "COMMENTS," "REPLY COMMENTS," "RECOMMENDATIONS," "TERMS AND CONDITIONS," or "PRESCRIPTIONS;" (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address and telephone number of the person submitting the filing; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, recommendations, terms and conditions or prescriptions must set forth their evidentiary basis and otherwise comply with the requirements of 18 CFR 4.34(b). Any of these documents must be filed by providing the original and the number of copies required by the Commission's regulations to: Secretary, Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426. An additional copy must be sent to: Director, Division of Project Review, Office of Hydropower Licensing, Federal Energy Regulatory Commission, Room 1027, at the above address. Each filing must be accompanied by proof of service on all persons listed on the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 4.34(b), 385.2010.

Lois D. Cashell,

Secretary.

[FR Doc. 92–8644 Filed 4–14–92; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. RP92-152-000]

Texas Eastern Transmission Corporation; Proposed Changes in FERC Gas Tariff

April 9, 1992.

Take notice that Texas Eastern Transmission Corporation (Texas Eastern) on April 7, 1992, tendered for filing as part of its FERC Gas Tariff, Fifth Revised Volume No. 1, the following tariff sheets with a proposed effective date of May 7, 1992:

Fifth Revised Sheet No. 523
Fifth Revised Sheet No. 524
Fifth Revised Sheet No. 525
Fifth Revised Sheet No. 526–599

By this filing, Texas Eastern proposed to include a new section 36 as part of the General Terms and Conditions of its FERC Gas Tariff. Proposed section 36 would provide that Texas Eastern may enter into operational balancing agreements with certain parties that operate natural gas facilities which interconnect with Seller's system (Third Party Pipelines).

Texas Eastern states that the proposed change to the General Terms and Conditions of Texas Eastern's Tariff will provide enhanced flexibility to Texas Eastern's shippers, consistent with open access transportation principles, and will promote equality of service by providing a means by which Texas Eastern and "Third Party Pipelines" can manage inadvertent over- and under-deliveries of gas from their transportation customers in a fair and consistent manner, while also maintaining operation requirements.

Texas Eastern states that copies of the filing were served on all authorized purchasers of gas from Texas Eastern, interested state commission, all Rate Schedule FT–1 and IT–1 shippers, and all "Third Party Pipelines" interconnecting with Texas Eastern.

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, 825 North Capitol Street, NE., Washington DC 20426, in accordance with 18 CFR 385.214 and 385.211 of the Commission's Rules and Regulations. All such motions or protests should be filed on or before April 16, 1992.

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. 92–8689 Filed 4–14–92; 8:45 am]
BILLING CODE 6717–01–M

Office of Fossil Energy

[FE Docket No. 92–33–NG]

Amoco Canada Marketing Corp., Application for Blanket Authorization to Import Natural Gas From Canada

AGENCY: Department of Energy, Office of Fossil Energy.

ACTION: Notice of application for blanket authorization to import natural gas from Canada.

SUMMARY: The Office of Fossil Energy of the Department of Energy (DOE) gives notice of receipt of an application filed on March 9, 1992, by Amoco Canada Marketing Corp. (Amoco Canada) requesting blanket authorization to import up to 200 Bcf of natural gas from Canada over a two-year period beginning with the date of first delivery. Amoco Canada intends to use existing facilities, and will submit quarterly reports of its transactions. Additionally, Amoco Canada requests a shortened notice period for its application.

The application is filed under section 3 of the Natural Gas Act and DOE Delegation Order Nos. 0204–111 and 0204–127. Protests, motions to intervene, notices of intervention, and written comments are invited.

DATES: Protests, motions to intervene or notices of intervention, as applicable, requests for additional procedures and written comments are to be filed at the address listed below no later than 4:30 p.m., eastern time, May 15, 1992.

ADDRESSES: Office of Fuels Programs, Fossil Energy, U.S. Department of Energy, Forrestal Building, room 3F–056, FE–50, 1000 Independence Avenue, SW., Washington, DC 20585, (202) 586–9478.

FOR FURTHER INFORMATION CONTACT:

Susan K. Gregersen, Office of Fuels Programs, Fossil Energy, U.S. Department of Energy, Forrestal Building, room 3F–070, 1000 Independence Avenue, SW., Washington, DC 20585, (202) 586–0063.

Diane Stubbs, Office of Assistant General Counsel for Fossil Energy, U.S. Department of Energy, Forrestal Building, room 6E–042, 1000 Independence Avenue, SW., Washington, DC 20585, (202) 586–6667.

SUPPLEMENTARY INFORMATION: Amoco Canada, a Delaware corporation with its principal place of business in Chicago, Illinois, is an indirect subsidiary of Amoco Corporation. Amoco Canada proposes to import gas for sale to a variety of purchasers in U.S. markets, including commercial and industrial end users, utility customers, pipelines and distribution companies, acting either on its own behalf or as an agent for others. The gas to be imported by Amoco Canada will be supplied by producers, associations and pipeline companies, and the terms of the supply contracts will depend upon current market demand for the gas. Amoco Canada will import the gas through existing facilities at various points along the international border.

In requesting a shortened notice period for its application, Amoco Canada states that its pending natural gas sales arrangements are dependent upon import authorization from DOE. DOE has determined that this reason stated by Amoco Canada for a shortened notice period is insufficient; consequently, the request is denied.

The decision on the request for import authority will be made consistent with the DOE's gas import policy guidelines, under which the competitiveness of an import arrangement in the market served is the primary consideration in determining whether it is in the public interest (49 FR 6684, February 22, 1994). Parties should comment on the issue of competitiveness as set forth in the policy guidelines. Amoco Canada asserts its proposed import transactions will be competitive. Parties opposing Amoco Canada's request for import authorization bear the burden of overcoming this assertion.

NEPA Compliance

The National Environmental Policy Act (NEPA), 42 U.S.C. 4321 *et seq.*, requires DOE to give appropriate consideration to the environmental effects of its proposed actions. No final decision will be issued in this proceeding until DOE has met its NEPA responsibilities.

Public Comment Procedures

In response to this notice, any person may file a protest, motion to intervene or notice of intervention, a applicable, and written comments. Any person wishing to become a party to the proceeding and to have their written comments considered as the basis for any decision on the application must, however, file a motion to intervene or notice of intervention, as applicable. The filing of a protest with respect to this application will not serve to make the protestant a party to the proceeding.

although protests and comments received from persons who are not parties will be considered in determining the appropriate action to be taken on the application. All protests, motions to intervene, notices of intervention, and written comments must meet the requirements that are specified by the regulations in 10 CFR part 590. Protests, motions to intervene, notices of intervention, requests for additional procedures, and written comments should be filed with the Office of Fuels Programs at the address listed above.

It is intended that a decisional record on the application will be developed through responses to this notice by parties, including the parties' written comments and replies thereto. Additional procedures will be used as necessary to achieve a complete understanding of the facts and issues. A party seeking intervention may request that additional procedures be provided, such as additional written comments, an oral presentation, a conference, or trial-type hearing. Any request to file additional written comments should explain why they are necessary. Any request for an oral presentation should identify the substantial question of fact, law, or policy at issue, show that it is material and relevant to a decision in the proceeding, and demonstrate why an oral presentation is needed. Any request for a conference should demonstrate why the conference would materially advance the proceeding. Any request for a trial-type hearing must show that there are factual issues genuinely in dispute that are relevant and material to a decision and that a trial-type hearing is necessary for a full and true disclosure of the facts.

If an additional procedure is scheduled, notice will be provided to all parties. If no party requests additional procedures, a final opinion and order may be issued based on the official record, including the application and responses filed by parties pursuant to this notice, in accordance with 10 CFR 590.316.

A copy of Amoco Canada's application is available for inspection and copying in the Office of Fuels Programs docket room, 3F-056, at the above address. The docket room is open between the hours of 8 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays.

Issued in Washington, DC, on April 8, 1992.

Charles F. Vacek,

Deputy Assistant Secretary for Fuels Programs, Office of Fossil Energy.

[FR Doc. 92-8710 Filed 4-15-92; 8:45 am]

BILLING CODE 6450-01-M

ENVIRONMENTAL PROTECTION AGENCY

[OPP-60029; FRL-4056-8]

Intent to Suspend Certain Pesticide Registrations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of issuance of notices of intent to suspend.

SUMMARY: This notice, pursuant to section 6 (f)(2) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 et seq., announces that EPA has issued Notice(s) of Intent to Suspend pursuant to section 3(c)(2)(B) of FIFRA. The notice(s) were issued following issuance of Data Call-In Notice(s) by the Agency and the failure of registrant(s) subject to the Data Call-In Notice(s) to take appropriate steps to secure the data required to be submitted to the Agency. This notice includes the text of a Notice of Intent to Suspend, absent specific chemical, product, or factual information. Table A of this notice further identifies the registrant(s) to whom the Notice(s) of Intent to Suspend were issued, the date each Notice of Intent to Suspend was issued, the active ingredient(s) involved, and the EPA registration number(s) and name(s) of the registered product(s) which are affected by the Notice(s) of Intent to Suspend. Moreover, Table B of this notice identifies the basis upon which the Notice(s) of Intent to Suspend were issued. Finally, matters pertaining to the timing of requests for hearing are specified in the Notice(s) of Intent to Suspend and are governed by the deadlines specified in section 3(c)(2)(B). As required by section 6(f)(2), the Notice(s) of Intent to Suspend were sent by certified mail, return receipt requested, to each affected registrant at its address of record.

FOR FURTHER INFORMATION CONTACT: Stephen L. Brozena, Office of Compliance Monitoring (EN-342), Laboratory Data Integrity Assurance Division, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460, (703) 308-8267.

SUPPLEMENTARY INFORMATION:

I. Text of a Notice of Intent to Suspend

The text of a Notice of Intent to Suspend, absent specific chemical, product, or factual information, follows:

United States Environmental Protection Agency

Office of Pesticides and Toxic Substances

Washington, DC 20460

Certified Mail

Return Receipt Requested

SUBJECT: Suspension of Registration of Pesticide Product(s) Containing _____ for Failure to Comply with the 3(c)(2)(B) Data Call-In Notice for _____ Dated _____.

Dear Sir/Madam:

This letter gives you notice that the pesticide product registration(s) listed in Attachment I will be suspended 30 days from your receipt of this letter unless you take steps within that time to prevent this Notice from automatically becoming a final and effective order of suspension. The Agency's authority for suspending the registration(s) of your product(s) is section 3(c)(2)(B) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Upon becoming a final and effective order of suspension, any violation of the order will be an unlawful act under section 12(a)(2)(J) of FIFRA.

You are receiving this Notice of Intent to Suspend because you have failed to comply with the terms of the 3(c)(2)(B) Data Call-In Notice. The specific basis for issuance of this Notice is stated in the Explanatory Appendix (Attachment III) to this Notice. Affected product(s) and the requirement(s) which you failed to satisfy are listed and described in the following three attachments:

Attachment I Suspension Report - Product List

Attachment II Suspension Report - Requirement List

Attachment III Suspension Report - Explanatory Appendix

The suspension of the registration of each product listed in Attachment I will become final unless at least one of the following actions is completed.

1. You may avoid suspension under this Notice if you or another person adversely affected by this Notice properly request a hearing within 30 days of your receipt of this Notice. If you request a hearing, it will be conducted in accordance with the requirements of section 6(d) of FIFRA and the Agency's procedural regulations in 40 CFR part 164.

Section 3(c)(2)(B), however, provides that the only allowable issues which may be addressed at the hearing are whether you have failed to take the actions which are the bases of this Notice and whether the Agency's decision regarding the disposition of existing stocks is consistent with FIFRA.

Therefore, no substantive allegation or legal argument concerning other issues, including but not limited to the Agency's original decision to require the submission of data or other information, the need for or utility of any of the required data or other information or deadlines imposed, and the risks and benefits associated with continued registration of the affected product, may be considered in the proceeding. The Administrative Law Judge shall by order dismiss any objections which have no bearing on the allowable issues which may be considered in the proceeding.

Section 3(c)(2)(B)(iv) of FIFRA provides that any hearing must be held and a determination issued within 75 days after receipt of a hearing request. This 75–day period may not be extended unless all parties in the proceeding stipulate to such an extension. If a hearing is properly requested, the Agency will issue a final order at the conclusion of the hearing governing the suspension of your product(s).

A request for a hearing pursuant to this Notice must (1) include specific objections which pertain to the allowable issues which may be heard at the hearing, (2) identify the registration(s) for which a hearing is requested, and (3) set forth all necessary supporting facts pertaining to any of the objections which you have identified in your request for a hearing. If a hearing is requested by any person other than the registrant, that person must also state specifically why he asserts that he would be adversely affected by the suspension action described in this Notice. Three copies of the request must be submitted to: Hearing Clerk, A–110, U.S. Environmental Protection Agency, 401 M St., SW., Washington, DC 20460, and an additional copy should be sent to the signatory listed below. The request must be *received* by the Hearing Clerk by the 30th day from your receipt of this Notice in order to be legally effective. The 30–day time limit is established by FIFRA and cannot be extended for any reason. Failure to meet the 30–day time limit will result in automatic suspension of your registration(s) by operation of law and, under such circumstances, the suspension of the registration for your affected product(s) will be final and effective at the close of business 30 days after your receipt of this Notice and will not be subject to further administrative review.

The Agency's Rules of Practice at 40 CFR 164.7 forbid anyone who may take part in deciding this case, at any stage of the proceeding, from discussing the merits of the proceeding *ex parte* with ar y party or with any person who has been connected with the preparation or presentation of the proceeding as an advocate or in any investigative or expert capacity, or with any of their representatives. Accordingly, the following EPA offices, and the staffs thereof, are designated as judicial staff to perform the judicial function of EPA in any administrative hearings on this Notice of Intent to Suspend: The Office of the Administrative Law Judges, the Office of the Judicial Officer, the Administrator, the Deputy Administrator, and the members of the staff in the immediate offices of the Administrator and Deputy Administrator. None of the persons designated as the judicial staff shall have any *ex parte* communication with trial staff or any other interested person not employed by EPA on the merits of any of the issues involved in this proceeding, without fully complying with the applicable regulations.

2. You may also avoid suspension if, within 30 days of your receipt of this Notice, the Agency determines that you have taken appropriate steps to comply with the section 3(c)(2)(B) Data Call-In Notice. In order to avoid suspension under this option, you must satisfactorily comply with Attachment II, Requirement List, for each product by submitting all required supporting data/information described in Attachment II and in the Explanatory Appendix (Attachment III) to the following address (preferably by certified mail):

Office of Compliance Monitoring (EN-342), Laboratory Data Integrity Assurance Division, U.S. Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

For you to avoid automatic suspension under this Notice, the Agency must also determine within the applicable 30–day period that you have satisfied the requirement(s) that are the bases of this Notice and so notify you in writing. You should submit the necessary data/information as quickly as possible for there to be any chance the Agency will be able to make the necessary determination in time to avoid suspension of your product(s).

The suspension of the registration(s) of your company's product(s) pursuant to this Notice will be rescinded when the Agency determines you have complied fully with the requirements which were the bases of this Notice. Such compliance may only be achieved by submission of the data/information described in the attachments to the signatory below.

Your product will remain suspended, however, until the Agency determines you are in compliance with the requirements which are the bases of this Notice and so informs you in writing.

After the suspension becomes final and effective, the registrant subject to this Notice, including all supplemental registrants of product(s) listed in Attachment I, may not legally distribute, sell, use, offer for sale, hold for sale, ship, deliver for shipment, or receive and (having so received) deliver or offer to deliver, to any person, the product(s) listed in Attachment I.

Persons other than the registrant subject to this Notice, as defined in the preceding sentence, may continue to distribute, sell, use, offer for sale, hold for sale, ship, deliver for shipment, or receive and (having so received) deliver or offer to deliver, to any person, the product(s) listed in Attachment I.

Nothing in this Notice authorizes any person to distribute, sell, use, offer for sale, hold for sale, ship, deliver for shipment, or receive and (having so received) deliver or offer to deliver, to any person, the product(s) listed in Attachment I in any manner which would have been unlawful prior to the suspension.

If the registration(s) of your product(s) listed in Attachment I are currently suspended as a result of failure to comply with another section 3(c)(2)(B) Data Call-In Notice or Section 4 Data Requirement Notice, this Notice, when it becomes a final and effective order of suspension, will be in addition to any existing suspension, i.e., all requirements which are the bases of the suspension must be satisfied before the registration will be reinstated.

You are reminded that it is your responsibility as the basic registrant to notify all supplementary registered distributors of your basic registered product that this suspension action also applies to their supplementary registered product(s) and that you may be held liable for violations committed by your distributors.

If you have any questions about the requirements and procedures set forth in this suspension notice or in the subject 3(c)(2)(B) Data Call-In Notice, please contact Stephen L. Brozena at (703) 308–8267.

Sincerely yours,

Director, Office of Compliance Monitoring

Attachments:

Attachment I - Product List

Attachment II - Requirement List

Attachment III - Explanatory Appendix

II. Registrant(s) Receiving and Affected by Notice(s) of Intent to Suspend; Date of Issuance; Active Ingredient and Product(s) Affected

A letter of notification has been sent for the following product(s):

TABLE A—PRODUCT LIST

Registrant Affected	EPA Registration Number	Active Ingredient	Name of Product	Date Issued
Akzo Chemie America	00692200024	Thiram	Perkacit Thiram - 99	3/25/92
Agrolinz, Inc.	04254500004	Thiram	B & G Thiram 75 Turf Fungicide	3/25/92
Amvac Chemical Corp.	00548100113	Mevinphos	Durham Duraphos EM 4 Organophosphorus Insecticide	3/25/92
	00548100114	Mevinphos	Durham Duraphos 400 Organophosphorus Insecticide	3/25/92
	00548100161	Mevinphos	Duraphos 10.3	3/25/92
	00548100248	Mevinphos	Royal Brand Phosdrin Spray Concentrate	3/25/92
	00548100249	Mevinphos	Royal Brand 2% Phosdrin Insecticide Dust	3/25/92
	00548100411	Mevinphos	Shell Phosdrin Insecticide 100%	3/25/92
	00548100412	Mevinphos	Phosdrin 4EC Insecticide.	3/25/92
	00548100425	Mevinphos	Mevinphos Insecticide	3/25/92
Hysan Corporation	00033400263	Thiram	Rampel Rodent Repellent	3/25/92
Helena Chemical Company	00590500228	Mevinphos	Helena Phosdrin 4-E	3/25/92
	00590500298	Mevinphos	Helena Phosdrin 2-E	3/25/92
Micro-Flo Company	05103600053	Thiram	Thiram 75WP	3/25/92
	05103600065	Thiram	Thiram 65WP	3/25/92
Milazzo Company, Samuel J.	00821800001	Thiram	Milazzo Brand Animal Chaser	3/25/92
Platte Chemical Company	03470400343	Mevinphos	Clean Crop Phosdrin 4.0 Miscible	3/25/92
Security Products Company of Delaware, Inc.	05664400080	Thiram	Repel #2 Wild Animal Repellent	3/25/92
	05664400082	Thiram	Chacon Rabbit, Deer, Rodent Repellent	3/25/92

III. Basis for Issuance of Notice of Intent; Requirement List

The following registrant(s) failed to submit the following required data or information:

TABLE B—REQUIREMENT LIST

Active Ingredient	Registrant Affected	Requirement Name	Guideline Reference Number	Original Due-Date
Mevinphos	Amvac Chemical Corp.	Fish Toxicity - Bluegill - TEP	72-1(b)	1/13/89
		Fish Toxicity - Rainbow Trout - TEP	72-1(d)	1/13/89
		Invertebrate Toxicity - TEP	72-2(b)	1/13/89
		Early Life Stage - Fish	72-4(a)	1/13/89
		Life Cycle - Invertebrate	72-4(b)	1/13/89
		Hydrolysis	161-1	1/13/89
Mevinphos	Platte Chemical Company	Fish Toxicity - Bluegill - TEP	72-1(b)	1/13/89
		Fish Toxicity - Rainbow Trout - TEP	72-1(d)	1/13/89
		Invertebrate Toxicity - TEP	72-2(b)	1/13/89
		Early Life Stage - Fish	72-4(a)	1/13/89
		Life Cycle - Invertebrate	72-4(b)	1/13/89
		Hydrolysis	161-1	1/13/89
	Helena Chemical Company	Fish Toxicity - Bluegill - TEP	72-1(b)	1/13/89
		Fish Toxicity - Rainbow Trout - TEP	72-1(d)	1/13/89
		Invertebrate Toxicity - TEP	72-2(b)	1/13/89
		Early Life Stage - Fish	72-4(a)	1/13/89
		Life Cycle - Invertebrate	72-4(b)	1/13/89
		Hydrolysis	161-1	1/13/89
Thiram	Hysan Corporation	90-Day Response		12/31/91
	Akzo Chemie America	90-Day Response		12/18/91
	Milazzo Company, Samuel J.	90-Day Response		12/18/91
	Agrolinz, Inc.	90-Day Response		12/18/91
	Micro-Flo Company	90-Day Response		12/19/91

TABLE B—REQUIREMENT LIST—Continued

Active Ingredient	Registrant Affected	Requirement Name	Guideline Reference Number	Original Due-Date
	Security Products Company of Delaware, Inc.	90-Day Response		12/30/91

IV. Attachment III Suspension Report--Explanatory Appendix

A discussion of the basis for the Notice of Intent to Suspend follows:

A. Mevinphos

On March 31, 1988, EPA issued a Registration Standard which included a Data Call-In Notice (DCI) pursuant to the authority of FIFRA section 3(c)(2)(B) which required registrants of products containing mevinphos used as an active ingredient to develop and submit data. These data were determined to be necessary to maintain the continued registration of affected products. Failure to comply with the requirements of a Data Call-In Notice is a basis for suspension under section 3(c)(2)(B) of FIFRA.

The Mevinphos Data Call-In required each affected registrant to submit materials demonstrating selection by the registrant of the options to address the data requirements within 90 days of the registrant's receipt of the DCI. On July 11, 1988, AMVAC Chemical Corp., registrant of certain affected mevinphos products, committed to generate and submit data for mevinphos by the deadlines required by the Data Call-In Notice. Helena Chemical Company and Platte Chemical Company applied for and were granted generic data exemptions and therefore, relied on the efforts of AMVAC Chemical Corp. to provide the Agency with the required data. A condition of a generic data exemption is that if the registrant who has committed to generate and submit the required data fails to take appropriate steps to meet the requirements or is no longer in compliance with a data requirement, the Agency will consider that both the registrant who has committed to submit the data and the registrants claiming a generic data exemption are not in compliance.

These deadlines have passed for the data requirements listed in Attachment II and to date the Agency has not received adequate data to satisfy these requirements. To follow is a summary of the data requirements that have not been met and a discussion of why they are included in this Notice.

1. *Hydrolysis—Guideline 161-1.* AMVAC Chemical Corp. did not conduct an adequate hydrolysis study for this chemical. AMVAC submitted a protocol for the hydrolysis study which EPA approved with the following conditions: (1) Separate studies were to be done on the alpha and beta isomers as well as on the mixture ratio of both isomers; and (2) the test material was to be radiolabeled and analytical separation techniques were to be upgraded. The company was notified of this in a letter sent by the Agency on May 11, 1990. The study received from the company, however, was conducted using only the mixture of isomers. The company did not submit the separate studies on each individual isomer as discussed in the Agency's May 11, 1990, letter. The justification by the company for conducting the study using a mixture of isomers rather than doing separate studies on each isomer was deemed inadequate by the Agency as discussed in the Agency's response to the protocol submission. Therefore, the requirement for the hydrolysis study has not been met because the company also did not submit separate studies on the alpha and beta isomers individually as discussed in the response to the protocol submission.

2. *Freshwater Fish Toxicity—Guidelines 72-1B & 72-1D and Acute Toxicity to Freshwater Invertebrates—Guideline 72-2.* The Mevinphos Registration Standard required that the Freshwater Fish Toxicity/Freshwater Invertebrate Toxicity studies be completed and the data submitted 9 months from the registrant's receipt of the Standard. AMVAC Chemical Corp. received the Registration Standard on April 13, 1988, therefore the original due date for the studies was January 13, 1989. Subsequently, on August 11, 1989, after the deadline had passed, the registrant requested a waiver for the Freshwater Fish Toxicity/Freshwater Invertebrate Toxicity studies. In a letter dated December 6, 1991, the Agency informed AMVAC Chemical Corp. that it was denying its waiver requests since the Agency has determined that these studies are still required for the products currently registered.

3. *Fish Early Life Stage—Guideline 72-4A and Aquatic Invertebrate Lifecycle—Guideline 72-4B.* The Mevinphos Registration Standard required that the Fish Early Life Stage/Aquatic Invertebrate Lifecycle studies be completed and the data submitted 15 months from the receipt of the Standard. AMVAC Chemical Corp. received the Registration Standard on April 13, 1988, therefore the original due date for the studies was July 13, 1989. Following the passing of the deadline, the registrant filed time extension requests on September 14, 1989, and May 24, 1991, which the Agency reviewed. In addition, also after the deadline passed, the registrant filed requests for a change in test species from the rainbow trout to the fathead minnow on July 25, 1989, and May 22, 1991. In a letter dated December 6, 1991, the Agency informed AMVAC Chemical Corp. that it concluded that the "justification provided does not warrant an extension of time for the studies or a change in test species for the Fish Early Life Stage study."

Because AMVAC Chemical Corp. (and thereby the Helena Chemical Company and Platte Chemical Company) have failed to provide appropriate or adequate data submissions within the time provided for the data requirements listed in Attachment II, the Agency is issuing this Notice of Intent to Suspend.

B. Thiram

On September 16, 1991, EPA issued a Data Call-In Notice (DCI) under authority of FIFRA section 3(c)(2)(B) which required registrants of products containing thiram used as an active ingredient to develop and submit data. These data were determined to be necessary to maintain the continued registration of affected products. Failure to comply with the requirements of a Data Call-In Notice is a basis for suspension under section 3(c)(2)(B) of FIFRA.

The Thiram Data Call-In Notice required each affected registrant to submit materials relating to the election of the options to address the data requirements. That submission was required to be received by the Agency within 90 days of the registrant's receipt of the DCI. Because the Agency has not received a response from you as a thiram registrant to undertake the required testing or any other appropriate response, the Agency is initiating through this Notice of Intent to Suspend

the actions which FIFRA requires it to take under these circumstances.

V. Conclusions

EPA has issued Notice(s) of Intent to Suspend on the dates indicated. Any further information regarding the Notice(s) may be obtained from the contact person noted above.

Dated: April 8, 1992.

Michael M. Stahl,

Director, Office of Compliance Monitoring.

[FR Doc. 92-8736 Filed 4-14-92; 8:45 am]

BILLING CODE 6560-50-F

FARM CREDIT ADMINISTRATION

Final Order Barring Claims, Discharging and Releasing the Farm Credit Bank of Spokane as Receiver and Canceling Articles of Incorporation of Glendive Production Credit Assoc.

AGENCY: Farm Credit Administration.

ACTION: Notice.

On March 25, 1992, the Chairman of the Farm Credit Administration Board executed a Final Order barring claims against the Farm Credit Bank of Spokane (FCB) as successor to the Federal Intermediate Credit Bank of Spokane, arising out of the liquidation of the Glendive Production Credit Association; discharging the FCB as receiver; and canceling the Articles of Incorporation of the Glendive Production Credit Association. The text of the Final Order is set forth below:

Final Order Barring Claims, Discharging and Releasing the Farm Credit Bank of Spokane as Receiver and Canceling Articles of Incorporation of Glendive Production Credit Association

Whereas, the Board of Directors of the Glendive Production Credit Association (Glendive PCA) adopted a resolution placing the PCA in voluntary liquidation and a Liquidation Plan (Plan) outlining the manner in which the liquidation was to proceed, which were approved by the Farm Credit Administration on January 16, 1985;

Whereas, pursuant to the Plan, Gerald Wharton was appointed Liquidating Agent by the Federal Intermediate Credit Bank of Spokane (FICB) on January 16, 1985; on April 22, 1985, Larry Butterfield was appointed successor Liquidating Agent; on June 18, 1985, Hugh Miller was appointed successor Liquidating Agent; on January 1, 1987, Ray W. Fiscus was appointed successor Liquidating Agent; on December 1, 1988, Robert Damon was appointed successor Liquidating Agent by the Farm Credit Bank of Spokane (successor to the FICB); on February 16, 1989, Kenneth Mathistad was appointed successor Liquidating Agent; and on May 1, 1990, Richard Pierson was appointed successor Liquidating Agent;

Whereas, on December 31, 1988, pursuant to the Sale and Purchase Agreement, the Farm Credit Bank of Spokane purchased substantially all remaining assets of the Glendive PCA and assumed substantially all remaining liabilities;

Whereas, all assets of the Glendive PCA have been disposed of in accordance with the Plan;

Whereas, the Glendive PCA has been audited and examined, and the accounts of the Glendive PCA for the period January 16, 1985, through the date of this Order have been approved;

Whereas, in accordance with the Plan, all claims filed by creditors and holders of equities have been paid or provided for, including, without limitation, certain administrative expenses which the Farm Credit Bank of Spokane (successor to the FICB), has paid; and

Whereas, all claims filed by creditors and holders of equities shall forever be discharged;

Now, therefore, it is hereby ordered that:

1. All claims of creditors, stockholders, and holders of participation certificates and other equities, and of any other persons and/or entities, against the Glendive Production Credit Association, or, to the extent arising out of the actions of the Federal Intermediate Credit Bank of Spokane or its successor, the Farm Credit Bank of Spokane, in carrying out the liquidation of the Glendive Production Credit Association, as approved by the Farm Credit Administration on January 16, 1985, against the Federal Intermediate Credit Bank of Spokane, the Farm Credit Bank of Spokane, and the Liquidating Agents, are hereby forever discharged, and the commencement of any action, the employment of any process, or any other act to collect, recover, or offset any such claims are hereby forever barred.

2. The accounts of the Glendive Production Credit Association for the period January 16, 1985, through the date of this Order are hereby approved.

3. The Farm Credit Bank of Spokane is hereby finally discharged and released from all responsibility or liability to the Farm Credit Administration or any other person or entity arising out of, related to, or in any manner connected with the administration and liquidation of the Glendive Production Credit Association during the period January 16, 1985, through the date of this Order. The discharge and release of the Liquidating Agents by the Farm Credit Bank of Spokane are hereby approved.

4. The Articles of Incorporation of the Glendive Production Credit Association are hereby cancelled.

Signed: March 25, 1992.

By Harold B. Steele,

Chairman, Farm Credit Administration Board.

Dated: April 9, 1992.

Curtis M. Anderson,

Secretary, Farm Credit Administration Board.

[FR Doc. 92-8694 Filed 4-14-92; 8:45 am]

BILLING CODE 6705-01-M

Final Order Barring Claims, Discharging and Releasing the Farm Credit Bank of Spokane as Receiver and Cancelling Articles of Incorporation of Milk River Production Credit Assoc.

AGENCY: Farm Credit Administration.

ACTION: Notice.

On March 25, 1992, the Chairman of the Farm Credit Administration Board executed a Final Order barring claims against the Farm Credit Bank of Spokane (FCB) as successor to the Federal Intermediate Credit Bank of Spokane, arising out of the liquidation of the Milk River Production Credit Association; discharging the FCB as receiver; and cancelling the Articles of Incorporation of the Milk River Production Credit Association. The text of the Final Order is set forth below:

Final Order Barring Claims, Discharging and Releasing the Farm Credit Bank of Spokane as Receiver and Cancelling Articles of Incorporation of Milk River Production Credit Association

Whereas, the Board of Directors of the Milk River Production Credit Association (Milk River PCA) adopted a resolution placing the PCA in voluntary liquidation and a Liquidation Plan (Plan) outlining the manner in which the liquidation was to proceed, which were approved by the Farm Credit Administration on January 16, 1985;

Whereas, pursuant to the Plan, Gerald Wharton was appointed Liquidating Agent by the Federal Intermediate Credit Bank of Spokane (FICB) on January 16, 1985; on April 22, 1985, Larry Butterfield was appointed successor Liquidating Agent; on June 18, 1985, Hugh Miller was appointed successor Liquidating Agent; on January 1, 1987, Ray W. Fiscus was appointed successor Liquidating Agent; on December 1, 1988, Robert Damon was appointed successor Liquidating Agent by the Farm Credit Bank of Spokane (successor to the FICB); on February 16, 1989, Kenneth Mathistad was appointed successor Liquidating Agent; and on May 1, 1990, Richard Pierson was appointed successor Liquidating Agent;

Whereas, on December 31, 1988, pursuant to the Sale and Purchase Agreement, the Farm Credit Bank of Spokane purchased substantially all remaining assets of the Milk River PCA and assumed substantially all remaining liabilities;

Whereas, all assets of the Milk River PCA have been disposed of in accordance with the Plan;

Whereas, the Milk River PCA has been audited and examined, and the accounts of the PCA for the period January 16, 1985, through the date of this Order have been approved;

Whereas, in accordance with the Plan, all claims filed by creditors and holders of equities, except any remaining obligations on direct loans from the Farm Credit Bank of Spokane (successor to the FICB) and

participation certificates issued to Interstate Production Credit Association, have been paid or provided for, including, without limitation, certain administrative expenses which the Farm Credit Bank of Spokane has paid; and

Whereas, all claims filed by creditors and holders of equities shall forever be discharged;

Now, therefore, it is hereby ordered that:

1. All claims of creditors, stockholders, and holders of participation certificates and other equities, and of any other persons and/or entities, against the Milk River Production Credit Association, or, to the extent arising out of the actions of the Federal Intermediate Credit Bank of Spokane or its successor, the Farm Credit Bank of Spokane, in carrying out the Liquidation of the Milk River Production Association, as approved by the Farm Credit Administration on January 16, 1985, against the Federal Intermediate Credit Bank of Spokane, the Farm Credit Bank of Spokane, and the Liquidating Agents, are hereby forever discharged, and the commencement of any action, the employment of any process, or any other act to collect, recover, or offset any such claims are hereby forever barred.

2. The accounts of the Milk River Production Credit Association for the period January 16, 1985, through the date of this Order are hereby approved.

3. The Farm Credit Bank of Spokane is hereby finally discharged and released from all responsibility of liability to the Farm Credit Administration or any other person or entity arising out of, related to, or in any manner connected with the administration and liquidation of the Milk River Production Credit Association during the period January 16, 1985, through the date of this Order. The discharge and release of the Liquidating Agents by the Farm Credit Bank of Spokane are hereby approved.

4. The Articles of Incorporation of the Milk River Production Credit Association are hereby cancelled.

Signed: March 25, 1992.

By Harold B. Steele,

Chairman, Farm Credit Administration Board.

Dated: April 9, 1992.

Curtis M. Anderson,

Secretary, Farm Credit Administration Board.

[FR Doc. 92-8693 Filed 4-14-92; 8:45 am]

BILLING CODE 6705-01-M

Final Order Barring Claims, Discharging and Releasing the Farm Credit Bank of Spokane as Receiver and Cancelling Articles of Incorporation of Southern Idaho Production Credit Assoc.

AGENCY: Farm Credit Administration.

ACTION: Notice.

On March 25, 1992, the Chairman of the Farm Credit Administration Board executed a Final Order barring claims against the Farm Credit Bank of Spokane (FCB) as successor to the Federal Intermediate Credit Bank of Spokane, arising out of the liquidation of the Southern Idaho Production Credit Association; discharging the FCB as receiver; and cancelling the Articles of Incorporation of the Southern Idaho Production Credit Association. The text of the Final Order is set forth below:

Final Order Barring Claims, Discharging and Releasing the Farm Credit Bank of Spokane as Receiver and Cancelling Articles of Incorporation of Southern Idaho Production Credit Association

Whereas, the Board of Directors of the Southern Idaho Production Credit Association (Southern Idaho PCA) adopted a resolution placing the PCA in voluntary liquidation and a Liquidation Plan (Plan) outlining the manner in which the liquidation was to proceed, which were approved by the Farm Credit Administration on December 12, 1983;

Whereas, pursuant to the Plan, Dan Williams was appointed Liquidating Agent by the Federal Intermediate Credit Bank of Spokane (FICB) on February 10, 1984, retroactive to December 12, 1983; on March 10, 1984, Gerald Wharton was appointed successor Liquidating Agent; on April 22, 1985, Larry Butterfield was appointed successor Liquidating Agent; on June 18, 1985, Hugh Miller was appointed successor Liquidating Agent; on January 1, 1987, Ray W. Fiscus was appointed successor Liquidating Agent; on December 1, 1988, Robert Damon was appointed successor Liquidating Agent by the Farm Credit Bank of Spokane (successor to the FICB); on February 16, 1989, Kenneth Mathistad was appointed successor Liquidating Agent; and on May 1, 1990, Richard Pierson was appointed successor Liquidating Agent;

Whereas, on December 31, 1988, pursuant to the Sale and Purchase Agreement, the Farm Credit Bank of Spokane purchased substantially all remaining assets of the Southern Idaho PCA and assumed substantially all remaining liabilities;

Whereas, all assets of the Southern Idaho PCA have been disposed of in accordance with the Plan;

Whereas, the Southern Idaho PCA has been audited and examined, and the accounts of the Southern Idaho PCA for the period December 12, 1983, through the date of this Order have been approved;

Whereas, in accordance with the Plan, all claims filed by creditors and holders of equities, except any remaining obligations on direct loans from the Farm Credit Bank of Spokane (successor to the FICB), have been paid or provided for, including, without limitation, certain administrative expenses which the Farm Credit Bank of Spokane has paid; and

Whereas, all claims filed by creditors and holders of equities shall forever be discharged;

Now, therefore, it is ordered that:

1. All claims of creditors, stockholders, and holders of participation certificates and other equities, and of any other persons and/or entities, against the Southern Idaho Production Credit Association, or, to the extent arising out of the actions of the Federal Intermediate Credit Bank of Spokane or its successor, the Farm Credit Bank of Spokane, in carrying out the liquidation of the Southern Idaho Production Credit Association, as approved by the Farm Credit Administration on December 12, 1983, against the Federal Intermediate Credit Bank of Spokane, the Farm Credit Bank of Spokane, and the Liquidating Agents, are hereby forever discharged, and the commencement of any action, the employment of any process, or any other act to collect, recover, or offset any such claims are hereby forever barred.

2. The accounts of the Southern Idaho Production Credit Association for the period December 12, 1983, through the date of this Order are hereby approved.

3. The Farm Credit Bank of Spokane is hereby finally discharged and released from all responsibility or liability to the Farm Credit Administration or any other person or entity arising out of, related to, or in any manner connected with the administration and liquidation of the Southern Idaho Production Credit Association during the period December 12, 1983, through the date of this Order. The discharge and release of the Liquidating Agents by the Farm Credit Bank of Spokane are hereby approved.

4. The Articles of Incorporation of the Southern Idaho Production Credit Association are hereby cancelled.

Signed: March 25, 1992.

By Harold B. Steele,

Chairman, Farm Credit Administration Board.

Dated: April 9, 1992.

Curtis M. Anderson,

Secretary, Farm Credit Administration Board.

[FR Doc. 92-8692 Filed 4-14-92; 8:45 am]

BILLING CODE 6705-01-M

Final Order Barring Claims, Discharging and Releasing the Farm Credit Bank of Spokane as Receiver and Cancelling Articles of Incorporation of Western Montana Production Credit Assoc.

AGENCY: Farm Credit Administration.

ACTION: Notice.

SUMMARY: On March 25, 1992, the Chairman of the Farm Credit Administration Board executed a Final Order barring claims against the Farm Credit Bank of Spokane (FCB) as successor to the Federal Credit Bank of Spokane, arising out of the liquidation of the Western Montana Production Credit Association; discharging the FCB as receiver; and cancelling the Articles of Incorporation of the Western Montana Production Credit Association. The text of the Final Order is set forth below:

Final Order Barring Claims, Discharging and Releasing the Farm Credit Bank of Spokane as Receiver and Cancelling Articles of Incorporation of Western Montana Production Credit Association.

Whereas, the Board of Directors of the Western Montana Production Credit Association (Western Montana PCA) adopted a resolution placing the PCA in voluntary liquidation and a Liquidation Plan (Plan) outlining the manner in which the liquidation was to proceed, which were approved by the Farm Credit Administration on January 16, 1985;

Whereas, pursuant to the Plan, Gerald Wharton was appointed Liquidating Agent by the Federal Intermediate Credit Bank of Spokane (FICB) on January 16, 1985; on April 22, 1985, Larry Butterfield was appointed successor Liquidating Agent; on June 18, 1985, Hugh Miller was appointed successor Liquidating Agent; on January 1, 1987, Ray W. Fiscus was appointed successor Liquidating Agent; on December 1, 1988, Robert Damon was appointed successor Liquidating Agent by the Farm Credit Bank of Spokane (successor to the FICB); on February 16, 1989, Kenneth Mathistad was appointed successor Liquidating Agent; and on May 1, 1990, Richard Pierson was appointed successor Liquidating Agent;

Whereas, on December 31, 1988, pursuant to the Sale and Purchase Agreement, the Farm Credit Bank of Spokane purchased substantially all remaining assets of the Western Montana PCA and assumed substantially all remaining liabilities;

Whereas, all assets of the Western Montana PCA have been disposed of in accordance with the Plan;

Whereas, the Western Montana PCA has been audited and examined, and the accounts of the PCA for the period January 16, 1985, through the date of this Order have been approved;

Whereas, in accordance with the Plan, all claims filed by creditors and holders of equities, except any remaining obligations on direct loans from the Farm Credit Bank of Spokane (successor to the FICB), have been paid or provided for, including, without limitation, certain administrative expenses which the Farm Credit Bank of Spokane has paid; and

Whereas, all claims filed by creditors and holders of equities shall forever be discharged;

Now, therefore, it is hereby ordered that:

1. All claims of creditors, stockholders, and holders of participation certificates and other equities, and of any other persons and/or entities, against the Western Montana Production Credit Association, or, to the extent arising out of the actions of the Federal Intermediate Credit Bank of Spokane or its successor, the Farm Credit Bank of Spokane, in carrying out the liquidation of the Western Montana Production Credit Association, as approved by the Farm Credit Administration on January 16, 1985, against the Federal Intermediate Credit Bank of Spokane, the Farm Credit Bank of Spokane, and the Liquidating Agents, are hereby forever discharged, and the commencement of any action, the employment of any process, or any other act to collect, recover, or offset any such claims are hereby forever barred.

2. The accounts of the Western Montana Production Credit Association for the period January 16, 1985, through the date of this Order are hereby approved.

3. The Farm Credit Bank of Spokane is hereby finally discharged and released from all responsibility of liability to the Farm Credit Administration or any other person or entity arising out of, related to, or in any manner connected with the administration and liquidation of the Western Montana Production Credit Association during the period January 16, 1985, through the date of this Order. The discharge and release of the Liquidating Agents by the Farm Credit Bank of Spokane are hereby approved.

4. The Articles of Incorporation of the Western Montana Production Credit Association are hereby cancelled.

Signed: March 25, 1992.

By Harold B. Steele,

Chairman, Farm Credit Administration, Board.

Dated: April 9, 1992.

Curtis M. Anderson,

Secretary, Farm Credit Administration Board.

[FR Doc. 92-8697 Filed 4-14-92; 8:45 am]

BILLING CODE 6705-01-M

Final Order Barring Claims, Discharging and Releasing the Farm Credit Bank of Spokane as Receiver and Cancelling Articles of Incorporation of Western Washington Production Credit Assoc.

AGENCY: Farm Credit Administration.

ACTION: Notice.

On March 25, 1992, the Chairman of the Farm Credit Administration Board executed a Final Order barring claims against the Farm Credit Bank of Spokane (FCB) as successor to the Federal Intermediate Credit Bank of Spokane, arising out of the liquidation of the Western Washington Production Credit Association; discharging the FCB as receiver; and cancelling the Articles of Incorporation of the Western Washington Production Credit Association. The text of the Final Order is set forth below:

Final Order Barring Claims, Discharging and Releasing the Farm Credit Bank of Spokane as Receiver and Cancelling Articles of Incorporation of Western Washington Production Credit Association

Whereas, the Board of Directors of the Western Washington Production Credit Association (Western Washington PCA) adopted a resolution placing the PCA in voluntary liquidation and a Liquidation Plan (Plan) outlining the manner in which the liquidation was to proceed, which were approved by the Farm Credit Administration on January 16, 1985;

Whereas, pursaunt to the Plan, Gerald Wharton was appointed Liquidating Agent by the Federal Intermediate Credit Bank of Spokane (FICB) on January 16, 1985; on April 22, 1985, Larry Butterfield was appointed successor Liquidating Agent; on June 18, 1985, Hugh Miller was appointed successor Liquidating Agent; on January 1, 1987, Ray W Fiscus was appointed successor Liquidating Agent; on December 1, 1988, Robert Damon was appointed successor Liquidating Agent by the Farm Credit Bank of Spokane (successor to the FICB); on February 16, 1989, Kenneth Mathistad was appointed successor Liquidating Agent; and on May 1, 1990, Richard Pierson was appointed successor Liquidating Agent;

Whereas, on December 31, 1988, pursuant to the Sale and Purchase Agreement, the Farm Credit Bank of Spokane purchased substantially all remaining assets of the Western Washington PCA and assumed substantially all remaining liabilities;

Whereas, all assets of the Western Washington PCA have been disposed of in accordance with the Plan;

Whereas, the Western Washington PCA has been audited and examined, and the accounts of the Western Washington PCA for the period January 16, 1985, through the date of this Order have been approved;

Whereas, in accordance with the Plan, all claims filed by creditors and holders of equities have been paid or provided for, including, without limitation, certain administrative expenses which the Farm Credit Bank of Spokane (successor to the FICB), has paid; and

Whereas, all claims filed by creditors and holders of equities shall forever be discharged;

Now, therefore, it is hereby ordered that:

1. All claims of creditors, stockholders, and holders of participation certificates and other equities, and of any other persons and/or entities, against the Western Washington Production Credit Association, or, to the extent arising out of the actions of the Federal Intermediate Credit Bank of Spokane or its successor, the Farm Credit Bank of Spokane, in carrying out the liquidation of the Western Washington Production Credit Association, as approved by the Farm Credit Administration on January 16, 1985, against the Federal Intermediate Credit Bank of Spokane, the Farm Credit Bank of Spokane, and the Liquidating Agents, are hereby forever discharged, and the commencement of any action, the employment of any process, or any other act to collect, recover, or offset any such claims are hereby forever barred.

2. The accounts of the Western Washington Production Credit Association for the period January 16, 1985, through the date of this Order are hereby approved.

3. The Farm Credit Bank of Spokane is hereby finally discharged and released from all responsibility or liability to the Farm Credit Administration or any other person or entity arising out of, related to, or in any manner connected with the administration and liquidation of the Western Washington Production Credit Association during the period January 16, 1985, through the date of this Order. The discharge and release of the

Liquidating Agents by the Farm Credit Bank of Spokane are hereby approved.

4. The Articles of Incorporation of the Western Washington Production Credit Association are hereby cancelled.

Signed: March 25, 1992.

By Harold B. Steele,

Chairman, Farm Credit Administration Board.

Dated: April 9, 1992.

Curtis M. Anderson,

Secretary, Farm Credit Administration Board.

[FR Doc. 92-8696 Filed 4-14-92; 8:45 am]

BILLING CODE 6705-01-M

Final Order Barring Claims, Discharging and Releasing the Farm Credit Bank of Spokane as Receiver and Cancelling Articles of Incorporation of Willamette Production Credit Assoc.

AGENCY: Farm Credit Administration.

ACTION: Notice.

On March 25, 1992, the Chairman of the Farm Credit Administration Board executed a Final Order barring claims against the Farm Credit Bank of Spokane (FCB) as successor to the Federal Intermediate Credit Bank of Spokane, arising out of the liquidation of the Willamette Production Credit Association; discharging the FCB as receiver; and cancelling the Articles of Incorporation of the Willamette Production Credit Association. The text of the Final Order is set forth below.

Final Order Barring Claims, Discharging and Releasing the Farm Credit Bank of Spokane as Receiver and Cancelling Articles of Incorporation of Willamette Production Credit Association

Whereas, the Board of Directors of the Willamette Production Credit Association (Willamette PCA) adopted a resolution placing the PCA in voluntary liquidation and a Liquidation Plan (Plan) outlining the manner in which the liquidation was to proceed, which were approved by the Farm Credit Administration on May 23, 1984;

Whereas, pursuant to the Plan, Gerald Wharton was appointed Liquidating Agent by the Federal Intermediate Credit Bank of Spokane (FICB) on May 23, 1984; on April 22, 1985, Larry Butterfield was appointed successor Liquidating Agent; on June 18, 1985, Hugh Miller was appointed successor Liquidating Agent; on January 1, 1987, Ray W. Fiscus was appointed successor Liquidating Agent; on December 1, 1988, Robert Damon was appointed successor Liquidating Agent by the Farm Credit Bank of Spokane (successor to the FICB); on February 16, 1989, Kenneth Mathistad was appointed successor Liquidating Agent; and on May 1, 1990, Richard Pierson was appointed successor Liquidating Agent;

Whereas, on December 31, 1988, pursuant to the Sale and Purchase Agreement, the Farm Credit Bank of Spokane purchased substantially all remaining assets of the Willamette PCA and assumed substantially all remaining liabilities;

Whereas, all assets of the Willamette PCA have been disposed of in accordance with the Plan;

Whereas, the Willamette PCA has been audited and examined, and the accounts of the Willamette PCA for the period May 23, 1984, through the date of this Order have been approved;

Whereas, in accordance with the Plan, all claims filed by creditors and holders of equities, except any remaining obligations on direct loans from the Farm Credit Bank of Spokane (successor to the FICB), have been paid or provided for, including, without limitation, certain administrative expenses which the Farm Credit Bank of Spokane has paid; and

Whereas, all claims filed by creditors and holders of equities shall forever be discharged;

Now, therefore, it is hereby ordered that:

1. All claims of creditors, stockholders, and holders of participation certificates and other equities, and of any other persons and/or entities, against the Willamette Production Credit Association, or, to the extent arising out of the actions of the Federal Intermediate Credit Bank of Spokane or its successor, the Farm Credit Bank of Spokane, in carrying out the liquidation of the Willamette Production Credit Association, as approved by the Farm Credit Administration on May 23, 1984, against the Federal Intermediate Credit Bank of Spokane, the Farm Credit Bank of Spokane, and the Liquidating Agents, are hereby forever discharged, and the commencement of any action, the employment of any process, or any other act to collect, recover, or offset any such claims are hereby forever barred.

2. The accounts of the Willamette Production Credit Association for the period May 23, 1984, through the date of this Order are hereby approved.

3. The Farm Credit Bank of Spokane is hereby finally discharged and released from all responsibility or liability to the Farm Credit Administration or any other person or entity arising out of, related to, or in any manner connected with the administration and liquidation of the Willamette Production Credit Association during the period May 23, 1984, through the date of this Order. The discharge and release of the Liquidating Agents by the Farm Credit Bank of Spokane are hereby approved.

4. The Articles of Incorporation of the Willamette Production Credit Association are hereby cancelled.

Signed: March 25, 1992.

By Harold B. Steele,

Chairman, Farm Credit Administration Board.

Dated: April 9, 1992.

Curtis M. Anderson,

Secretary, Farm Credit Administration Board.

[FR Doc. 92-8695 Filed 4-14-92; 8:45 am]

BILLING CODE 6705-01-M

FEDERAL COMMUNICATIONS COMMISSION

Agency Information Collection Requirements Under OMB Review

April 9, 1992.

The following information collection requirements have been approved by the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, (44 U.S.C. 3507). For further information contact Judy Boley, Federal Communications Commission, (202) 632-7513.

OMB No.: 3060-0003.

Title: Application for Amateur Radio Station/Operator License.

Form No.: FCC 610.

A revised application form FCC 610 has been approved for use through 2/28/95. The current edition of the form is dated March 1992. The previous edition of 2/90 may be used until revised forms are available.

OMB No.: 3060-0027.

Title: Application for Construction Permit for Commercial Broadcast Station.

Form No.: FCC 301.

A revised application form FCC 301 has been approved for use through 11/30/94. The current edition of the form is dated February 1992. After June 15, 1992, the Commission will no longer accept the previous edition dated June 1989.

OMB No.: 3060-0029.

Title: Application for New Broadcast Station License.

Form No.: FCC 302.

A revised application form FCC 302 has been approved for use through 11/30/94. The June 1988 edition with the previous OMB expiration date of 9/30/90 will remain in use until updated forms are available.

OMB No.: 3060-0034.

Title: Application for Construction Permit for Noncommercial Educational Broadcast Station.

Form No.: FCC 340.

A revised application form FCC 340 has been approved for use through 11/30/94. The current edition of the form is dated February 1992. After June 15, 1992, the Commission will no longer accept the previous edition dated May 1989.

OMB No.: 3060-0050.

Title: Application for Ship Radio Inspection or Survey.

Form No.: FCC 801.

A revised application form FCC 801 has been approved for use through 1/31/95. The current edition of the form is dated March 1992. The previous edition is obsolete.

OMB No.: 3060-0059.

Title: Statement Regarding the Importation of Radio Frequency Devices Capable of Causing Harmful Interference.

Form No.: FCC 740.

A revised statement form FCC 740 has been approved for use through 7/31/94. The current edition of the form is dated April 1992. The previous edition is obsolete.

OMB No.: 3060–0095.

Title: Cable Television Annual Employment Report.

Form No.: FCC 395–A and 395–AS.

The approval on FCC 395–A and 395–AS has been extended through 3/31/95. The January 1988 edition of FCC 395–A and the March 1989 edition of FCC 395–AS (Supplemental Investigation) will remain in use until updated forms are available.

Federal Communications Commission.

William F. Caton,

Acting Secretary.

[FR Doc. 92–8729 Filed 4–14–92; 8:45 am]

BILLING CODE 6712-01-M

FEDERAL MARITIME COMMISSION

[Docket No. 92-14]

Arpin International Group v. Sea Lion International; Filing of Complaint and Assignment

Notice is given that a complaint filed by Arpin International Group ("Complainant") against Sea Lion International ("Respondent") was served April 9, 1992. Complainant alleges that Respondent engaged in violations of sections 8(a), 10(b)(6) (D) and (E) and 10(d)(1) and/or 19(a) of the Shipping Act of 1984, 46 U.S.C. app. 1707(a), 1709(b)(6) (D) and (E), 1709(d)(1) and 1718(a), by ordering and receiving Complainant's shipment of household goods at Respondent's terminal, retaining Complainant's monies, failing to arrange and pay for ocean transportation, and booking Complainant's shipment with a vessel operating common carrier on a collect basis.

This proceeding has been assigned to Administrative Law Judge Norman D. Kline ("Presiding Officer"). Hearing in this matter, if any is held, shall commence within the time limitations prescribed in 46 CFR 502.61. The hearing shall include oral testimony and cross-examination in the discretion of the Presiding Officer only upon proper showing that there are genuine issues of material fact that cannot be resolved on the basis of sworn statements, affidavits, depositions, or other documents or that the nature of the matter in issue is such that an oral hearing and cross-examination are necessary for the development of an adequate record. Pursuant to the further terms of 46 CFR 502.61, the initial decision of the Presiding Officer in this proceeding shall be issued by April 9, 1993, and the final decision of the Commission shall be issued by August 9, 1993.

Joseph C. Polking,

Secretary.

[FR Doc. 92-8720 Filed 4-14-92; 8:45 am]

BILLING CODE 6730-01-M

FEDERAL RESERVE SYSTEM

Keystone Financial, Inc., et al.; Formations of; Acquisitions by; and Mergers of Bank Holding Companies

The companies listed in this notice have applied for the Board's approval under section 3 of the Bank Holding Company Act (12 U.S.C. 1842) and § 225.14 of the Board's Regulation Y (12 CFR 225.14) to become a bank holding company or to acquire a bank or bank holding company. The factors that are considered in acting on the applications are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

Each application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank or to the offices of the Board of Governors. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Unless otherwise noted, comments regarding each of these applications must be received not later than May 11, 1992.

A. Federal Reserve Bank of Philadelphia (Thomas K. Desch, Vice President) 100 North 6th Street, Philadelphia, Pennsylvania 19105:

1. Keystone Financial, Inc., Harrisburg, Pennsylvania; to merge with Main Line Bancshares, Inc., Wayne, Pennsylvania, and thereby indirectly acquire National Bank of the Main Line, Wayne, Pennsylvania.

B. Federal Reserve Bank of Richmond (Lloyd W. Bostian, Jr., Senior Vice President) 701 East Byrd Street, Richmond, Virginia 23261:

1. Allied Bank Capital, Inc., Sanford, North Carolina; to become a bank holding company by acquiring 100 percent of the voting shares of Summit Savings Bank, Inc., SSB, Sanford, North Carolina.

2. CB&T Financial Corp., Fairmont, West Virginia; to acquire 100 percent of the voting shares of First State Bancorporation, Inc., Elkins, West Virginia, and thereby indirectly acquire First State Bank, Elkins, Inc., Elkins, West Virginia.

C. Federal Reserve Bank of Dallas (W. Arthur Tribble, Vice President) 400 South Akard Street, Dallas, Texas 75222:

1. Lea County Bancshares, Inc., Hobbs, New Mexico; to become a bank holding company by acquiring 100 percent of the voting shares of Lea County State Bank, Hobbs, New Mexico.

Board of Governors of the Federal Reserve System, April 9, 1992.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 92–8663 Filed 4–14–92; 8:45 am]

BILLING CODE 6210-01-F

Mike C. and Tamara M. Daly, et al.; Change in Bank Control Notices; Acquisitions of Shares of Banks or Bank Holding Companies

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. Once the notices have been accepted for processing, they will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than May 6, 1992.

A. Federal Reserve Bank of Kansas City (John E. Yorke, Senior Vice President) 925 Grand Avenue, Kansas City, Missouri 64198:

1. Mike C. and Tamara M. Daly, Wheatland, Wyoming; to acquire an additional 6.45 percent of the voting shares of Wheatland Bankshares, Inc., Wheatland, Wyoming, and thereby indirectly acquire First State Bank of Wheatland, Wheatland, Wyoming.

B. Federal Reserve Bank of Dallas (W. Arthur Tribble, Vice President) 400 South Akard Street, Dallas, Texas 75222:

1. Jimmie Luecke, Timothy A. Kleinschmidt as Trustee for the Susan Luecke Trust and the Fred Luecke Trust; to acquire an additional 11.52 percent of the voting shares of Giddings Bancshares, Inc., Giddings, Texas, and thereby indirectly acquire First National Bank of Giddings, Giddings, Texas.

2. Norman Dean Oswald, Duncanville, Texas; to acquire 34.89 percent of the voting shares of Metroplex Bancshares, Inc., Dallas, Texas, and thereby indirectly acquire Bent Tree National Bank, Dallas, Texas.

Board of Governors of the Federal Reserve System, April 9, 1992.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 92-8662 Filed 4-14-92; 8:45 am]

BILLING CODE 6210-01-F

Redwood Empire Bancorp; Acquisition of Company Engaged in Permissible Nonbanking Activities

The organization listed in this notice has applied under § 225.23(a)(2) or (f) of the Board's Regulation Y (12 CFR 225.23(a)(2) or (f)) for the Board's approval under section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1843(c)(8)) and § 225.21(a) of Regulation Y (12 CFR 225.21(a)) to acquire or control voting securities or assets of a company engaged in a nonbanking activity that is listed in § 225.25 of Regulation Y as closely related to banking and permissible for bank holding companies. Unless otherwise noted, such activities will be conducted throughout the United States.

The application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether consummation of the proposal can "reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices." Any request for a hearing on this question must be accompanied by a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal.

Comments regarding the application must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than May 11, 1992.

A. Federal Reserve Bank of San Francisco (Kenneth R. Binning, Director, Bank Holding Company) 101 Market Street, San Francisco, California 94105:

1. Redwood Empire Bancorp, Santa Rosa, California; to acquire Lake Savings and Loan Association, Lakeport, California, and thereby engage in operating a savings association pursuant to § 225.25(b)(9) of the Board's Regulation Y.

Board of Governors of the Federal Reserve System, April 9, 1992.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 92-8664 Filed 4-14-92; 8:45 am]

BILLING CODE 6210-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Interest Rate on Overdue Debts

Section 30.13 of the Department of Health and Human Services' claims collection regulations (45 CFR part 30) provides that the Secretary shall charge an annual rate of interest as fixed by the Secretary of the Treasury after taking into consideration private consumer rates of interest prevailing on the date that HHS becomes entitled to recovery. The rate generally cannot be lower than the Department of Treasury's current value of funds rate or the applicable rate determined from the "Schedule of Certified Interest Rates with Range of Maturities." This rate may be revised quarterly by the Secretary of the Treasury and shall be published quarterly by the Department of Health and Human Services in the **Federal Register.**

The Secretary of the Treasury has certified a rate of 14⅜% for the quarter ended March 31, 1992. This interest rate will remain in effect until such time as the Secretary of the Treasury notifies HHS of any change.

Dated: April 9, 1992.

Dennis J. Fischer,

Deputy Assistant Secretary, Finance.

[FR Doc. 92-8684 Filed 4-14-92; 8:45 am]

BILLING CODE 4150-04-M

Food and Drug Administration

[Docket No. 83F-0206]

Hercules, Inc.; Withdrawal of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal, without prejudice to a future filing, of a food additive petition (FAP 3B3726) proposing that the food additive regulations be amended to provide for the safe use of dicyandiamide-diethylenetriamine-epichlorohydrin resin in paper and paperboard intended for use in contact with food.

FOR FURTHER INFORMATION CONTACT: Hortense S. Macon, Center for Food Safety and Applied Nutrition (HFF-335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-254-9500.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of July 12, 1983 (48 FR 31909), FDA announced that a food additive petition (FAP 3B3726) had been filed by Hercules, Inc., 910 Market St., Wilmington, DE 19899. This petition proposed that § 176.170 *Components of paper and paperboard in contact with aqueous and fatty foods* (21 CFR 176.170) be amended to provide for the safe use of dicyandiamide-diethylenetriamine-epichlorohydrin resin as a sizing promoter and retention aid in papermaking. Hercules, Inc., has now withdrawn the petition without prejudice to a future filing (21 CFR 171.1).

Dated: April 8, 1992.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 92-8671 Filed 4-14-92; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 91F-0424]

Sherex Chemical Co., Inc.; Filing of Food Additive Petition; Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is amending a filing notice filed by Sherex Chemical Co., Inc., that proposed to amend the food additive regulations to provide for the safe use of imidazolium compounds,

2–C_{17} and C_{17} unsaturated alkyl)–1– [2–(C_{18} and C_{18} unsaturated amido) ethyl]–4,5-dihydro-1-methyl, methyl sulfates as a wet strength agent in paper products intended to contact food. The previous filing notice is amended to designate the additive as a debonding agent rather than as a wet strength agent.

FOR FURTHER INFORMATION CONTACT: Vir Anand, Center for Food Safety and Applied Nutrition (HFF–335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–254–9500.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of November 29, 1991 (56 FR 61022), FDA announced that a petition (FAP 1B4282) had been filed by Sherex Chemical Co., Inc., P.O. Box 6464, Dublin, OH 43017. The petition proposed to amend the food additive regulations to provide for the safe use of imidazolium compounds,2-(C_{17} and C_{17} unsaturated alkyl)-1-[2-(C_{18} and C_{18} unsaturated amido) ethyl]-4,5-dihydro-1-methyl, methyl sulfates as a wet strength agent in paper products intended to contact food. The petitioner, in a letter dated December 13, 1991, has stated that the additive is proposed for use as a debonding agent in paper products. Therefore, notice is given that the additive is proposed for use as a debonding agent rather than as a wet strength agent as indicated in the previous filing notice.

The potential environmental impact of this action is being reviewed. If the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the **Federal Register** in accordance with 21 CFR 25.40(c).

Dated: April 8, 1992.

Fred R. Shank

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 92–8670 Filed 4–10–92; 8:45 am]

BILLING CODE 4160–01–M

[Docket No. 92N–0136]

Proposed Implementation of International Conference on Harmonisation Consensus Regarding New Drug Applications; Proposed Implementation Document; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a proposed implementation document that is consistent with the consensus developed by the Safety Working Group at the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) meeting held in November 1991, in Brussels, Belgium. This proposed implementation document describes scientific and technical aspects of conducting single-dose toxicity studies, reproduction and developmental studies, long-term toxicity studies, carcinogenicity studies, and the timing and duration of studies to be submitted to FDA in support of new drug applications (NDA's). The proposed implementation document is titled "U.S. FDA's Proposed Implementation of ICH Safety Working Group Consensus Regarding New Drug Applications."

DATES: Written comments by June 15, 1992.

ADDRESSES: Submit written requests for single copies of the proposed implementation documents to Judi Weissinger, Center for Drug Evaluation and Research (HFD–502), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send two self-addressed adhesive labels to assist that office in processing your requests. Submit written comments on the proposed implementation document to the contact person (address below) and to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857. Requests and comments should be identified with the docket number found in brackets in the heading of this document. A copy of the proposed implementation document and the comments received may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Judi Weissinger, Center for Drug Evaluation and Research (HFD–502), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–2544.

SUPPLEMENTARY INFORMATION: In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations, to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce unnecessary differences in technical requirements for drug development. The results of such efforts can shorten the development time for new products, thus providing patients with speedier access to new therapies. On November 13, 1991, the Council on Competitiveness, chaired by the Vice President, announced a number of recommendations for improving the drug approval process in the United States and bringing this process into harmonization with other industrialized countries. One of the council's recommendations was that FDA and other countries develop a common set of requirements for animal testing. This notice makes available an implementation document that would achive the goal of that recommendation.

The ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. The ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products in three regions: the European Community, Japan, and the United States. The six ICH organizing groups are the European Commission, the European Federation of Pharmaceutical Industry Associations, the Japanese Ministry of Health and Welfare, the Japanese Pharmaceutical Manufacturers Association, the U.S. Food and Drug Administration, and the U.S. Pharmaceutical Manufacturers Association. In addition, the International Federation of Pharmaceutical Manufacturers Associations (IFPMA) provides the ICH Secretariat, which coordinates the preparation of documentation.

The ICH Steering Committee includes representatives from each of the organizing bodies and the IFPMA, as well as observers from the World Health Organization, the Canadian Health Protection Branch, and the European Free Trade Area (EFTA). The Steering Committee oversees the work of preparing for the conferences, assures broad participation in the process, and follows up on recommendations that arise from the conferences. Three Expert Working Groups, on "Safety," "Quality," and "Efficacy," have been established to develop draft technical consensus positions. In this process, "safety" includes all nonclinical studies, in vitro and in animals; "quality" includes all aspects of product chemistry and manufacturing controls; and "efficacy" includes all clinical data on safety and effectiveness. The main technical

discussions of the conference are conducted in open workship sessions.

The first meeting of the ICH was held in November 1991, in Brussels, Belgium. The second meeting of the ICH will be held in the United States in 1993, and the third meeting will be held in Japan in 1995. At the November 1991 meeting, workship sessions in the three main areas of safety, quality, and efficacy were held to develop recommendations that identify scientific and technical inconsistencies appropriate for harmonization, define appropriate objectives, and suggest procedures for accomplishing the objectives.

The ICH process is an evolving approach for bringing drug development programs and the regulatory considerations of the three regions concerning human pharmaceutical products closer together. As discussion leads to consensus, the regulatory authorities may then begin to implement changes that reflect that consensus, as the individual regulatory authorities deem appropriate consistent with their national procedures for establishing policy and regulations. Although the ICH process will continue for some time, when consensus has been reached on specific issues, the FDA intends to propose implementation of those changes it finds acceptable as soon as possible.

FDA believes that it is possible to modify some of the agency's current technical requirements for drug development, in keeping with the tripartite consensus reached through the ICH process, while still maintaining the current high standards of safety, efficacy, and quality.

Among the goals of the Expert Working Group on Safety is to seek ways to avoid unnecessary duplication of animal testing and address concerns about single and repeat dose toxicity, carcinogenicity, and reproductive toxicology. At the November 1991 ICH meeting, consensus emerged among participants at the Safety Workshop on certain scientific and technical issues that had been identified.

FDA has developed a document that describes the agency's proposed implementation of the ICH Safety Working Group's scientific consensus regarding certain aspects of preclinical studies to support new drug applications. This document discusses FDA's proposed plan for adopting guidance to industry on(1) single-dose (acute) toxicity studies, (20 reproductive and developmental studies, (3) long-term toxicity studies, and (4) carcinogenicity studies. The proposed implementation document also describes the timing and duration of animal studies relative to the expected extent and duration of human exposure to the drug.

Attachments to the proposed implementation document include draft guidance on single-dose (acute) toxicity studies (Attachment I); current guidelines for reproduction studies for safety evaluation of drugs for human use (Attachment II); and a draft table summarizing the timing and duration of nonclinical studies generally necessary to support clinical trials and NDA submissions (Attachment III). FDA and other ICH participants are in the process of developing revised guidelines for reproduction studies that have been made available in draft form for comments (Ref. 1). FDA is at this time specifically seeking comment on the draft guidance in Attachments I and III. These comments will be taken into account as FDA proceeds to refine and develop guidance on single-dose (acute) toxicity studies and on the timing and duration of nonclinical studies.

As the ICH process continues and consensus is reached on additonal safety, quality, and efficacy issues, FDA will continue to seek input from interested persons and will continue to revise its guidance to industry as expeditiously as possible.

Interested persons may, on or before June 15, 1992, submit written comments on the proposed implementation document (including the draft guidance in Attachments I and III) to the Dockets Management Branch and the contact person (addresses above). Two copies of any comments are to be submitted to the Dockets Management Branch and a single copy is to be submitted to the contact person.

Reference

The following information has 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. Bass, R., B. Ulbrich., A. G. Hildebrandt, J. Weissinger, O. Doi, A. Baeder, S. Fumero, Y. Harada, H. Lehmann, J. Manson, D. Neubert, Y. Omori, A. Palmer, F. Sullivan, S. Takayama, T. Tanimura, "Draft Guideline on Detection of Toxicity to Reproduction for Medicinal Products," *Adverse Drug React. Toxicol Rev.*, Oxford University Press, 9(3): 127–141, 1991.

Dated: April 6, 1992.

Michael R. Taylor

Deputy Commissioner for Policy.

[FR Doc. 92–8401 Filed 4–14–92; 8:45 am]

BILLING CODE 4160–01–M

Health Care Financing Administration

[ORD–064–N]

Medicare and Medicaid Programs; Small Business Innovation Research Grants for Fiscal Year 1992

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice.

SUMMARY: This notice announces the availability of HCFA funding, through grants, for small businesses under the Small Business Innovation Research Program. This notice contains information about the subject areas for grants that will be given priority, application requirements, review procedures, and other relevant information.

DATES: Grant applications must be submitted by July 14, 1992. In order to be considered under the fiscal year (FY) 1992 annual funding cycle. For an explanation of a timely submission see section IV. of this notice entitled, "Submission of Grant Applications".

ADDRESSES: Standard application forms and related instructions are available from and must be formally submitted to: HCFA Grants Officer, Contract Administration & Grants Branch, Division of Contracts and Grants, Office of Acquisitions and Grants/OBA, Health Care Financing Administration, 389 East High Rise Building, 6325 Security Boulevard, Baltimore, Maryland 21207–5187, (410) 966–5157.

FOR FURTHER INFORMATION CONTACT: Questions on the HCFA SBIR Program may be addressed to: Sydney P. Galloway, SBIR Coordinator, Office of Research and Demonstrations, Health Care Financing Administration, Room 2226 Oak Meadows Building, 6325 Security Building, Baltimore, Maryland 21207–5187, (410) 966–6645. Questions regarding completion of the application forms may be addressed to: HCFA Grants Officer, (410) 965–5157.

SUPPLEMENTARY INFORMATION:

I. Small Business Innovation Research Program

The Small Business Innovation Development Act of 1982 (Pub. L. 97–219), as amended by the Small Business Innovation Research Program, Extension (Pub. L. 99–443), requires Federal agencies to reserve a specific amount of their extramural research and development (R&D) budgets for a Small Business Innovation Research (SBIR) Program. This SBIR Program is intended to—

- Stimulate technological innovation;

• Use Small businesses to meet Federal research and development needs;

• Increase private sector commercialization of innovations derived from Federal research and development; and

• Foster and encourage participation by minority and disadvantaged persons in technological innovation.

The principal purpose of HCFA's SBIR Program is to provide assistance to creative applicants so that innovations can be encouraged and so that this innovation will result in better health care.

A. SBIR Program Phases, Award Amounts and Period of Support

The SBIR Program consists of the following three phases:

Phase I

The objective of this phase is to establish the technical merit and feasibility of proposed research or R&D efforts and to determine the quality of performance of the small business awardee organization before furnishing further Federal support in Phase II.

Phase I awards will generally be approximately $35,000 (for both direct and indirect costs) for a period normally not to exceed 6 months.

Phase II

The objective of this phase is to continue the research or R&D efforts initiated in Phase I. Funding is based on the results of Phase I and the scientific and technical merit of the Phase II application. (Only Phase I awardees are eligible to apply for Phase II funding and Phase II applications may be submitted only after the Phase I budget period has expired, as specified in 15 U.S.C. 638(e)(4). Phase I grantees are eligible to apply for Phase II funding only from the Federal agency that supported their Phase I profect.)

Phase II awards will generally be approximately $10,000 (for both direct and indirect costs) for a period normally not to exceed 2 years. Only one Phase II award may be made for any SBIR project.

Phase III

The objective of this phase, where approporiate, is for the small business to pursue with non-Federal funds the commercialization of the results of the research of R&D in Phase I and II.

The purpose of this notice is to invite Phase I grant applications from domestic small businesses that have the expertise to develop new innovatiove technology that is compatible with the general mission of HCFA and which will contribute to the health care field. HCFA is responsible for the Medicare program, Federal participation in the Medicaid program, and related health care quality assurance programs. HCFA's mission is to promote the timely delivery of appropriate, quality health care to its beneficiaries and recipients; approximately 51 million of the nations's aged, disabled and poor. The agency must also ensure that program beneficiaries/recipients are aware of the services for which they are eligible and that those serrvices are accessible and of high quality.

In carrying out its mission, HCFA conducts studies and projects that examine and demonstrate payment, coverage, eligibility, and management alternatives to the present programs. HCFA also studies the impact of HCFA programs on health care costs, program expenditures, beneficiary/recipient access to services, health care providers, and the health care segment of the American economy. In addition, HCFA monitors national health care expenditures and prices and provides analyses of the costs of current programs as well as the impact of possible legislative or administrative changes in the programs. HCFA's Office of Research and Demonstrations (ORD) is responsible for the technical aspects of the SBIR Program described above.

This notice outlines the eligibility requirements for those organizations wishing to participate in the HCFA SBIR Program, and the research grant application and review processes. It also provides both general program information as well as specific research topics and sub-topics that may be of interest to small businesses.

Although areas of special programmatic interest or priority are described in section VII. of this notice, we will consider grant applications in any area within the field of health care R&D unless other wise specifically excluded.

B. Eligibility

Each organization submitting a grant application under the SBIR Program must qualify as a small business in accordance with the definition given below. In determining whether an applicant is a small business, an assessment will be made of several factors, including whether or not it is independently owned and operated and whether or not it is an affiliate of a larger organization whose employees, when added to those of the applicant organization, exceed 500. In conducting this assessment, all appropriate factors will be considered, including common ownership, common management, and contractural relationships.

In accordance with title 13 Code of Federal Regulations (CFR) 121.401, affiliation exists when one concern controls or has the power to control the other. Control may be affirmative or negative, and it is immaterial whether it is exercised so long as the power to control exists. One of the circumstances that would lead to a finding that an organization is controlling, or has the power to control another organization is the sharing of common office space, employees or other facilities (for example, laboratory space). Although access to special facilities or equipment in another organization is permitted (as in cases in which the SBIR applicant has entered into a sub-contractural agreement with another institution for a specific, limited portion of the research project), research space occupied by an SBIR applicant must be space which is not generally shared with another organization and over which the applicant has exclusive control. When there is indication of sharing of common employees, a determination will be made on a case-by-case basis of whether or not such sharing constitutes control or the power to control.

This same regulation also states that control or the power to control exists when "key employees of one concern organize a new concern * * * and serve as its officers, directors, principal stockholders, and/or key employees, and the one concern is furnishing or will furnish the other concern with subcontractors, financial or technical assistance, bid or performance bond indemnification, and/or other facilities, whether for a fee or otherwise." (See 13 CFR 121.401(j).)

All SBIR grant applications will be reviewed with the above considerations in mind. If it appears that an applicant organization does not meet eligibility requirements, HCFA will request a size determination of the organization from the applicable Small Business Administration (SBA) regional office. The review of the application for scientific merit may be deferred until a definitive response is furnished by SBA.

The regulations concerning grants for research projects defines the concept of a principal investigator as "a single individual designated by the grantee in the grant application * * * who is responsible for the scientific and technical direction of the project." (See 42 CFR 52.2.) We are adopting this "principal investigator" concept from 42 CFR Part 52, and this concept will be used to assure that support is furnished to a carefully directed working group led

by an individual personally committed to the development of the innovation. The primary employment of the principal investigator must also be with the firm at the time of award and during the conduct of the proposed project. Primary employment means that more than one-half of the principal investigator's time is spent in the employment of the small business. Primary employment with a small business precludes full-time employment at another organization.

In accordance with SBA's SBIR Program Policy Directive published on June 24, 1988, 53 FR 23829, we have further restricted the definition of primary employment of the principal investigator to more accurately reflect HCFA's needs. All applications must declare the primary employment of the principal investigator. In the event that the principal investigator: (1) Is a less-than-full-time employee of the small business, (2) is concurrently employed by another organization, or (3) gives the appearance of being concurrently employed by another organization, whether for a paid or unpaid position, at the time of submission of application, it is essential that documentation be submitted with the application to verify his or her eligibility. Thus, if the principal investigator is also employed or appears to be employed by an institution other than the applicant organization (for example, a university, non-profit research institute, or a company other than the applicant), a letter must be furnished by the non-applicant organization confirming that the principal investigator, if awarded an SBIR grant, is or will become a less-than-half-time employee of such organization and will remain so for the duration of the SBIR project. If the principal investigator is employed by a university, such a letter must be furnished by the dean of the school or the departmental chairperson. If the principal investigator is employed by another for-profit organization, the letter must be signed by a corporate official. This documentation of the primary employment of the principal investigator is required for every application that is submitted, even one that is a revision of a previously submitted application. In cases where the principal investigator fails to furnish adequate documentation, the application may be returned without review.

For both Phase I and Phase II, the research or R&D must be performed in its entirety in the United States (U.S.), that is, the States, territories, and possessions of the U.S.; the Commonwealths of Puerto Rico and the Northern Mariana Islands; and the District of Columbia.

II. Definitions

The words and phrases that appear on the SBIR application form, or are needed in the application narrative, are not readily defined. Therefore, for convenience and clarity, we have furnished the following definitions which, except as noted, are taken from SBA's SBIR Program Policy Directive published on June 24, 1988, 53 FR 23829, that implements this program. This policy directive requires an agency to define in a separate section whatever terms it uses that are unique to either the SBIR Program, a specific SBIR solicitation, or a portion of the solicitation. However, such section must also include, at a minimum, specific terms as defined in the policy directive. Accordingly, in addition to the terms required by the policy directive, we are also defining the terms "Contract" and "Grant" and including the policy directive's definition of the term "Research and Development."

A. Contract

A "contract" is an award instrument establishing a binding legal procurement relationship between a funding agency and the recipient, obligating the latter to furnish an end product or service and binding the agency to furnish payment therefor.

B. Grant

A "grant" is a finanical assistance mechanism whereby either money or direct assistance, or both is furnished to carry out approved activities.

C. Minority and Disadvantaged Individual

A "minority and disadvantaged individual" is defined as a member of any of the following groups:

- Asian-Pacific Americans
- Black Americans
- Hispanic Americans
- Native Americans
- Sub-continent Asian Americans

D. Minority and Disadvantaged Small Business

A "minority and disadvantaged" small business concern is one—

- In which at least 51 percent is owned by one or more minority and disadvantaged individuals or, in the case of any publicly owned business, at least 51 percent of the voting stock is owned by one or more minority and disadvantaged individuals; and
- Whose management and daily business operations are controlled by one or more of such individuals.

For the sake of clarity, we have divided the SBA's policy directive's definition of "Miority and Disadvantaged Small Business" into the above two definitions.

E. Research and Development

"Research" or "research and development" (R&D) is defined as any activity that is—

- A systematic, intensive study directed toward greater knowledge or understanding of the subject studies;
- A systematic study directed specifically toward applying new knowledge to meet a recognized need; or
- A systematic application of knowledge toward the production of useful materials, devices, and systems or methods, inlcuding design, development, and improvement of prototypes and new processes to meet specific requirements.

F. Small Business

At the time of award of Phase I and of Phase II, a "small business" is a concern that—

- Is organized for profit, independently owned and operated, not dominant in the field of operation in which it is proposing, and has its principal place of business located in the U.S.;
- Is at least 51 percent owned or, in the case of a publicly owned business, at least 51 percent of its voting stock is owned by U.S. citizens or lawfully admitted permanent resident aliens; and
- Has, including its affiliates, ("affiliation" is defined in greater detail in 13 CFR 121.401) a number of employees (as defined in 13 CFR 121.407) not exceeding 500, and meets the other small business size regulation requirements found in 13 CFR part 121. Business concerns, other than investment companies licensed, or state development companies qualifying, under the Small Business Investment Act of 1958, (15 U.S.C. 661, et seq.) are affiliates of one another when either directly or indirectly (A) one concern controls or has the power to control the other; or (B) a third party or parties controls or has the power to control both. Control can be exercised through common ownership, common management and contractual relatonships. Business concerns include, but are not limited to, any individual, partnership, corporation, joint venture, association, or cooperative.

G. Subcontract

A "subcontract" is any agreement, other than one involving an employer-employee relationship, entered into by a

Federal Government contractor or grantee calling for supplies or services required solely for the performance of the basic contract or grant.

H. Women-owned Small Business

A "women-owned small business" is a business which is at least 51 percent owned, controlled, and operated by a woman or women. "Control" is defined as exercising the power to make policy decisions; "operate" is defined as being actively involved in the day-to-day management.

III. Preparation of Grant Applications

The forms and instructions will be supplied by the HCFA Grants Officer (see **ADDRESSES** above) and are designed for use in applying for SBIR Phase I research grants. The instructions contain the SBA policy directive's guidelines on proposal content and limitations.

Potential applicants are encouraged to contact the SBIR Coordinator (see **FOR FURTHER INFORMATION CONTACT** above) for preapplication technical assistance and for more specific information on the research topics described in section VII. of this notice.

Health science research literature is available at academic and health science libraries throughout the U.S. Information retrieval services are available at these libraries and Regional Medical Libraries through a network supported by the National Library of Medicine. A list of Regional Medical Libraries and information about network services may be requested from the Public Information Office, National Library of Medicine, Bethesda, Maryland 20894, (301) 496–6308.

Other sources that provide technology search and document services include the organizations listed below. They should be contacted directly for service and cost information.

National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161, (703) 487–4600

NASA Industrial Applications Center, 701 LIS Building, University of Pittsburgh, Pittsburgh, PA 15260, (412) 624–5211

North Carolina Science and Technology Research Center, Post Office Box 12235, Research Triangle Park, NC 27709, (919) 549–0671

NASA/Florida State Technology Applications Center, State University System of Florida, 500 Weil Hall, Gainesville, FL 32611, (904) 392–6626

NASA/UK Technology, University of Kentucky, 109 Kinkead Hall, Lexington, KY 40506, (606) 257–6322

Aerospace Research Applications Center, 611 N. Capitol Avenue, Indianapolis, IN 46204, (317) 262–5003

Kerr Industrial Applications Center, Southeastern Oklahoma State University, Durant, OK 74701, (405) 924–6822

IV. Submission of Grant Applications

Grant applications must be submitted to the HCFA Grants Officer (see the **ADDRESSES** section above).

The following schedule applies to the receipt, review, and award of SBIR applications.

	1992
Receipt date	July 14.
Technical review	August 14.
Award decisions	September 14.
Approximate start	October 14.

Applications must be received by July 14, 1992. Applications mailed through the U.S. Postal Service or a commercial delivery service will be "on time" if they are received on or before the closing date, or are postmarked on or before the closing date and received in time for submission to the technical review panel. Applications that do not meet the above criteria will be considered late applications. Respondents are warned that if their application is late it may be returned without review.

V. Method of Selection and Evaluation Criteria

All Phase I and Phase II grant applications will be evaluated and judged on a competitve basis. Applications will be screened and those found to be inadequate for review or programmatically unrelated to HCFA's mission may be returned to the applicant. Those passing the screening will be reviewed for technical and scientific merit. Each application will be judged individually, as described below. HCFA is under no obligation to fund any application or make any specific number of awards in a given topic area. It may also elect to fund several (or none) of the proposed projects within a given topic area.

A. Review Process

Grant applications are subject to a review process involving two sequential steps. The first step is performed by the technical review panel composed primarily of Federal and non-Federal professionals selected for their competence in particular fields. The task of the panel is to evaluate applications for scientific and technical merit. The reviewers furnish a numeric rating, make an overall recommendation and, on occasion, make highly specific recommendations related to the scope, direction, and conduct of the proposed research. The second level of review is made by the senior management of HCFA ORD. ORD management decisions are based on judgments about, not only the technical merit of the proposed research, but also its relevance to the mission of the awarding component. Generally, HCFA may award a grant only if the corresponding application has been recommended for approval by the panel. However, applications recommended for approval are not automatically funded.

B. Review Criteria

In considering the scientific and technical merit of each application, the following criteria and weights will be used:

- The soundness and technical merit of the proposed approach—35 percent.
- The potential of the research for technological innovation including the potential for commercial application—30 percent.
- The qualifications of the proposed principal investigator, support staff and consultants—20 percent.
- The appropriateness of the budget—10 percent.
- The adequacy and suitability of the facilities and research environment—5 percent.

C. Funding Decisions

When making funding decisions, ORD takes into consideration the following: (a) Ratings resulting from the technical evaluation process, (b) program relevance, and (c) available funds.

D. Release of Grant Application Review Information

Summary statements will be sent to principal investigators following decisions on grant applications.

E. Submission of Similar Grant Applications by the Applicant Organization

HCFA discourages the submission of similar grant applications by the same applicant organization. Principal investigators are cautioned not to prepare multiple grant applications with essentially the same research focus; that is, a produt or technology that, with non-substantive modifications, can be applied to a variety of purposes. In evaluating groupings of applications

with a common scientific focus or objective, technical review groups are in a position to eastily identify multiple grant applications from the same organization for essentially the same project. In these cases, HCFA will give funding consideration to only one application.

VI. Considerations

SBA's SBIR Program Policy Directive (53 FR 23829) specifies that the following information and conditions be furnished:

A. Awards

- There will be approximately six to eight Phase I awards in FY 92.
- The dollar amount of each Phase I award (including both direct and indirect costs) will be approximately $35,000.
- The dollar amount of each Phase II award (including both direct and indirect costs) will be approximately $100,000.
- The primary award mechanism will be the grant instrument.
- In accordance with the administration of grant regulations, specifically 45 CFR 74.705, no fee or profit will be furnished.

B. Reports

The grantee organization will be required to submit short monthly progress reports, a complete draft final report and a final report. The award will specify the schedule for these reports and place of delivery.

C. Payment Schedule

Once an SBIR grant is awarded, the grantee organization will receive information and forms regarding requests for cash, manner of payment, and associated reporting requirements. Payment may be made on a cost-reimbursement or advance basis. Cost reimbursements may be requested montly, quarterly, or at other periodic intervals. Advance payments may be requested on a monthly basis only.

D. Limited Rights Information and Data

1. Proprietary Information

Information contained in unfunded grant applications will remain the property of the applicant. HCFA may, however, retain copies of all applications. Public release of information in any application will be subject to existing requirements found in the statute and regulations.

If proprietary information furnished in an application constitutes trade secrets or proprietary commercial or financial information, confidential personal information or data affecting the national security, it will be treated in confidence, to the extent permitted by law, provided this information is clearly identified by the appropriate page numbers under the Notice of Proprietary Information in the SBIR grant application.

Any other notice may be unacceptable to HCFA and may constitute grounds for return of the application without further considerations and without assuming any liability for inadvertent disclosure. When possible, HCFA will limit dissemination of such proprietary information within official channels.

2. Title to Property

Title to real property, equipment, and supplies acquired by a for-profit recipient under a financial assistance award or sub-ward will vest, upon acquisition, in the Federal Government. However, such title may be transferred to the awardee upon termination of the project if the transfer would be more cost-effective than recovery of the property by the Federal Government. It is recommended that applicants consider leasing arrangements whenever possible. HCFA will generally not fund projects that require the acquisition of real property, equipment or supplies.

3. Rights in Data Developed Under the SBIR Grant.

Rights in data, including software developed under the terms of any grant resulting from an application submitted in response to this notice will remain with the grantee, except that the Federal Government will have the limited right to use such data for internal Federal Government purposes. These data will not be released outside the Federal Government without permission of the grantee for a period of 2 years from completion of the project from which the data were generated. However, at the end of this two year period a royalty-free license will be provided to HCFA to use, and to authorize others to use on its behalf, these data for Federal Government purposes, but is relieved of all disclosure prohibitions and assumes no liability for unauthorized use of these data by third parties. This notice will be affixed to any reproductions of these data, in whole or in part.

4. Copyrights.

With prior written permission of the Grants Officer, the awardee may normally copyright and publish (consistent with appropriate national security considerations, if any) material developed with HCFA's support. HCFA receives a royalty-free license for the Federal Government and requires that each publication contain an appropriate acknowledgement of agency support and a disclaimer statement.

5. Patents.

Small business firms may normally retain the principal worldwide patent rights to any invention developed with HCFA support. The Federal Government receives a royalty-free license for Federal Government use, reserves the right to require the patentholder to license others in certain circumstances, and requires that anyone exclusively licensed to sell the invention in the U.S. must normally manufacture it substantially in the U.S. The law concerning confidentiality (35 U.S.C. 205) specifies that the Federal Government will not make public any information disclosing a Government-supported invention for a 2-year period to allow the awardee a reasonable time to pursue a patent.

E. Profit or Fee

Current regulations at 45 CFR 74.705, concerning prohibition against profit, states, in effect, that no profit or fee will be furnished to for-profit organizations through grants. A profit is considered to be any amount in excess of actural direct and indirect costs incurred in the conduct of a grant project. However, 45 CFR 74.705 is superseded by the SBA Program Policy Directive (53 FR 23829) for the SBIR Program. This policy directive does permit the payment of a reasonable fee or profit under the SBIR Program.

F. Joint Ventures and Limited Partnerships

Joint ventures and limited partnerships are eligible provided the entity created qualifies as a small business in accordance with the definition included in this notice.

G. Performance of Research and Analytical Work by the Applicant Organization

In Phase I, a minimum of two-thirds or 67 percent of the research or analytical effort must be carried out by the small business; that is, consultant fees and contracts to a third party for portions of the scientific/technical effort may not exceed 33 percent of the total proposed budget.

In Phase II, a minimum of one-half or 50 percent of the research or analytical effort must be carried out by the small business; that is, consultant fees and contracts to a third party for portions of the scientific/technical effort may not exceed 50 percent of the total proposed budget.

H. Terms and Conditions of Awards

Upon acceptance of a grant, the awardee must comply with the terms and conditions contained or referenced in the Notice of Grant Award document. These terms and conditions, constituting legal requirements imposed on a grantee by statute, regulations, administrative policy, or the award document itself, are comprised of the following "standard" and "special" provisions:

• Standard Provisions. Terms and conditions required as part of each Notice of Grant Award.

a. Grant program legislation
b. Grant program regulations
c. The inclusion of special terms and conditions, if any (see below).
d. 45 CFR part 74

• Special Provisions. Additional terms and conditions judged necessary to attain the objectives for which the grant is being made, to facilitate post-award administration of the grant, to conserve grant funds, or to otherwise protect the interests of the Federal Government.

a. Requirement for written progress reports and due dates.
b. Requirement for a draft final report and due date.
c. The availability of the HCFA Project Officer.
d. Grantees responsibility with respect to information contained in technical documents.
e. HCFA's rights to suspend or terminate the grant.
f. Protection of individually identifiable data.
g. Grantees responsibilities with respect to presentation of information.
h. Key personnel.
i. Submission of data to the Federal Government.
j. Submission of items developed to the Federal Government.
k. Other special terms and conditions that are appropriate to the circumstances of the award.

Grants must be administered in accordance with the following regulations:

42 CFR Part 52—Grants for Research Projects
45 CFR Part 46—Protection of Human Subjects
45 CFR Part 74—Administration of Grants
CFR Part 80—Nondiscrimination Under Programs Receiving Federal Assistance Through the DHHS Effectuation of Title VI of the Civil Rights Act of 1964
45 CFR Part 84—Nondiscrimination on the Basis of Handicap in Programs and Activities Receiving Federal Financial Assistance
45 CFR Part 91—Nondiscrimination on the Basis of Age in HHS Programs or Activities Receiving Federal Financial Assistance

I. Cost Sharing

Cost sharing is not required not will it be an evaluation factor in consideration of your proposal. However, due to the special nature of the SBIR Program the applicant may choose to share the costs of a project. This may be done through cash or in-kind contributions. Most frequently we expect that the applicant will contribute more labor or use unreimbursed equipment as the applicant's share.

J. Additional Information

This Federal Register notice is intended for informational purposes and reflects current planning. If there is any inconsistency between the information contained herein and the terms of any resulting SBIR grant, the terms of the grant are controlling.

Before award of a SBIR grant, HCFA may request the applicant to submit certain organizational, management, personnel, and financial information in order to assure responsiblity of the applicant.

The Federal Government is not responsible for any monies expended by the applicant before the award of any grant.

This notice is not an offer by HCFA and does not obligate HCFA to make any specific number of awards. Awards under this SBIR Program are contingent upon the scientific/technical merit of an application and the availability of funds for R&D.

The SBIR Program is not a substitute for HCFA's existing unsolicited proposal mechanisms and unsolicited proposals will not be accepted under either Phase I or Phase II of the SBIR Program.

The applicant may be required to certify that it has not previously been nor is currently being paid for essentially equivalent work by an agency of the Federal Government. If a grant is made under this notice for a project, some of whose elements are being or will be supported by another Federal agency, HCFA and the applicant will negotiate a budget that reflects the elimination of any overlapping support.

This program is not covered by Executive Order 1372, "Intergovernmental Review of Federal Programs."

VII. Research Topic Areas

This notice invites SBIR Phase I applications in the following areas. Please note that the topics are defined in very general terms. The topics are intended to indicate generally where we feel we can properly offer assistance to the development of new innovative technology. ORD will consider any idea that is within the general subject of a topic area. In addition, ORD will review any idea that is within the general purview of HCFA as described in section I. of this notice. Applicants are reminded that the overall intent of the HCFA SBIR Program is to provide assistance to the development of products and processes that have commercial potential and not to the acquisition of products for its own use.

A. High Quality/Effective Care

HCFA invites ideas that would develop products to assist all participants in health care in assessing and monitoring the quality of care and level of care being furnished to patients. Projects should aim to develop tools for health care professionals, providers and managers that permit them to examine patterns of services being delivered and the health and social outcomes of those services. Projects that would assist private organizations in developing patient guidelines and in conducting technology assessments are of interest. These tools should provide a way to monitor and measure the delivery of health services and the outcomes from those services. They should also make possible a judgment about the quality of the care or the effectiveness of the care or both. The technical efficiency with which are is delivered and the appropriateness of the overall outcome for the patient should be addressed.

B. Management of Ambulatory Services

HCFA invites ideas that would develop generally useable tools to monitor, assess and control overutilization of ambulatory servcies and products at all levels of the health care system. Separate and apart from the sheer inflation in the price of each service, a significant cause of the rising cost of health services is execessive utilization. Traditionally, utilization review techniques have been applied to high cost, acute services such as surgery and hospitalizations. We now wish to focus on physician services and other ambulatory services and products, for example, drugs, medical equipment and testing. HCFA invites applications related to services or products commonly associated with Medicare beneficiaries and Medicaid recipients, who are primiarly the aged, the poor, the disabled and persons with end-stage renal disease. Techniques to be explored involve systems both for retrospective utilization pattern review

and for managing prospective interventions in individual physician or beneficiary/receipient service or product use. This area also includes broader management tools, based on information derived from utilization review, that promote or assure more efficient and effective service delivery.

C. Beneficiary Information and Assistance

HCFA invites ideas which may make the Medicare and medicaid programs more understandable to beneficiaries and recipients, respectively, and that provide assistance to these individuals in their attempts to deal with the programs. Potential program users (Medicare beneficiaries and Medicaid recipients) need to understand when they are and when they are not eligible, what services or products are (and are not) covered and what their rights and responsibilities are within each program. An example would be an information project that would assist health care consumers in general, including Medicare beneficiaries and Medicaid recipients, by providing aggregate data on provider performance and utilization trends, discrete price information, and information on related copayments, etc.; in a sense a "Blue Book for Consumers." Another example is related to the fact that one of the most frequent problems encountered by Medicare beneficiaries is obtaining payment for claims. The process of dealing with Medicare's fiscal intermediaries and carriers is difficult for many. Tools that would ease this process would be welcome. There are distinct advantages to Medicare beneficiaries if they "assign" their rights to claim Medicare payment to the physician who furnishes the services. Yet, this concept is hard to explain and is not well understood by beneficiaries. Beneficiaries also need to be able to decide whether they should join, or exit from, a health maintenance organization and the advantages and disadvantages of such a decision. Beneficiaries need to understand what considerations to take into account when long term care is a possibility. Likewise, beneficiaries need to be assisted in the decision about the purchase of health insurance in addition to Medicare. HCFA invites ideas in beneficiary communication and assistance approaches that are tailored to special sub-populations (such as significant demographic, socio-cultural or disease-related sub-groups of beneficiaries), as well as approaches that could be used by supplemental health benefit program sponsors (for example, employers and unions) in assisting Medicare-eligible retirees.

Applicants who are considering this topic should understand that the SBIR Program generally seeks to support the development of commercially viable products and that there is already a fair amount of existing commercial activity in this area.

D. Program Efficiencies and Improvement

The existing systems for health care delivery and financing have undergone, and are continuing to undergo, changes due to new technology, legislation, regulation and market forces. Major payers for health care are continually studying the feasibility of new approaches to improving the management of care, the delivery of care, and financing. Therefore, HCFA invites applications that focus on tools to assist in the goal of improved management of the Medicare and Medicaid programs. The term management here is used in a very broad sense. These could be tools which are directed toward providers who furnish services or products to Medicare beneficiaries or Medicaid recipients, organizations that handle the financing of care, organizations that oversee the quality of services and products, or the beneficiaries/recipients themselves, and State or local organizations that deal primarily with Medicare and Medicaid populations.

HCFA will consider any innovative idea that appears to have the potential of improving the programs for any of the several parties involved, and which has a potential for sale in the normal/commercial market. An example of an innovative idea would be the development of improved personal computer based case management systems for community care services. Case management programs are commonly being used to coordinate community based care for frail elderly and other populations under Medicaid and other programs. Automated systems that use client eligibility and assessment information to assist case management agencies in preparing appropriate plans of care based on the clients condition, that select service providers and prepare service orders, and that interface with service approval/financial/billing systems could improve the cost-efficiency of case management programs.

Proposed systems should compliment or integrate existing mandated HCFA instruments (particularly functional assessment tools, minimum data sets, discharge planning, etc.). New redundant instruments will not be considered for funding.

E. Other Health Care R&D

We encourage small businesses to submit applications for propose research in any area within the field of health care R&D.

Authority: Pubd. L. 97-219, 96 Stat. 217-221, Pub. L. 99-443, 100 Stat. 1120, Sec. 108, Pub. L. 100-590, 102 Stat. 2994 (15 U.S.C. 638).

(Catalog of Federal Domestic Assistance Program No. 93.779, Health Financing Research, Demonstrations and Experiments)

Dated: February 10, 1992.

Gail R. Wilensky,

Administratior, Health Care Financing Administration.

[FR Doc. 92-8625 Filed 4-14-92; 8:45 am]

BILLING CODE 4120-01-M

Health Resources and Services Administration

Program Announcement for Scholarships for Disadvantaged Students

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Correction and extension of deadline date.

SUMMARY: In notice document 92-6754, in the issue of Tuesday, March 24, 1992, make the following correction:

On page 10182 in the third column, the national average enrollment of Blacks, Hispanics and Native Americans (in combination) in schools of osteopathic medicine should read 7.8 percent.

On page 10183, in column 2, the deadline date published in the **Federal Register** has been extended to May 15, 1992.

Dated: April 9, 1992.

Robert G. Harmon,

Administrator.

[FR Doc. 92-8668 Filed 4-14-92; 8:45am]

BILLING CODE 4160-15-M

Health Education Assistance Loan Program; Maximum Interest Rates for Quarter Ending June 30, 1992

Section 727 of the Public Health Service Act (42 U.S.C. 294) authorizes the Secretary of Health and Human Services to establish a Federal program of student loan insurance for graduate students in health professions schools.

Section 60.13(a)(4) of the program's implementing regulations (42 CFR part 60, previously 45 CFR part 126) provides that the Secretary will announce the interest rate in effect on a quarterly basis.

The Secretary announces that for the period ending June 30, 1992, three

interest rates are in effect for loans executed through the Health Education Assistance Loan (HEAL) program.

1. For loans made before January 27, 1981, the variable interest rate is 7⅝ percent. Using the regulatory formula (45 CFR 126.13(a)), in effect prior to January 27, 1981, the Secretary would normally compute the variable rate for this quarter by finding the sum of the fixed annual rate (7 percent) and a variable component calculated by subtracting 3.50 percent from the average bond equivalent rate of the 91-day U.S. Treasury bills for the preceding calendar quarter (4.02 percent), and rounding the result (7.521 percent) upward to the nearest ⅛ percent (7⅝ percent).

However, the regulatory formula also provides that the annual rate of the variable interest rate for a 3-month period shall be reduced to the highest one-eighth of 1 percent which would result in an average annual rate not in excess of 12 percent for the 12-month period concluded by those 3 months. Because the average rate of the 4 quarters ending June 30, 1992, is not in excess of 12 percent, there is no necessity for reducing the interest rate. For the previous 3 quarters the variable interest at the annual rate was as follows: 9⅜ percent for the quarter ending September 30, 1991; 9⅛ percent for the quarter ending December 31, 1991; 8¼ percent for the quarter ending march 31, 1992.

2. For variable rate loans executed during the period of January 27, 1981 through October 21, 1985, the interest rate is 7⅝ percent. Using the regulatory formula (42 CFR 60.13(a)) in effect for that time period, the Secretary computes the maximum interest rate at the beginning of each calendar quarter by determining the average bond equivalent rate for the 91-day U.S. Treasury bills during the preceding quarter (4.02 percent); adding 3.50 percent (7.52 percent) and rounding that figure to the next higher one-eighth of one percent 7⅝ percent).

3. For fixed rate loans executed during the period of April 1, 1992 through June 30, 1992, and for variable rate loans executed on or after October 22, 1985, the interest rate is 7⅛ percent. The Health Professions Training Assistance Act of 1985 (Pub. L. 99–129), enacted October 22, 1985, amended the formula for calculating the interest rate by changing 3.5 percent to 3 percent. Using the regulatory formula (42 CFR 60.13(a)), the Secretary computes the maximum interest rate at the beginning of each calendar quarter by determining the average bond equivalent rate for the 91-day U.S. Treasury bills during the preceding quarter (4.02 percent); adding 3.0 percent (7.02 percent) and rounding that figure to the next higher one-eighth of one percent (7⅛ percent).

Dated: April 9, 1992.

Robert G. Harmon,

Administrator.

(Catalog of Federal Domestic Assistance No. 13.108, Health Education Assistance Loans)

[FR Doc. 92–8730 Filed 4–14–92; 8:45 am]

BILLING CODE 4160–15–M

Advisory Council; Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), announcement is made of the following National Advisory body scheduled to meet during the month of May 1992:

Name: Advisory Council on Nurses Education

Date and time: May 14–15, 1992 8:30 a.m.–5 p.m.

Place: Conference Room G, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857.

Closed on May 14, 8:30 a.m.–2 p.m.

Open for remainder of meeting.

Purpose: The Council advises the Secretary and Administator, Health Resources and Services Administration, concerning general regulations and policy matters arising in the administration of the Nursing Shortage Reduction and Education Extension Act of 1988 (Pub. L. 100–607). The Council also performs final review of grant applications for Federal Assistance, and makes recommendations to the Administrator, HRSA.

Agenda: The open portion of the meeting will cover announcements; considerations of minutes of previous meeting; the reports of the Administrator, Health Resources and Services Administration, the Director, Bureau of Health Professions the Chair and co-Chair of the Advisory Council on Nurses Education and staff reports. The meeting will be closed to the public on May 14, from 8:30 a.m. to 2 p.m. for the review of grant applications for Special Project Grants; Nursing Education Opportunities for Individuals from Disadvantaged Backgrounds, Advance Nurse Education, Nurse Practitioner Grants and Nurse Anesthetist Program Grants. The closing is in accordance with the provisions set forth in section 552b(c), title 5 U.S.C. Code, and the Determination by the Administrator, Health Resources and Services Administration, pursuant to Public Law 92–463.

Anyone requiring information regarding the subject Council should contact Dr. Mary S. Hill, Executive Secretary, Advisory Council on Nurses Education, room 5C–14, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone (301) 443–6193.

Agenda Items are subject to change as priorities dictate.

Dated: April 10, 1992.

Jackie E. Baum,

Advisory Committee Management Officer, HRSA.

[FR Doc. 92–8669 Filed 4–14–92; 8:45am]

BILLING CODE 4160–15–M

Public Health Service

Agency for Health Care Policy and Research; Development of Guidelines on Management of Cancer-Related Pain

The Agency for Health Care Policy and Research (AHCPR) announces that it is inviting nominations of qualified individuals to serve on a panel of experts and health care consumers to develop clinical practice guidelines for the Management of Cancer-Related Pain. This is the second clinical guideline being developed on the management of pain. The AHCPR released on March 5, 1992, a guideline on "Acute Pain Management: Operative or Medical Procedures and Trauma."

Background

The Omnibus Budget Reconciliation Act of 1989 (Pub. L. 101–239) enacted on December 19, 1989, added a new title IX to the Public Health Service Act (the Act) (42 U.S.C. 299–299c–6), which established the Agency for Health Care Policy and Research (AHCPR) to enhance the quality, appropriateness, and effectiveness of health care services, and access to such services.

Section 911 of the Act (42 U.S.C. 299b) established within AHCPR, the Office of the Forum for Quality and Effectiveness in Health Care (the Forum). Through this office, AHCPR is arranging for the development and periodic review and updating of clinically relevant guidelines that may be used by physicians, educators, other health care practitioners, and consumers to assist in determining how diseases, disorders, and other health conditions can most effectively and appropriately be prevented, diagnosed, treated, and managed clinically.

Section 912 of the Act (42 U.S.C. 299b–1(d)) provides for the development of initial guidelines, standards, performance measures, and review criteria that:

1. Account for a significant portion of expenditures under the Medicare program, and have a significant variation in the frequency or the type of treatment provided; or

2. Otherwise meet the needs and priorities of the Medicare program.

Section 914 of the Act (42 U.S.C. 299b–3) identifies factors to be considered in establishing priorities for guidelines, including the extent to which the guidelines would:

1. Improve methods of prevention, diagnosis, treatment, and clinical management, and thereby benefit a significant number of individuals;

2. Reduce clinically significant variations among clinicians in the particular services and procedures utilized in making diagnoses and providing treatments; and

3. Reduce clinically significant variations in the outcomes of health care services and procedures.

The following topics were selected in 1990 for guideline development:

1. Management of Functional Impairment Due to Cataract in the Adult.

2. Diagnosis and Treatment of Benign Prostatic Hyperplasia.

3. Urinary Incontinence in Adults.

4. Prediction, Prevention and Early Intervention of Pressure Ulcers.

5. Sickle Cell Disease.

6. Acute Pain Management: Operative or Medical Procedures and Trauma.

7. Diagnosis and Treatment of Depressed Outpatients in Primary Care Settings.

In 1991, the following additional topics were selected for guideline development by panels of experts and consumer representatives.

1. Management of Cancer-Related Pain.

2. Treatment of Stage Two and Greater Pressure Ulcers.

3. HIV Positive Asymptomatic Patient: Evaluation and Early Intervention.

4. Low Back Problems.

5. Development of Quality Determinants of Mammography.

6. Secreening for Alzheimer's and Related Dementias.

Also in 1991, three topics were selected for guideline development by contractors, with assistance from panels of experts and consumer representatives.

1. Diagnosis and Treatment of Otitis Media in Children.

2. Diagnosis and Treatment of Heart Failure Secondary to Coronary Vascular Disease.

3. Post Stroke Rehabilitation.

Responsibilities of the expert panels and contractors, assisted by contract panels, include determination of the scope of the guidelines, assessment of the available scientific evidence and clinical consensus, and conducting peer and pilot review of drafts of the guidelines.

Panel Nominations

This notice requests nominations of qualified individuals to serve on a panel to develop clinical practice guidelines for the Management of Cancer-Related Pain. Panel members will report to the panel chairs. The chairs provide leadership to the panel regarding the methodology, literature review, panel deliverations, and formation of the final product. It is expected that the panel will meet on a quarterly basis. Individuals selected for the panel will be asked to serve from one to three years.

The panel will consist of two co-chairs and fifteen panel members. The panel co-chairs are:

Ada Jacox, R.N., Ph.D., F.A.A.N., Professor, School of Nursing, The Johns Hopkins University.
Specialties: Health Policy, Nursing.

Daniel Carr, M.D., Director, Division of Pain Management, Department of Anesthesia, Massachusetts General Hospital.
Specialties: Internal Medicine, Anesthesiology, Endocrinology.

To assist in identifying members for the panel, the AHCPR is requesting recommendations from interested individuals and organizations of nominees with substantial clinical or research experience in the management of cancer-related pain in adults and children, and consumers with pertinent experience or information. The AHCPR is especially interested in receiving nominations of general practitioners, anesthesiologists, oncologists, psychiatrists, internal medicine specialists, adult and pediatric surgeons, neurologists, oncology nurses experienced with adult and pediatric populations, nurse anesthetists, ethicists, adult and child psychologists, pharmacists, allied health professionals, and other health care practitioners and consumers with relevant experience.

The nominations received will be submitted for review and consideration to the co-chairs who in turn will recommend proposed panel members to AHCPR. Appointments of panel members will be made by AHCPR after review of the proposed members' qualifications and the overall composition of the panel to ensure representation of range a of experience and expertise.

Nominations must include a copy of the individual's curriculum vitae or resume, plus a statement of the rationale for the specific nomination. Nominees should not have a conflict of interest that would impair their impartial participation in the development of the clinical practice guidelines.

To be considered, nominations must be received by May 8, 1992 at the following address: Office of the Forum for Quality and Effectiveness in Health Care, Agency for Health Care Policy and Research, 2102 East Jefferson Street, Suite 401, Rockville, MD 20852.

FOR ADDITIONAL INFORMATION:

Additional information on the guideline development process is contained in the AHCPR Fact Sheet, "AHCPR-Commissioned Clinical Practice Guidelines," dated January 1992. More detailed information on the guideline process and criteria for selecting panels is contained in the AHCPR Program Note "Clinical Guideline Development," dated August 1990. These documents may be obtained by calling the Cener for Reserach Dissemination and Liaison, Agency for Health Care Policy and Research, at (301) 227–8366.

For further information on the process for developing guidelines for the Management of Cancer-Related Pain, contact Kathleen A. McCormick, Ph.D., R.N., Director, Office of the Forum for Quality and Effectiveness in Health Care, Agency for Health Care Policy and Research, at the above address.

Dated: April 7, 1992.

J. Jarrett Clinton,

Administrator.

[FR Doc. 92–8607 Filed 4–14–92; 8:45 am]

BILLING CODE 4160-90-M

Office of the Assistant Secretary for Health; Delegation of Authority

Notice is hereby given that in furtherance of the delegation of authority to the Assistant Secretary for Health on January 14, 1981, by the Secretary of Health and Human Services, the Assistant Secretary for Health has delegated to the Administrator, Alcohol, Drug Abuse, and Mental Health Administration, with authority to redelegate, all of the authorities under title III, part A, section 307 of the Public Health Service Act, as amended, pertaining to International Cooperation.

Dated: April 3, 1992.

James O. Mason,

Assistant Secretary for Health.

[FR Doc. 92–8620 Filed 4–14–92; 8:45 am]

BILLING CODE 4160-20-M

Office of the Assistant Secretary for Health; Privacy Act of 1974; Addition of Routine Use to an Existing System of Records

AGENCY: Public Health Service, HHS.

ACTION: Notice of addition of new routine use to an existing system of records.

SUMMARY: The Public Health Service (PHS) is publishing notice of its intent to add a new routine use for the disclosure of information from the following Privacy Act system of records: 09–15–0056, "National Vaccine Injury Compensation Program, HHS/HRSA/BHPr."

DATE: PHS invites public comments on the new routine use on or before May 15, 1992. This routine use will become effective without further notice 30 days after the date of publication unless we receive comments which would result in a contrary determination.

ADDRESS: Please address comments to the Privacy Act Coordinator, Health Resources and Services Administration (HRSA), Parklawn Building, Room 14A–20, 5600 Fishers Lane, Rockville, Maryland 20857, telephone (301) 443–3780. This is not a toll-free number.

FOR FURTHER INFORMATION CONTACT: Chief, Division of Vaccine Injury Compensation, BHPr/HRSA, Room 702, 6001 Montrose Road, Rockville, Maryland 20852, telephone (301) 443–6593. This is not a toll-free number.

SUPPLEMENTARY INFORMATION: HRSA maintains system of records 09–15–0056, "National Vaccine Injury Compensation Program, HHS/HRSA/BHPr", to: (1) Determine eligibility of petitioners to receive compensation under the National Vaccine Injury Compensation Program; (2) compensate successful petitioners in the amount determined by the court; and (3) evaluate vaccine safety through research programs.

HRSA is proposing to add a new routine use to permit disclosures of the complete individual file to organizations deemed qualified by the Secretary for the purpose of evaluating the administration, process, or outcomes of the National Vaccine Injury Compensation Program.

The purpose of the disclosure is to document the extent to which the National Vaccine Injury Compensation Program is satisfying the goals and objectives of its authorizing legislation, i.e., maintaining a fair and expeditious system for compensating those who have been injured by a vaccine.

This routine use is compatible with the purpose for which the records were collected.

Dated: April 7, 1992.

Wilford J. Forbush,

Director, Office of Management.

SYSTEM NAME:

National Vaccine Injury Compensation Program, HHS/HRSA/BHPr.

A new routine use, number 6, is added as follows:

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSE OF SUCH USES:

* * * * *

6. Records may be disclosed to organizations deemed qualified by the Secretary for the purpose of evaluating the administration, process, or outcomes of the Vaccine Injury Compensation Program (as required by Congress). The purpose of the disclosure is to document the extent to which the Vaccine Injury Compensation Program is satisfying the goals and objectives of its authorizing legislation, i.e., maintaining a system for compensating those who have been injured by a vaccine that is fair and expeditious. Organizations to which information is disclosed for this use shall be required to maintain Privacy Act safeguards with respect to such records.

* * * * *

[FR Doc. 92–8621 Filed 4–14–92; 8:45 am]

BILLING CODE 4160–15–M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[WY–040–02–4760–10; WYW–125681]

Public Notice of a Site Possibly Containing Hazardous Waste

AGENCY: Bureau of Land Management, Interior.

ACTION: Emergency closure of public lands.

SUMMARY: Notice is hereby given that effective April 15, 1992, all public lands north of the Dewar Ranch access road in the area described as follows:.

T.16N., R.114 W., 6th P.M.,
Section 22, NW¼SE¼NE¼,
Uinta County, Wyoming, are closed to the public because of the discovery of possible hazardous waste on public lands.

EFFECTIVE DATE: April 15, 1992. The closure will remain in effect until July 14, 1992.

FOR FURTHER INFORMATION CONTACT: Mark R. Hatchel, Realty specialist, Kemmerer Resource Area, Rock Springs District, Bureau of Land Management, 312 Highway 189 North, Kemmerer, Wyoming 83101, (307) 877–3933.

SUPPLEMENTARY INFORMATION: The purpose of this closure is to protect the health and safety of the public while all materials suspected to contain hazardous substances are removed from the described public land. The authority for this closure is contained in 43 CFR 8364. Any person who fails to comply with this closure may be subject to a fine not to exceed $1,000 and/or imprisonment not to exceed 12 months.

Dated: April 10, 1992

Darrel J. Short,

Area Manager.

[FR Doc. 92–8888 Filed 4–14–92; 8:45 am]

BILLING CODE 4310–22–M

National Park Service

Concession Contract; Nilon Inc.

AGENCY: National Park Service, Interior.

ACTION: Public notice.

SUMMARY: Public notice is hereby given that the National Park Service proposes to negotiate a concession contract with Nilon, Incorporated authorizing it to provide food and beverage facilities and services for the public at Independence National Historical Park, Pennsylvania for a period of ten (10) years from the date of execution of the contract.

EFFECTIVE DATE: June 8, 1992.

ADDRESSES: Interested parties should contact the Regional Director, Mid-Atlantic Region, 143 South Third Street, Philadelphia, Pennsylvania 19106, for information as to the requirements of the proposed contract.

SUPPLEMENTARY INFORMATION: This contract renewal 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 foregoing concessioner has performed its obligations to the satisfaction of the Secretary under an existing contract which expired by limitation of time on December 31, 1990, 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 permit and in the negotiation of a new contract as defined in 36 CFR 51.5.

The Secretary will consider all proposals received as a result of this

notice. Any proposal, including that of the existing concessioner, must be postmarked or hand delivered on or before the sixtieth (60th) day following publication of this notice to be considered and evaluated.

Dated: November 15, 1991.

Charles P. Clapper, Jr.

Deputy Regional Director, Mid-Atlantic Region.

[FR Doc. 92-8652 Filed 4-14-92; 8:45 am]

BILLING CODE 4310-70-M

Native American Graves Protection and Repatriation Review Committee: Meeting

AGENCY: National Park Service, Department of the Interior.

ACTION: Notice of meeting of the Native American Graves Protection and Repatriation Review Committee.

Notice is hereby given in accordance with the Federal Advisory Committee Act (FACA), 5 U.S.C. appendix (1988), that the first meeting of the Native American Graves Protection and Repatriation Act Review Committee will be held on April 29, 30, and May 1, 1992, in Washington, DC.

All meetings will be held at the Department of the Interior, Main Building, 1849 C Street NW, Washington DC 20240. On April 29, the meeting will be held in room 3004 and will begin at 9 a.m. and conclude not later than 5 p.m. On April 30, the meeting will be held in room 3004 and will begin at 9 a.m. and conclude not later than noon. On May 1, the meeting will be held in room 3119 and will begin at 9 a.m. and conclude not later than noon.

The Native American Graves Protection and Repatriation Act Review Committee was established by Public Law 101-601 to monitor, review, and assist in implementation of the inventory and identification process and repatriation activities required under the statute.

The matters to be discussed at this meeting include an overview of Public Law 101-601; development of a list of person consented to by all current members from which the Secretary shall appoint the seventh member of the Review Committee; and, development of draft proposed regulations implementing the statute.

The meeting will be open to the public. However, facilities and space for accommodating members of the public are limited and persons will be accommodated on a first-come, first-served basis. Any member of the public may file a written statement concerning the matters to be discussed with Dr. Francis P. McManamon, Department Consulting Archeologist.

Persons wishing information concerning this meeting, or who which to submit written statements may contact Dr. Francis P. McManamon, Departmental Consulting Archeologist, Archeological Assistance Division, National Park Service, P.O. Box 37127, Washington DC 20013, Telephone (202) 343-4101. Draft summary minutes of the meeting will be available for public inspection about eight weeks after the meeting at the office of the Departmental Consulting Archeologist, room 4315, 1100 L Street, NW. Washington, DC.

Dated: April 6, 1992.

Francis P. McManamon,

Departmental Consulting Archeologist, Chief, Archeological Assistance Division.

[FR Doc. 92-8650 Filed 4-14-92; 8:45 am]

BILLING CODE 4310-70-M

Vancouver Historical Study Commission; Meetings

AGENCY: National Park Service, Interior.

ACTION: Notice of meetings of Vancouver Historical Study Commission.

Notice is hereby given in accordance with the Federal Advisory Committee Act, 5 U.S.C. appendix (1988), of the next four scheduled meetings of the Vancouver Historical Study Commission. The next four meetings will be held on Tuesday, May 14, 1992, Tuesday, June 9, 1992, Tuesday, July 14, 1992, and Tuesday, August 11, 1992. All four meetings will be held in the Vancouver City Council Chambers, 210 East 13th Street, Vancouver, Washington. Commission meetings start at 1 p.m., and are planned to adjourn no later than 5 p.m.

The purpose of the meetings are for the Vancouver Historical Study Commission to conduct discussions on the preparation of a study report for Congress which will make recommendations regarding: (1) The preservation, protection, enhancement, enjoyment, and utilization of the historic, cultural, natural, and recreational resources of the Area; and (2) the feasibility of establishing a Vancouver National Historical Reserve.

All Commission meetings are open to the public. Seating space and facilities at the Vancouver City Council Chambers to accommodate members of the public are somewhat limited, and persons will be accommodated on a first come, first served basis. Anyone may file with the Commission a written statement concerning matters to be discussed. At each meeting, the public will be provided an opportunity to provide both written and verbal comment to the Commission. However, the Commission Chairman may restrict the length of public statements as necessary to allow the Commission to complete its agenda with in the allotted time.

Persons wishing further information concerning the meeting, or who wish to submit written statements, may contact Mr. Keith Dunbar, Chief of Planning and Environmental Compliance, Pacific Northwest Region, National Park Service, 83 South King Street, suite 212, Seattle, Washington 98104 or telephone 206-553-4579.

Draft summary minutes of each Commission meeting will be available for public inspection approximately three (3) weeks after the meeting in Park Headquarters, Fort Vanvouver National Historic Site, 612 East Reserve Street, Vancouver, Washington 98661.

Dated: March 24, 1992.

Charles H. Odegaard,

Regional Director.

[FR Doc. 92-8651 Filed 4-14-92; 8:45 am]

BILLING CODE 4310-70-M

INTERNATIONAL TRADE COMMISSION

[Investigation 337-TA-324]

Certain Acid-Washed Denim Garments and Accessories; Receipt of Initial Determination Terminating Respondents on the Basis of Consent Order Agreement

AGENCY: U.S. International Trade Commission.

ACTION: Notice is hereby given that the Commission has received an initial determination from the presiding officer in the above captioned investigation terminating the following respondents on the basis of a consent order agreement: Gitano Group, Inc., Jordache International, Inc., Fast Forward Ltd., Four Ninety Eight Ltd., and Jordache International (Hong Kong).

SUPPLEMENTARY INFORMATION: This investigation is being conducted pursuant to section 337 of the Tariff Act of 1930 (19 U.S.C. 1337). Under the Commission's rules, the presiding officer's initial determination will

become the determination of the Commission thirty (30) days after the date of the service upon the parties, unless the Commission orders review of the initial determination. The initial determination in this matter was served upon parties on April 7, 1992.

Copies of the initial determination, the consent order agreement, and all other nonconfidential documents filed in connection with this investigation are available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street, SW., Washington, DC 20436, telephone (202) 205–2000. Hearing impaired individuals are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

WRITTEN COMMENTS: Interested persons may file written comments with the Commission concerning termination of the aforementioned respondents. The original and 14 copies of all such documents must be filed with the Secretary of the Commission, 500 E Street, SW., Washington, DC 20436, no later than 10 days after publication of this notice in the **Federal Register**. Any person desiring to submit a document or portions thereof) to the Commission in confidence must request confidential treatment. Such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why confidential treatment should be granted. The Commission will either accept the submission in confidence or return it.

FOR FURTHER INFORMATION CONTACT: Ruby J. Dionne, Office of the Secretary, U.S. International Trade Commission, Telephone (202) 205–1802.

By order of the Commission.

Issued: April 7, 1992.

Kenneth R. Mason,

Secretary.

[FR Doc. 92–8706 Filed 4–14–92; 8:45 am]

BILLING CODE 7020–02–M

[Investigation 337–TA–324]

Certain Acid-Washed Denim Garments and Accessories; Receipt of Initial Determination Terminating Respondent on the Basis of Consent Order Agreement

AGENCY: U.S. International Trade Commission.

ACTION: Notice is hereby given that the Commission has received an initial determination from the presiding officer in the above captioned investigation terminating the following respondent on the basis of a consent order agreement: Socieded Exportadora Ltda. and Sao Paolo Alpargats, S.A.

SUPPLEMENTARY INFORMATION: This investigation is being conducted pursuant to section 337 of the Tariff Act of 1930 (19 U.S.C. 1337). Under the Commission's rules, the presiding officer's initial determination will become the determination of the Commission thirty (30) days after the date of its service upon the parties, unless the Commission orders review of the initial determination. The initial determination in this matter was served upon parties on April 7, 1992.

Copies of the initial determination, the consent order agreement, and all other nonconfidential documents filed in connection with this investigation are available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street, SW., Washington, DC 20436, telephone (202) 205–2000. Hearing impaired individuals are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

WRITTEN COMMENTS: Interested persons may file written comments with the Commission concerning termination of the aforementioned respondents. The original and 14 copies of all such documents must be filed with the Secretary to the Commission, 500 E Street, SW., Washington, DC 20436, no later than 10 days after publication of this notice in the **Federal Register**. Any person desiring to submit a document (or portions thereof) to the Commission in confidence must request confidential treatment. Such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why confidential treatment should be granted. The Commission will either accept the submission in confidence or return it.

FOR FURTHER INFORMATION CONTACT: Ruby J. Dionne, Office of the Secretary, U.S. International Trade Commission, Telephone (202) 205–1802.

Issued: April 7, 1992.

By order of the Commission.

Kenneth R. Mason,

Secretary.

[FR Doc. 92–8707 Filed 4–14–92; 8:45 am]

BILLING CODE 7020–02–M

[Investigation No. 731–TA–518 (Final)]

Aspherical Ophthalmoscopy Lenses From Japan

Determination

On the basis of the record [1] developed in the subject investigation, the Commission determines, pursuant to section 735(b) of the Tariff Act of 1930 (19 U.S.C. 1673d(b)) (the Act), that an industry in the United States is threatened with material injury by reason of imports from Japan of aspherical ophthalmoscopy lenses,[2] provided for in subheading 9018.50.00 of the Harmonized Tariff Schedule of the United States, that have been found by the Department of Commerce to be sold in the United States at less than fair value (LTFV).

Background

The Commission instituted this investigation effective October 15, 1991, following a preliminary determination by the Department of Commerce that imports of aspherical ophthalmoscopy lenses from Japan were being sold at LTFV within the meaning of section 733(b) of the Act (19 U.S.C. 1673b(b)). Notice of the institution of the Commission's investigation and of a public hearing to be held in connection therewith was given by posting copies of the notice in the Office of the Secretary, U.S. International Trade Commission, Washington, DC, and by publishing the notice in the **Federal Register** of November 6, 1991 (56 FR 56660). The hearing was held in Washington, DC, on February 26, 1992, and all persons who requested the opportunity were permitted to appear in person or by counsel.

The Commission transmitted its determination in this investigation to the Secretary of Commerce on April 6, 1992. The views of the Commission are contained in USITC Publication 2498 (April 1992), entitled "Aspherical Ophthalmoscopy Lenses from Japan: Determination of the Commission in Investigation No. 731–TA–518 (Final) Under the Tariff Act of 1930, Together With the Information Obtained in the Investigation."

Issued: April 8, 1992.

[1] The record is defined in § 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR 207.2(f)).

[2] Vice Chairman Brunsdale and Commissioner Crawford also find that there is present material injury by reason of the subject imports.

By Order of the Commission.

Kenneth R. Mason,

Secretary.

[FR Doc. 92-8715 Filed 4-14-92; 8:45 am]

BILLING CODE 7020-02-M

[Investigation No. 731-TA-517 (Final)]

Refined Antimony Trioxide From the People's Republic of China

Determination

On the basis of the record [1] developed in the subject investigation, the Commission determines, pursuant to section 735(b) of the Tariff Act of 1930 (19 U.S.C. 1673d(b)) (the act), that an industry in the United States is not materially injured or threatened with material injury, and the establishment of an industry in the United States is not materially retarded, by reason of imports from the People's Republic of China of refined antimony trioxide, provided for in subheading 2825.80.00 of the Harmonized Tariff Schedule of the United States, that have been found by the Department of Commerce to be sold in the United States at less than fair value (LTFV).

Background

The Commission instituted this investigation effective October 7, 1991, following a preliminary determination by the Department of Commerce that imports of refined antimony trioxide from the People's Republic of China were being sold at LTFV within the meaning of section 733(b) of the act (19 U.S.C. 1673b(b)). Notice of the institution of the Commission's investigation and of a public hearing to be held in connection therewith was given by posting copies of the notice in the Office of the Secretary, U.S. International Trade Commission, Washington, DC, and by publishing the notice in the **Federal Register** of October 23, 1991 (56 F.R. 54887). Subsequent to Commerce's postponement of its final LTFV determination (56 FR 56631, November 6, 1991), the Commission revised its schedule to conform with Commerce's new schedule (56 FR 63524, December 4, 1991). The hearing was held in Washington, DC, on February 25, 1992, and all persons who requested the opportunity were permitted to appear in person or by counsel.

By Order of the Commission.

[1] The record is defined in § 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR 207.2(f)).

Issued: April 8, 1992.

Kenneth R. Mason,

Secretary.

[FR Doc. 92-8703 Filed 4-14-92; 8:45 am]

BILLING CODE 7020-02-M

[Investigation No. 731-TA-538 (Final)]

Sulfanilic Acid the People's Republic of China

AGENCY: United States International Trade Commission.

ACTION: Institution and scheduling of a final antidumping investigation.

SUMMARY: The Commission hereby gives notice of the institution of final antidumping investigation No. 731-TA-538 (Final) under section 735(b) of the Tariff Act of 1930 (19 U.S.C. 1673d(b)) (the act) to determine whether an industry in the United States is materially injured, or is threatened with material injury, or the establishment of an industry in the United States is materially retarded, by reason of imports from the People's Republic of China (China) of sulfanilic acid and sodium sulfanilate,[1] provided for in subheadings 2921.42.24 and 2921.42.70 of the Harmonized Tariff Schedule of the United States.

For further information concerning the conduct of this investigation, hearing procedures, and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A through E (19 CFR part 201), and part 207, subparts A and C (19 CFR part 207).

EFFECTIVE DATE: March 18, 1992.

FOR FURTHER INFORMATION CONTACT: Lori Hylton (202-205-3199), Office of Investigations, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202-205-1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202-205-2000.

[1] The products covered by this investigation are all grades of sulfanilic acid, which include technical (or crude) sulfanilic acid, refined (or purified) sulfanilic acid, and sodium salt of sulfanilic acid (sodium sulfanilate). For a comprehensive description of the merchandise subject to this investigation, see International Trade Administration, Preliminary Determination of Sales at Less Than Fair Value: Sulfanilic Acid from the People's Republic of China (57 FR 9409, March 18, 1992).

SUPPLEMENTARY INFORMATION:

Background

This investigation is being instituted as a result of an affirmative preliminary determination by the Department of Commerce that imports of sulfanilic acid from China are being sold in the United States at less than fair value within the meaning of section 733 of the act (19 U.S.C. § 1673b). The investigation was requested in a petition filed on October 3, 1991, by R-M Industries, Inc., Fort Mill, SC.

Participation in the Investigation and Public Service List

Persons wishing to participate in the investigation as parties must file an entry of appearance with the Secretary to the Commission, as provided in section 201.11 of the Commission's rules, not later than twenty-one (21) days after publication of this notice in the **Federal Register**. The Secretary will prepare a public service list containing the names and addresses of all persons, or their representatives, who are parties to this investigation upon the expiration of the period for filing entries of appearance.

Limited Disclosure of Business Proprietary Information (BPI) Under an Administrative Protective Order (APO) and BPI Service List

Pursuant to § 207.7(a) of the Commission's rules, the Secretary will make BPI gathered in this final investigation available to authorized applicants under the APO issued in the investigation, provided that the applicatien is made not later than twenty-one (21) days after the publication of this notice in the **Federal Register**. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

Staff Report

The prehearing staff report in this investigation will be placed in the nonpulic record on June 15, 1992, and a public version will be issued thereafter, pursuant to § 207.21 of the Commission's rules.

Hearing

The Commission will hold a hearing in connection with this investigation beginning at 9:30 a.m. on June 30, 1992, at the U.S. International Trade Commission Building. Requests to appear at the hearing should be filed in writing with the Secretary to the Commission on or before June 19, 1992. A nonparty who has testimony that may aid the Commission's deliberations may request permission to present a short statement at the hearing. All parties and

nonparties desiring to appear at the hearing and make oral presentations should attend a prehearing conference to be held at 9:30 a.m. on June 24, 1992, at the U.S. International Trade Commission Building. Oral testimony and written materials to be submitted at the public hearing are governed by §§ 201.6(b)(2), 201.13(f), and 207.23(b) of the Commisssion's rules.

Written submissions

Each party is encouraged to submit a prehearing brief to the Commission. Prehearing briefs must conform with the provisions of § 207.22 of the Commission's rules; and deadline for filing is June 25, 1992. Parties may also file written testimony in connection with their presentation at the hearing, as provided in § 207.23(b) of the Commission's rules, and posthearing briefs, which must conform with the provisions of § 207.24 of the Commission's rules. The deadline for filing posthearing briefs in July 8, 1992; witness testimony must be filed no later than three (3) days before the hearing. In addition, any person who has not entered an appearance as a party to the investigation may submit a written statement of information pertinent to the subject of the investigation on or before July 8, 1992. All written submissions must conform with the provisions of § 201.8 of the Commission's rules; any submissions that contain BPI must also conform with the requirements of §§ 201.6, 207.3 and 207.7 of the Commission's rules.

In accordance with §§ 201.16(c) and 207.3 of the rules, each document filed by a party to the investigation must be served on all other parties to the investigation (as identified by either the public of BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

Authority: This investigation is being conducted under authority of the Tariff Act of 1930, title VII. This notice is published pursuant to § 207.20 of the Commission's rules.

Issued: April 8, 1992

By order of the Commission.

Kenneth R. Mason,

Secretary.

[FR Doc. 92-8705 Filed 4-14-92; 8:45 am]

BILLING CODE 7020-02-M

INTERSTATE COMMERCE COMMISSION

[Finance Docket No. 31965]

Beard Land and Investment Co. and Modesto Empire and Traction Co., Merger Exemption, Modesto Interurban Railway

The Beard Land and Investment Co. (Beard Investment) and the Modesto Empire and Traction Company (MET) have jointly filed a notice of exemption to merge Modesto Interurban Railway (MIR) into MET. The last step in the transaction was to occur March 31, 1992.

Beard Investment, MIR MET, and Beard Land compose a single, integrated carrier system. MIR and MET are rail carriers. Beard Investment owns 100 percent of the stock of MIR and 100 percent of the stock of MET, which in turn owns 100 percent of the stock of Beard Land Improvement Company (Beard Land), a noncarrier. Beard Land owns railroad equipment, portions of the right-of-way, easements, and house tracks serving its warehouse properties. MIR owns tracks and portions of the right-of-way. MET owns tracks, franchises, and railroad equipment. MET operates a short-line railroad over its own tracks and franchises, over the tracks and the right-of-way owned by MIR, and over the rights-of-way and easements owned by Beard Land. Pursuant to the proposed transaction, Beard Investment will transfer 100 percent of the stock of MIR to MET as a contribution to the capital of MET, and MIR will thereafter be merged into MET. The name of the surviving company will be Modesto and Empire Traction Company.

The lines of MIR and MET extend from Modesto, CA, to Empire, CA. There are 33.08 miles of line involved, of which 5 miles are main line and 28.08 miles are switch lines. At Modesto, cars are interchanged with the Union Pacific Railroad Company and the Southern Pacific Transportation Company. At Empire, cars are interchanged with The Atchison, Topeka & Santa Fe Railway Company.

The proposed transaction is a corporate family restructuring. This is a transaction within a corporate family of the type specifically exempted from prior approval under 49 CFR 1180.29d)(3). It will not result in adverse changes in service levels, significant operational changes, or a change in the competitive balance with carriers outside the corporate family.

To ensure that all employees who may be affected by the transaction are given the minimum protection afforded under 49 U.S.C. 10505(g)(2) and 49 U.S.C. 11347, the labor conditions set forth in *New York Dock Ry.—Control—Brooklyn Eastern Dist.*, 360 I.C.C. 60 (1979), are imposed.

Petitions to revoke the exemption under 49 U.S.C. 10505(d) may be filed at any time. The filing of a petition to revoke will not stay the transaction. Pleadings must be filed with the Commission and served on: John B. Lowry, Esq., McCutchen, Doyle, Brown & Enersen, 3 Embarcadero Center, San Francisco, CA 94111.

Decided: April 9, 1992.

By the Commission, David M. Konschnik, Director, Office of Proceedings.

Sidney L. Strickland, Jr.,

Secretary.

[FR Doc. 92-8716 Filed 4-14-92; 8:45 am]

BILLING CODE 7035-01-M

[Finance Docket No. 32020]

CSX Transportation, Inc.—Operation Exemption—Richmond, Fredericksburg and Potomac Railway Co.

CSX Corporation (CSX), CSX Transportation, Inc. (CSXT), and Richmond, Frederickburg and Potomac Railway Company (RF&P) filed a verified notice of exemption for CSXT to operate the railroad properties of RF&P.[1] Under the agreement, CSXT will assume all of the rights and obligations of RF&P under the latter's existing licenses, leases, easements, agreements and contracts. The operating agreement was to become effective April 1, 1992.

This is a transaction within a corporate family of the type specifically exempted from the necessity of prior review and approval under 40 CFR 1180.2(d)(3). It will not result in adverse changes in service levels, significant operational changes, or a change in the competitive balance with carriers outside the corporate family.

As a condition to use of this exemption, any employees affected by the transaction shall be protected pursuant to *New York Dock Ry.—Control—Brooklyn Eastern District*, 360 I.C.C. 60 (1979). This will satisfy the requirements of 49 U.S.C. 10505(g)(2).

Petitions to revoke the exemption under 49 U.S.C. 10505(d) may be filed at any time. The filing of a petition to revoke will not stay the transaction. Pleadings must be filed with the

[1] CSX is a non-carrier holding company that owns 100 percent of the common stock of CSXT, a Class 1 rail carrier. CSXT controls RF&P through indirect ownership of all RF&P's outstanding capital stock.

Commission and served on: Peter J. Shudtz, One James Center, Richmond, VA 23219.

Decided: April 7, 1992.

By the Commission, David M. Konschnik, Director, Office of Proceedings.

Sidney L. Strickland, Jr.,

Secretary.

[FR Doc. 92-8715 Filed 4-14-92; 8:45 am]

BILLING CODE 7035-01-M

DEPARTMENT OF JUSTICE

Antitrust Division

Cable Television Laboratories, Inc./ Tele-Communications, Inc./Viacom International Inc./Public Broadcasting Service; Notification

Notice is hereby given that, pursuant to section 6(a) of the National Cooperative Research Act of 1984, 15 U.S.C. 4301 *et seq.* ("the Act"), Cable Television Laboratories, Inc. ("CableLabs"), Tele-Communications, Inc. ("TCI"), Viacom International Inc. ("Viacom") and Public Broadcasting Service ("PBS") on February 18, 1992, filed a written notification simultaneously with the Attorney General and the Federal Trade Commission disclosing additions to the membership. The additional notification was filed for the purpose of invoking the protections of section 4 of the Act, which limit the recovery of antitrust plaintiffs to actual damages under specified circumstances.

On November 27, 1991, CableLabs, TCI, Viacom and PBS filed their original notification pursuant to section 6(a) of the Act. The Department published a notice in the **Federal Register** pursuant to section 6(b) of the Act of February 3, 1992 (57 FR 4061).

Pursant to section 6(b) of the Act, the identities of the additional members and the general areas of activity are given below.

The identities of the additional members are: Fairmont Cable TV of Fairmont, Minnesota, Shaw Cable Systems Ltd. of Alberta, Canada. Videotron Ltee. of Montreal, Quebec, Canada, Windbreak Cable of Gehring, Nebraska.

The area of activity remains the participation and coordination with each other in a Request For Proposals ("RFP") for development of one or more Digital Compression Delivery System(s) that will enable cable television program suppliers to provide multiple programs per satellite transponder channel to cable television system headends and customers. The parties intend to evaluate the responses to the RFP and mayd independently award contract(s) to develop the System(s).

Joseph H. Widmar,

Director of Operations, Antitrust Division.

[FR Doc. 92-8612 Filed 4-14-92; 8:45 am]

BILLING CODE 4410-01-M

Bell Communications Research , Inc.; Notifications

Notice is hereby given that, pursuant to section 6(a) of the National Cooperative Research Act of 1984, 15 U.S.C. 4301 et seq. ("the Act"), Bell Communications Research, Inc. ("Bellcore") on January 28, 1992, filed a written notification on behalf of Bellcore and EEsof Incorporated ("EEsof") simultaneously with the Attorney General and the Federal Trade Commission disclosing (1) The identities of the parties to the venture and (2) the nature and objective of the venture. The notification was filed for the purpose of invoking the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Pursuant to section 6(b) of the Act, the identities of the parties to the venture, and its general areas of planned activities, are given below.

Bellcore is a Delaware coporation with its principal place of business in Livingston, New Jersey.

EEsof is a California corporation with its principal place of business in Westlake Village, California.

Bellcore and EEsof entered into an agreement effective as of January 7, 1992 to engage in cooperative research collaboration to enable engineers and researchers to be able to define mathematical models for analyzing optical communications devices and networks for exchange access services.

Joseph H. Widmar,

Director of Operations, Antitrust Division.

[FR Doc. 92-8609 Filed 4-14-92; 8:45 am]

BILLING CODE 4410-01-M

Bethlehem Steel Corp.; Notification

Notice is hereby given that, pursuant to section 6(a) of the National Cooperative Research Act of 1984, 15 U.S.C. 4301 *et seq.* ("the Act"), Bethlehem Steel Corporation ("Bethlehem") on March 3, 1992, filed a written notification on behalf of Bethlehem and Lafayette Steel and Processing ("Lafayette") simultaneously with the Attorney General and the Federal Trade Commission disclosing (1) the identities of the parties to the venture and (2) the nature and objective of the venture. The notification was filed for the purpose of invoking the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Pursuant to section 6(b) of the Act, the identities of the parties to the venture, and its general areas of planned activities, are given below.

Bethlehem is located in Bethlehem, Pennsylvania.

Lafayette is located in Detroit, Michigan.

Bethlehem and Lafayette have formed a venture called IMPICS Computer Solutions to conduct research activities directed to the development of a fully integrated on-line interactive computer system for handling steel orders, material and deliveries and to license any resulting inventions, software and know-how.

Joseph H. Widmar,

Director of Operations, Antitrust Division.

[FR Doc. 92-8618 Filed 4-14-92; 8:45 am]

BILLING CODE 4410-01-M

CAD Framework Initiative, Inc.; Notification

Notice is hereby given that, pursuant to section 6(a) of the National Cooperative Research Act of 1984, 15 U.S.C. 4301 *et seq.* ("the Act"), CAD Framework Initiative, Inc. ("CFI") on December 18, 1991, has filed an additional written notification simultaneously with the Attorney General and the Federal Trade Commission disclosing certain changes in the membership of CFI. The additional written notification was filed for the purpose of extending the protections of section 4 of the Act, limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances.

On December 30, 1988, CFI filed its original notification pursuant to section 6(a) of the Act. That filing was amended on February 7, 1989. The Department published a notice concerning the amended filing in the **Federal Register** pursuant to section 6(b) of the Act on March 13, 1989 (54 FR 10456). A correction to this notice was published on April 20, 1989 (54 FR 16013). On May 17, 1989, CFI filed an additional written notification. The Department published a notice in response to this additional notification on June 22, 1989 (54 FR 26265). A correction to the June 22, 1989 notice was published on August 4, 1989 (54 FR 32141); a further correction was published on August 23, 1989 (54 FR 35091). On August 16, 1989, CFI filed an additional written notification. The Department published a notice in response to the further additional

notification on September 21, 1989 (54 FR 38912). CFI filed a further additional notification on November 15, 1989. The Department published a notice in response to the further additional notification on January 10, 1990 (55 FR 925). On February 15, 1990, CFI filed an additional written notification. The Department published a notice in response to the further additional notification on April 23, 1990 (55 FR 15295). CFI filed an additional notification on May 15, 1990. The Department published a notice in response to the additional notification on June 29, 1990 (55 FR 26792). CFI filed an additional notification on August 16, 1990. The Department published a notice in response to the additional notification on September 18, 1990 (55 FR 38417). CFI filed an additional notification on October 22, 1990. The Department published a notice in response to the additional notification on December 10, 1990 (55 FR 50786). On January 25, 1991, CFI filed an additional written notification. The Department published a notice in response to the additional notification on March 25, 1991 (56 FR 12387). CFI filed an additional notification on April 22, 1991. The Department published a notice in response to the additional notification on May 23, 1991 (56 FR 23722). On August 12, 1991, CFI filed an additional written notification. The Department published a notice in response to the additional notification on September 25, 1991 (56 FR 48580). A correction to this notice was published on November 5, 1991 (56 FR 56528).

The purpose of this notification is to disclose certain changes in the membership of CFI. The changes consist of the following: (1) The addition to Corporate Member Racal-Redac of Gloucester, England; (2) the deletion of Jack Madesky, who has not renewed his Associate Membership in CFI; (3) the change of name under which the following members are listed: AT&T of Allentown, PA, a Corporate Member, is now listed as AT&T Bell Laboratories; Harris Corp. of Fishers, NY, a Corporate Member, is now listed as Harris Semiconductor Corp.; NCR Corp. of Fort Collins, CO, a Corporate Member, is now listed as NCR Microelectronics Corporation; Nippon Telegraph of Kanagawa, Japan, a Corporate Member, is now listed as Nippon Telegraph & Technology; Philips of Eindhoven, The Netherlands, a Corporate Member, is now listed as Philips Research Laboratories; Seiko Instruments USA, Inc. of Chiba, Japan, a Corporate Member, is now listed as Seiko Instruments, Inc.; Sharp Research Corporation of Tenri Nara, Japan, a Corporate Member, is now listed as Sharp Corporation; Siemens Informationssysteme AG of Munich, Germany, a Corporate Member, is now listed as Siemens Nixdorf Informationssysteme; Teamone Systems, Inc. of Sunnyvale, CA, a Corporate Member, is now listed as Team One Systems; Zuken, Inc. of Santa Clara, CA, a Corporate Member, is now listed as Zuken America, Inc.; STC of Essex, United Kingdom, an Associate Member, is now listed as STC Technology, Inc.; and Teradyne, Inc. of Santa Clara, CA, an Associate Member, is now listed as Teradyne EDA.

Joseph H. Widmar,

Director of Operations, Antitrust Division.

[FR Doc. 92-8617 Filed 4-14-92; 8:45 am]

BILLING CODE 4410-01-M

Advanced Television Test Center, Inc./ Cable Television Laboratories, Inc.

Notice is hereby given that, pursuant to section 6(a) of the National Cooperative Research Act of 1984, 15 U.S.C. 4301 et seq. ("Act"), Advanced Television Test Center, Inc. ("Test Center") and Cable Television Laboratories, Inc. ("CableLabs") on February 18, 1992, filed an additional written notification simultaneously with the Attorney General and the Federal Trade Commission disclosing additions to the membership. The additional notification was filed for the purpose of extending the protections of section 4 of the Act, limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances.

On October 2, 1989, Test Center and CableLabs filed their original notification pursuant to section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to section 6(b) of the Act on November 8, 1989 (54 FR 46997). On February 20, 1991, CableLabs and Test Center filed an additional written notification. The Department published a notice in the **Federal Register** in response to the additional notification on April 10, 1991 (56 FR 14542).

Pursuant to section 6(b) of the Act, the identities of the additional members of CableLabs and the general areas of activity are given below.

The identities of the additional members are: Fairmont Cable TV of Fairmont, Minnesota, Shaw Cable Systems Ltd. of Alberta, Canada, Videotron Ltee. of Montreal, Quebec, Canada, Windbreak Cable of Gehring, Nebraska.

The area of activity remains the coordination of testing efforts to facilitate the development of data that the FCC and its Advisory Committee on Advanced Television Service, as well as the Advanced Television Systems Committee, will require and utilize to determine appropriate actions with regard to the introduction of advanced television service in the United States. The parties may also undertake additional ATV tests not required by the Advisory Committee on Advanced Television Service.

Joseph H. Widmar,

Director of Operations, Antitrust Division.

[FR Doc. 92-8610 Filed 4-14-92; 8:45 am]

BILLING CODE 4410-01-M

Cable Television Laboratories, Inc., Notification

Notice is hereby given that, pursuant to section 6(a) of the National Cooperative Research Act of 1984, 15 U.S.C. 4301, et seq. ("the Act"), Cable Television Laboratories, Inc. ("CableLabs") on February 18, 1992, filed an additional written notification simultaneously with the Attorney General and the Federal Trade Commission disclosing addtions to the membership. The additional notification was filed for the purpose of extending the protections of section 4 of the Act, limiting the recovery of antitrust plaintiffs to actual damages under specified circumstanmces.

On August 8, 1988, CableLabs filed its original notification pursuant to section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to section 6(b) on September 7, 1988 (53 FR 34593). On November 7, 1988, February 3, 1989, October 12, 1989, and February 20, 1991, CableLabs filed additional written notifications. The Department published notices in response to the additional notifications on December 16, 1988 (53 FR 50590), March 1, 1989 (54 FR 8608), December 15, 1989 (54 FR 51510), and April 10, 1991 (56 FR 14543), respectively.

As of January 1, 1992, the following parties have become members of CableLabs: Fairmont Cable TV of Fairmont, Minnesota, Shaw Cable Systems Ltd. of Alberta, Canada, Videotron Ltee. of Montreal, Quebec, Canada, Windbreak Cable of Gehring, Nebraska.

No other changes have been made in either the membership or planned

activity of CableLabs. The membership remains open.

Joseph H. Widmar,

Director of Operations, Antitrust Division.

[FR Doc. 92-8611 Filed 4-14-92; 8:45 am]

BILLING CODE 4410-01-M

Cable Television Laboratories, Inc./ Nexus Engineering Corp./General Instrument Corp.; Notification

Notice is hereby given that, pursuant to section 6(a) of the National Cooperative Research Act of 1984, 15 U.S.C. 4301 et seq. ("the Act"), Cable Television Laboratories, Inc. ("CableLabs"), Nexus Engineering Corp. ("NEXUS") and General Instrument Corporation ("GI") on February 18, 1992, filed a written notification simultaneously with the Attorney General and the Federal Trade Commission disclosing additions to the membership. The notification was filed for the purpose of invoking the protections of section 4 of the Act, which limit the recovery of antitrust plaintiffs to actual damages under specified circumstances.

On June 27, 1991, CableLabs, Nexus and GI filed their original notification pursuant to section 6(a) of the Act. The Department published a notice in the **Federal Register** pursuant to section 6(b) of the Act on July 25, 1991 (56 FR 34075).

Pursuant to section 6(b) of the Act, the identities of the additional members and the general areas of activity are given below.

The identities of the additional members are: Fairmont Cable TV of Fairmont, Minnesota, Shaw Cable Systems Ltd. of Alberta, Canada, Videotron Ltee. of Montreal, Quebec, Canada, Windbreak Cable of Gehring, Nebraska.

The area of activity remains the cooperation in the development of interface concepts between personal communications networks and cable system networks, including the exchange of information related to the functions and architecture of personal communications networks and cooperation in the conduct of radio frequency tests in connection with experimental personal communications networks licenses issued by the FCC.

Joseph H. Widmar,

Director of Operations, Antitrust Division.

[FR Doc. 92-8613 Filed 4-14-92; 8:45 am]

BILLING CODE 4410-01-M

Cable Television Laboratories, Inc. and General Instruction Corp.; Notification

Notice is hereby given that, pursuant to section 6(a) of the National Cooperative Research Act of 1984, 15 U.S.C. 4301 et seq. ("the Act"), Cable Television Laboratories, Inc. ("CableLabs") and General Instrument Corporation through its Jerrold Communications Division ("GI") on February 18, 1992, filed an additional written notification simultaneously with the Attorney General and the Federal Trade Commission disclosing additions to the membership. The additional notification was filed for the purpose of extending the protections of section 4 of the Act, limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances.

On September 20, 1990, CableLabs and GI filed their original notification pursuant to section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to section 6(b) of the Act on November 1, 1990 (55 FR 46111). On February 20, 1991, CableLabs and GI filed an additional written notification. The Department published a notice in the **Federal Register** in response to the additional notification on April 10, 1991 (56 Fr 14542).

Pursuant to section 6(b) of the Act, the identities of the additional members of CableLabs and the general areas of activity are given below.

The identities of the additional members are: Fairmont Cable TC of Fairmont, Minnesota, Shaw Cable Systems Ltd. of Alberta, Canada, Videotron Ltee. of Montreal, Quebec, Canada, Windbreak Cable of Gehring, Nebraska.

The area of activity remains the coordination in the conduct of National Television System Committee (NTSC) visual degradation tests to evaluate the subjective effects of typical impairments and other conditions on NTSC television pictures generated in cable television systems.

Joseph H. Widmar,

Director of Operations, Antitrust Division.

[FR Doc. 92-8614 Filed 4-14-92; 8:45 am]

BILLING CODE 4410-01-M

Cable Television Laboratories, Inc./ General Instrument Corp./Scientific-Atlanta, Inc.; Notification

Notice is hereby given that, pursuant to section 6(a) of the National Cooperative Research Act of 1984, 15 U.S.C. 4301 et seq. ("the Act"), Cable Television Laboratories, Inc. ("CableLabs"), General Instrument Corporation ("GI") and Scientific-Atlanta, Inc. ("S-A") on Febuary 18, 1992, filed an additional written notification simultaneously with the Attorney General and the Federal Trade Commission disclosing additions to the membership. The additional notification was filed for the purpose of invoking the protections of section 4 of the Act, which limit the recovery of antitrust plaintiffs to actual damages under specified circumstances.

On June 21, 1991, CableLabs, GI and S-A filed their original notification pursuant to section 6(a) of the Act. The Department published a notice in the **Federal Register** pursuant to section 6(b) of the Act of August 1, 1991 (56 FR 36847).

Pursuant to section 6(b) of the Act, the identities of the additional members and the general areas of activity are given below.

The identities of the additional members are: Fairmont Cable TV of Fairmont, Minnesota, Shaw Cable Systems Ltd. of Alberta, Canada, Videotron Ltee. of Montreal, Quebec, Canada, Windbreak Cable of Gehring, Nebraska.

The area of activity remains the cooperation in the education of the cable industry and the public concerning the availability of, and potential for, digital video transmission and compression technologies in the distribution and delivery of cable television programming. The parties also plan to cooperate in demonstrations of: (a) The distribution of compressed, digitally-transmitted NTSC signals to cable television systems and (b) the delivery and telecast of advanced television (ATV) programming by the cable industry. These demonstrations will be coordinated by CableLabs using high definition television (HDTV) and other ATV proponent television systems that wish to participate.

Joseph H. Widmar,

Director of Operations, Antitrust Division.

[FR Doc. 92-8615 Filed 4-14-92; 8:45 am]

BILLING CODE 4410-01-M

Cable Television Laboratories, Inc./ PCN America, Inc.; Notification

Notice is hereby given that, pursuant to section 6(a) of the National Cooperative Research Act of 1984, 15 U.S.C. 4301 et seq. ("the Act"), Cable Television Laboratories, Inc. ("CableLabs") and PCN America, Inc. ("PCN America") on February 18, 1992, filed a written notification simultaneously with the Attorney General and the Federal Trade

Commission disclosing additions to the membership. The additional notification was filed for the purpose of invoking the protections of Section 4 of the Act, which limit the recovery of antitrust plaintiffs to actual damages under specified circumstances.

On March 25, 1991, CableLabs and PCN America filed their original notification pursuant to section 6(a) of the act. The Department published a notice in the **Federal Register** pursuant to section 6(b) of the Act on June 14, 1991 (56 FR 27539).

Pursuant to section 6(b) of the Act, the identities of additional members and the general areas activity are given below:

The identities of the additional members are: Fairmont Cable TV of Fairmont, Minnesota, Shaw Cable Systems Ltd of Alberta, Canada, Videotron Ltee. of Montreal, Quebec, Canada, Windbreak Cable of Gehring, Nebraska.

The area of activity remains the cooperation in the development of interface concepts between personal communication networks and cable work networks, including the exchange of information relating to the functions and architecture of personal communication networks, and cooperation in the conduct of radio frequency tests in connection with experimental personnel networks licenses issued by the FCC.

Joseph H. Widmar,

Director of Operations, Antitrust Division.

[FR Doc. 92-8616 Filed 4-14-92; 8:45 am]

BILLING CODE 4410-01-M

Lodging of Consent Decree Pursuant to Clean Air Act

In accordance with Departmental policy, 28 CFR 50.7, notice is herby given that on February 13, 1992, a proposed consent decree in *United States* v. *Eastwood Mall, Inc. and Dezcon, Inc.*, Civil Action No. 90CV1355, was lodged with the United States District Court for the Northern District of Ohio, Eastern Division. The proposed consent decree concerns a complaint filed by the United States that alleged violations of section 112 of the Clean Air Act, 42 U.S.C. 7412, and the National Emission Standard for Hazardous Air Pollutants ("NESHAP") for asbestos. The complaint alleges that both Eastwood Mall, Inc. and Dezcon, Inc. violated the asbestos NESHAP by failing to provide notice of an asbestos demolition/renovation project and by failing to follow work practice standards set forth in the asbestos NESHAP.

The consent decrees requires Eastwood Mall, Inc. and Dezcon, Inc. to comply fully with the Clean Air Act and with the asbestos NESHAP in future operations. The decree also requires the demolition contractor to submit monthly reporting of its asbestos renovation and demolition activities. The decree additionally requires the payment of a civil penalty totalling $31,900. The Department of Justice will receive for a period of thirty (30) days from the date of the publication comments relating to the proposed consent decree. Comments should be addressed to the Assistant Attorney General of the Environment and Natural Resources Division, Department of Justice, Washington, DC 20530, and should refer to *United States* v. *Eastwood Mall, Inc. and Dezcon, Inc.*, D.J. Ref. 90-5-2-1-1485.

The proposed consent decree may be examined at the Region V Office of the United States Environmental Protection Agency, 230 S. Dearborn Street, Chicago, Illinois 60604. Copies of the consent decree may also be examined at the Envrionmental Enforcement Section Document Center, 601 Pennsylvania Avenue, NW., Washington, DC 20004 ((202) 347-2072). A copy of the proposed decree may be obtained in person or by mail from the Document Center, 601 Pennsylvania Avenue, NW., Box 1097, Washington, DC 20004. In requesting a copy, please enclose a check in the amount of $3.30 (25 cents per page reproduction cost) payable to "Consent Decree Library." In requesting a copy, please refer to the referenced case name and the D.J. Ref. number.

John C. Cruden,

Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 92-8608 Filed 4-14-92; 8:45 am]

BILLING CODE 4410-01-M

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

Records Schedules; Availability and Request for Comments

AGENCY: National Archives and Records Administration, Office of Records Administration.

ACTION: Notice of availability of proposed records schedules; request for comments.

SUMMARY: The National Archives and Records Administration (NARA) publishes notice at least one monthly of certain Federal agency requests for records disposition authority (records schedules). Records schedules identify records of sufficient value to warrant preservation in the National Archives of the United States. Schedules also authorize agencies after a specified period to dispose of records lacking administrative, legal, research, or other value. Notice is published for records schedules that (1) propose the destruction of records not previously authorized for disposal, or (2) reduce the retention period for records already authorized for disposal. NARA invites public comments on such schedules, as required by 44 U.S.C. 3303a(a).

DATE: Request for copies must be received in writing on or before June 1, 1992. Once the appraisal of the records is complete, NARA will send a copy of the schedule. The requester will be given 30 days to submit comments.

ADDRESS: Address requests for single copies of schedules identified in this notice to the Records Appraisal and Disposition Division (NIR), National Archives and Records Administration, Washington, DC 20408. Requesters must cite the control number assigned to each schedule when requesting a copy. The control number appears in the parentheses immediately after the name of the requesting agency.

SUPPLEMENTARY INFORMATION: Each year U.S. Government agencies create billions of records on paper, film, magnetic tape, and other media. In order to control this accumulation, agency records managers prepare records schedules specifying when the agency no longer needs the records and what happens to the records after this period. Some schedules are comprehensive and cover all the records of an agency or one of its major subdivisions. These comprehensive schedules provide for the eventual transfer to the National Archives of historically valuable records and authorize the disposal of all other records. Most schedules, however, cover records of only one office or program or a few series of records, and many are updates of previously approved schedules. Such schedules also may include records that are designated for permanent retention.

Destruction of records the approval of the Archivist of the United States. This approval is granted after a thorough study of the records that takes into account their administrative use by the agency of origin, the rights of the Government and of private persons directly affected by the Government's activities, and historical or other value.

This public notice identifies the Federal agencies and their subdivisions requesting disposition authority, includes the control number assigned to each schedule, and briefly describes the records proposed for disposal. The records schedule contains additional information about the records and their disposition. Further information about

the disposition process will be furnished to each requester.

Schedules Pending

1. Defense Logistics Agency N1–361–92–3. Routine and facilitative records relating to planning and resource management.

2. Interstate Commerce Commission, Bureau of Traffic N1–134–92–1. Reduction in retention period for confidential rail contracts.

3. Tennessee Valley Authority, Finance and Administration (N1–142–92–3). Financial reports and accounting procedure files.

4. Tennessee Valley Authority, Customer Group (N1–142–92–9). Record of hourly water elevation and discharges at TVA reservoirs; uncollectible loan records for the home insulation program.

5. Department of the Treasury, Office of Thrift Supervision (N1–483–92–2). Comprehensive schedule for the Directives Management Division.

6. United States Railway Association (N1–464–92–1). Electronic case tracking system and sample of litigation files that are software dependent.

Dated: April 8, 1992.

Claudine J. Weiher,

Acting, Archivist of the United States.

[FR Doc. 92–8666 Filed 4–14–92; 8:45 am]

BILLING CODE 7515–01–M

NATIONAL SCIENCE FOUNDATION

Special Emphasis Panel in Chemical and Thermal Systems; Meetings

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation (NSF) announces the following four meetings:

Name: Special Emphasis Panel in Chemical and Thermal Systems.

Date and Time: April 24, 1992; 8:30 a.m. to 5 p.m.

Place: NSF, room 1243, 1800 G St. NW., Washington, DC 20550.

Agenda: Review and evaluate nominations for the initiative on Materials Synthesis and Processing plus standard NSF proposals.

Contact Person: Dr. Michael M. Chen, Program Director (202) 357–9606.

Date and Time: April 24, 1992; 8:30 a.m. to 5 p.m.

Place: NSF, rm. 1133, 1800 G Street NW., Washington, DC 20550.

Agenda: Review and evaluate nominations for the Engineering Research Equipment Grant (REG) Program.

Contact Persons: Drs. Charles Maldarelli & Robert Wellek, Program Directors (202) 357–9606.

Date and Time: May 11–12, 1992; 8 a.m. to 5 p.m.

Place: NSF, rm. 540–B, 1800 G St. NW., Washington, DC 20550.

Agenda: Review and evaluate nominations for Engineering Research Equipment Grant (REG) Program.

Contact Persons: Drs. Stephen Traugott and M.C. Roco, Program Directors, (202) 357–9606.

Date and Time: April 27–28, 1992; 8:30 a.m. to 5 p.m.

Place: NSF, rm. 504–B, 2800 G St. NW., Washington, DC 20550.

Agenda: Review and evaluate nominations for Research Initiation Awards (RIA) Program.

Contact Persons: Drs. Stephen Traugott and M.C. Roco, Program Directors, (202) 357–9606.

Purpose of Meetings: To provide advice and recommendations to the Division of Chemical and Thermal Systems concerning proposals submitted to the Division for financial support.

Type of Meetings: Closed.

Reason for Closing: The nominations and proposals being reviewed include information of a proprietary or confidential nature, including technical information; financial data, such as salaries; and personal information; financial data, such as salaries; and personal information concerning individuals associated with the nominations and proposals. These matters are exempt under 5 U.S.C. 552b(c) (4) and (6) of the Government in the Sunshine Act.

Reason for Late Notice: Some announcements late due to administrative oversight.

Dated: April 10, 1992.

M. Rebecca Winkler,

Committee Management Officer.

[FR Doc. 92–8711 Filed 4–14–92; 8:45 am]

BILLING CODE 7555–01–M

NUCLEAR REGULATORY COMMISSION

Advisory Committee on Reactor Safeguards and Advisory Committee on Nuclear Waste; Proposed Meetings

In order to provide advance information regarding proposed public meetings of the ACRS Subcommittees and meetings of the ACRS full Committee, of the ACNW, and the ACNW Working Groups the following preliminary schedule is published to reflect the current situation, taking into account additional meetings that have been scheduled and meetings that have been postponed or canceled since the last list of proposed meetings was published March 18, 1992 (57 FR 9433). Those meetings that are firmly scheduled have had, or will have, an individual notice published in the **Federal Register** approximately 15 days (or more) prior to the meeting. It is expected that sessions of ACRS and ACNW full Committee meetings designated by an asterisk (*) will be closed in whole or in part to the public. The ACRS and ACNW full Committee meetings begin at 8:30 a.m. and ACRS Subcommittee and ACNW Working Group meetings usually begin at 8:30 a.m. The time when items listed on the agenda will be discussed during ACRS and ACNW full Committee meetings, and when ACRS Subcommittee and ACNW Working Group meetings will start will be published prior to each meeting. Information as to whether a meeting has been firmly scheduled, canceled, or rescheduled, or whether changes have been made in the agenda for the May 1992 ACRS and ACNW full Committee meetings can be obtained by a prepaid telephone call to the Office of the Executive Director of the Committees (telephone: 301/492–4600 (recording) or 301/492–7288, Attn: Barbara Jo White) between 7:30 a.m. and 4:15 p.m., eastern time.

ACRS Subcommittee Meetings

Joint Individual Plant Examinations/Severe Accidents

April 21, 1992, Bethesda, MD. The Subcommittees will discuss the status of the Individual Plant Examination (IPE) program and the development of Severe Accident Management Guidelines.

Joint Probabilistic Risk Assessment/Control and Electrical Power Systems

April 22, 1992, Bethesda, MD. The Subcommittees will discuss the proposed rule on Diesel Generator Reliability and related matters.

Thermal Hydraulic Phenomena

April 23, 1992, Bethesda, MD. The Subcommittee will discuss the test program proposed by the General Electric Company to support certification of the Simplified Boiling Water Reactor passive plant design, as well as the associated NRC staff actions. Portions of this meeting may be closed to discuss Proprietary Information.

Joint Computers in Nuclear Power Plant Operations/Advanced Boiling Water Reactors

May 5, 1992, Bethesda, MD, 8:30 a.m.–2:30 p.m. The Subcommittees will discuss the control room design for the GE ABWR. Portions of this meeting will be closed to discuss Proprietary Information.

Joint Computers in Nuclear Power Plant Operations/Human Factors

May 5, 1992, Bethesda, MD, 3 p.m.–5 p.m. The Subcommittees will discuss international computer activities with the NRC staff. Portions of this meeting will be closed to discuss foreign Proprietary Information.

Planning and Procedures

May 5, 1992, Bethesda, MD, 3 p.m.–5:30 p.m. The Subcommittee will discuss proposed ACRS activities and related matters. Qualifications of candidates nominated for

appointment to the ACRS will also be discussed. Portions of this meeting will be closed to discuss information the release of which would represent a clearly unwarranted invasion of personal privacy.

Ad Hoc Subcommittee on Design Acceptance Criteria,

May 6, 1992, Bethesda, MD, 8:30 a.m.–12 Noon. The Ad Hoc Subcommittee will discuss use of DAC in the regulatory process and other related matters.

Regional Programs

May 20, 1992, NRC Region V Office, Walnut Creek, CA. The Subcommittee will discuss the activities of the NRC Region V Office.

Joint Materials and Metallurgy/Advanced Reactor Designs

May 21, 1992, San Francisco, CA. The Subcommittees will discuss the application of the high temperature structural materials in the Advanced Liquid-Metal Reactor (ALMR).

Ad Hoc Working Group on Multinational Meeting

May 26, 1992 (tentative), Bethesda, MD. The Working Group will hold a preliminary discussion with some members of the German Advisory Committee, RSK, to develop plans for the Second International Quadripartite meeting to be held in the late 1992 or 1993.

Severe Accidents

May 27, 1992, Bethesda, MD. The Subcommittee will discuss the revision to NUREG–1365, Severe Accident Research Program Plan (to be provided about May 1, 1992).

Thermal Hydraulic Phenomena

June 3, 1992, Bethesda, MD. The Subcommittee will discuss the Westinghouse Electric Corporation's and the NRC staff's proposed test programs for support of the AP600 passive plant design certification effort. Portions of this meeting may be closed to discuss Proprietary Information.

Planning and Procedures

June 3, 1992, Bethesda, MD, 3 p.m.–5:30 p.m. The Subcommittee will discuss proposed ACRS activities and related matters. Qualifications of candidates nominated for appointment to the ACRS will also be discussed. Portions of this meeting will be closed to discuss information the release of which would represent a clearly unwarranted invasion of personal privacy.

Advanced Boiling Water Reactors

September 23, 1992, Bethesda, MD. The Subcommittee will review the Final Safety Evaluation Report (FSER) for the GE ABWR design.

Advanced Boiling Water Reactors

October 21, 1992, Bethesda, MD. The Subcommittee will continue its review of the Final Safety Evaluation Report (FSER) for the GE ABWR design.

ACRS Full Committee Meetings

385th ACRS Meeting

May 6 (1 p.m.), 7–9 (8:30 a.m.), 1992, Bethesda, MD. Items are tentatively scheduled.

A. Implementation of NRC Safety Goal Policy

Discuss proposed alternate plan for implementation of NRC Safety Goal Policy.

B. Policy Issues for Certification of Evolutionary and Passive Plants

Review and comment on technical policy issues identified by the NRC staff in need of resolution in connection with the certification of standardized nuclear plants per 10 CFR part 52. Representatives of the NRC staff and the nuclear industry will participate, as appropriate.

C. Update of NRC Standard Review Plan

Briefing and discussion regarding the status of the NRC staff program to update the Standard Review Plan in order to better accommodate the review of future nuclear power plants. Representatives of the NRC staff will participate, as appropriate.

D. Implementation of NRC Maintenance Rule

Briefing and discussion regarding the status of the NRC staff effort to develop a Regulatory Guide to implement the Maintenance Rule. Representatives of the NRC staff and the nuclear industry will participate, as appropriate.

E. Severe Accidents and Containment Performance Criteria

Review and comment on the proposed notice of advanced rulemaking regarding proposed 10 CFR part 50 changes to address severe accidents and containment performance criteria. Representatives of the NRC staff and the nuclear industry will participate, as appropriate.

* F. GE Simplified Boiling Water Reactor

Review and report on the test program proposed for the GE SBWR. Representatives of the NRC staff and GE Nuclear Energy will participate, as appropriate.

G. Pilot Simulator Examination Program

Briefing and discussion on the results of the NRC pilot simulator examination program. Representatives of the NRC staff will participate, as appropriate.

* H. Activities of ACRS Subcommittee and Committee Members

Reports on and discussion of the activities of cognizant ACRS Subcommittee in designated areas of responsibility and activities of ACRS members related to Committee assignments including:

(1) The status of activities related to integral system testing requirements for the AP600 passive nuclear plant,

(2) The ABWR control room design,

(3) The Design Acceptance Criteria process,

(4) Status of IPEs and development of Severe Accident Management Guidelines, and

(5) Plans for multinational meeting of advisory groups.

I. Proposed Definition of a Large Release Consistent with NRC Safety Goal Policy

Review and comment regarding NRC staff proposed definition of a large release of fission products consistent with the NRC safety goal policy.

J. Reactor Operating Experience

Briefing and discussion regarding the results of the AIT investigation of the November 6, 1991 event at the Millstone Nuclear Plant Unit 2 which involved failure of a moisture separator reheater drain line. Representatives of the NRC staff and the license will participate, as appropriate.

K. Diesel-Generator Reliability

Briefing and discussion regarding the proposed NRC rule on diesel-generator reliability. Representatives of the NRC staff and the nuclear industry will participate, as appropriate.

L. Future Committee Activities

Discuss anticipated Subcommittee activities and items proposed for consideration by the full Committee.

* M. Appointment of ACRS Members

Discuss the qualifications of candidates proposed for consideration as Committee members.

N. Reconciliation of ACRS Comments/ Recommendations

Discuss applicable replies from the NRC Executive Director for Operations regarding specific ACRS comments and recommendations.

O. Miscellaneous

Discuss topics related to the conduct of ACRS activities and specific issues that were not completed during previous meeting as time and availability of information permit.

386th ACRS Meeting

June 4–6, 1992, Bethesda, MD—Agenda to be announced.

387th ACRS Meeting

July 9–11, 1992, Bethesda, MD—Agenda to be announced.

388th ACRS Meeting

August 6–8, 1992, Bethesda, MD—Agenda to be announced.

389th ACRS Meeting

September 10–12, 1992, Bethesda, MD—Agenda to be announced.

390th ACRS Meeting

October 8–10, 1992, Bethesda, MD—Agenda to be announced.

391st ACRS Meeting

November 5–7, 1992, Bethesda, MD—Agenda to be announced.

392nd ACRS Meeting

December 10–12, 1992, Bethesda, MD—Agenda to be announced.

ACNW Full Committee and Working Group Meetings

42nd ACNW Meeting

April 22–14, 1992, Bethesda, MD. Items are tentatively scheduled.

A. Periodic meeting with NRC Commissioners to discuss topics of mutual interest.

B. Discussion of the Pathfinder Nuclear Power Plant decommissioning, including lessons learned and residual levels of contamination. Also, briefing and discussion regarding the status of decommissioning plans for Rancho Seco, Ft. St. Vrain, Shoreham, and potentially other Nuclear Power Stations.

C. Review of an expedited rulemaking effort concerning on-site storage of low-level waste.

D. Preparation of the next four month plan of ACNW activities for the Commission's information.

E. Continue efforts to investigate the feasibility of a systems analysis approach to reviewing the overall high-level waste program.

F. Hear a Status Report on New York's challenge to the LLWPAA of 1985.

G. Discuss NRC's Draft HLW Research Program Plan—NUREG–1406.

H. Briefing by Louisiana Energy Services on their private uranium enrichment facility plans.

I. Review a Technical Position on Alternate Concentration Limits for Uranium Mill Tailings Sites.

J. Discuss anticipated and proposed Committee activities, future meeting agenda, administrative, and organizational matters, as appropriate. Also, discuss matters and specific issues that were not completed during previous meetings as time and availability of information permit.

43rd ACNW Meeting

May 28–29, 1992, Bethesda, MD—Items are tentatively scheduled.

A. Review proposed changes to 10 CFR part 72, concerning Emergency Planning for Independent Spent Fuel Storage Installation and Monitored Retrievable Storage facilities.

B. Consider rulemaking for a Controlled-Use Area/Design Basis Accident Dose Limit for the operation of a high-level radioactive waste repository.

C. Briefing on the adoption by EPA of a revised Hazard Ranking System for use in assessing the threat associated with the release or potential release into the environment of hazardous chemicals and/or radioactive materials.

D. Briefing on the NRC staff's review of the DOE reports on the Exploratory Studies Facility Alternatives Study.

E. Seek an update on the status of the low-level radioactive waste state compacts.

F. Discuss anticipated and proposed Committee activities, future meeting agenda, administrative, and organizational matters, as appropriate. Also, discuss matters and specific issues that were not completed during previous meetings as time and availability of information permit.

ACNW Working group on NRC Staff Comments on the DOE's Early Site Suitability Evaluation (ESSE) for the Yucca Mountain High-Level Repository

June 16, 1992. The Working Group will discuss the issues, concerns, and conclusions resulting from the NRC staff's review of DOE's ESSE.

44th ACNW Meeting

June 23-25, 1992 Hanford, WA—Agenda to be announced.

45th ACNW Meeting

July 30–31, 1991, Bethesda, MD—Agenda to be announced.

46th ACNW Meeting

August 13-14, 1992, Bethesda, MD—Agenda to be announced.

ACNW Working Group on Performance Assessment

September 23, 1992 (tentative), Bethesda, MD. The Working Group will discuss the progress of Phase 2 of the HLW Iterative Performance Assessment effort by NRC. Also, this Group will hear a briefing by DOE representatives regarding the status of the DOE's Total System Performance Assessment.

47th ACNW Meeting

September 24–25, 1992, Bethesda, MD—Agenda to be announced.

ACNW Working Group on Inadvertent Human Intrusion Related to the Presence of Natural Resources at a High-Level Repository Site

October 21, 1992, Bethesda, MD. The Working Group will discuss methodologies for the assessment of the potential for natural resources at the proposed high-level waste repository site at Yucca Mountain. The relationship between such resources and the potential for human intrusion will be emphasized.

48th ACNW Meeting

October 22–23, 1992, Las Vegas, NV—Agenda to be announced.

ACNW Working Group on the Impact of Long-Range Climate Change in the Area of the Southern Basin and Range

November 18, 1992 (tentative), Bethesda, MD. The Working Group will discuss the historical evidence and the potential for climate changes in the Southern Basin and Range and the impact of climate changes on the performance of the proposed high-level waste repository at Yucca Mountain.

49th ACNW Meeting

November 19–20, 1992, Bethesda, MD—Agenda to be announced.

50th ACNW Meeting

December 17–18, 1992, Bethesda, MD—Agenda to be announced.

Dated: April 10, 1992

John C. Hoyle,

Advisory Committee Management Officer.

[FR Doc. 92–8731 Filed 4–14–92; 8:45 am]

BILLING CODE 7590-01-M

Biweekly Notice Applications and Amendments to Operating LicensesInvolving No Significant Hazards Considerations

I. Background

Pursuant to Public Law (P.L.) 97-415, the Nuclear Regulatory Commission(the Commission or NRC staff) is publishing this regular biweekly notice. P.L.97-415 revised section 189 of the Atomic Energy Act of 1954, as amended (theAct), to require the Commission to publish notice of any amendments issued, orproposed to be issued, under a new provision of section 189 of the Act. Thisprovision grants the Commission the authority to issue and make immediatelyeffective any amendment to an operating license upon a determination by theCommission that such amendment involves no significant hazards consideration,notwithstanding the pendency before the Commission of a request for a hearingfrom any person.

This biweekly notice includes all notices of amendments issued, orproposed to be issued from March 23, 1992 through April 3, 1992. The lastbiweekly notice was published on April 1, 1992 (57 FR 11100).

Notice of Consideration of Issuance of Amendment to Facility OperatingLicense and Proposed No Significant Hazards Consideration Determination andOpportunity for Hearing

The Commission has made a proposed determination that the followingamendment requests involve no significant hazards consideration. Under theCommission's regulations in 10 CFR 50.92, this means that operation of thefacility in accordance with the proposed amendments would not (1) involve asignificant increase in the probability or consequences of an accidentpreviously evaluated; or (2) create the possibility of a new or different kindof accident from any accident previously evaluated; or (3) involve asignificant reduction in a margin of safety. The basis for this proposeddetermination for each amendment request is shown below.

The Commission is seeking public comments on this proposed determination.Any comments received within 30 days after the date of publication of thisnotice will be considered in making any final determination. The Commissionwill not normally make a final determination unless it receives a request fora hearing.

Written comments may be submitted by mail to the Regulatory PublicationsBranch, Division of Freedom

of Information and Publications Services, Officeof Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555,and should cite the publication date and page number of this FederalRegister notice. Written comments may also be delivered to Room P-223,Phillips Building, 7920 Norfolk Avenue, Bethesda, Maryland from 7:30 a.m. to4:15 p.m. Federal workdays. Copies of written comments received may beexamined at the NRC Public Document Room, the Gelman Building, 2120 L Street,NW., Washington, DC 20555. The filing of requests for hearing and petitionsfor leave to intervene is discussed below.

By May 15, 1992, the licensee may file a request for a hearing withrespect to issuance of the amendment to the subject facility operating licenseand any person whose interest may be affected by this proceeding and whowishes to participate as a party in the proceeding must file a written requestfor a hearing and a petition for leave to intervene. Requests for a hearingand a petition for leave to intervene shall be filed in accordance with theCommission's "Rules of Practice for Domestic Licensing Proceedings" in 10CFR Part 2. Interested persons should consult a current copy of 10 CFR 2.714which is available at the Commission's Public Document Room, the GelmanBuilding, 2120 L Street, NW., Washington, DC 20555 and at the local publicdocument room for the particular facility involved. If a request for a hearingor petition for leave to intervene is filed by the above date, the Commissionor an Atomic Safety and Licensing Board, designated by the Commission or bythe Chairman of the Atomic Safety and Licensing Board Panel, will rule on therequest and/or petition; and the Secretary or the designated Atomic Safety andLicensing Board will issue a notice of hearing or an appropriate order.

As required by 10 CFR 2.714, a petition for leave to intervene shall setforth with particularity the interest of the petitioner in the proceeding, andhow that interest may be affected by the results of the proceeding. Thepetition should specifically explain the reasons why intervention should bepermitted with particular reference to the following factors: (1) the natureof the petitioner's right under the Act to be made a party to the proceeding;(2) the nature and extent of the petitioner's property, financial, or otherinterest in the proceeding; and (3) the possible effect of any order which maybe entered in the proceeding on the petitioner's interest. The petition shouldalso identify the specific aspect(s) of the subject matter of the proceedingas to which petitioner wishes to intervene. Any person who has filed apetition for leave to intervene or who has been admitted as a party may amendthe petition without requesting leave of the Board up to fifteen (15) daysprior to the first prehearing conference scheduled in the proceeding, but suchan amended petition must satisfy the specificity requirements described above.

Not later than fifteen (15) days prior to the first prehearing conferencescheduled in the proceeding, a petitioner shall file a supplement to thepetition to intervene which must include a list of the contentions which aresought to be litigated in the matter. Each contention must consist of aspecific statement of the issue of law or fact to be raised or controverted.In addition, the petitioner shall provide a brief explanation of the bases ofthe contention and a concise statement of the alleged facts or expert opinionwhich support the contention and on which the petitioner intends to rely inproving the contention at the hearing. The petitioner must also providereferences to those specific sources and documents of which the petitioner isaware and on which the petitioner intends to rely to establish those facts orexpert opinion. Petitioner must provide sufficient information to show that agenuine dispute exists with the applicant on a material issue of law or fact.Contentions shall be limited to matters within the scope of the amendmentunder consideration. The contention must be one which, if proven, wouldentitle the petitioner to relief. A petitioner who fails to file such asupplement which satisfies these requirements with respect to at least onecontention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject toany limitations in the order granting leave to intervene, and have theopportunity to participate fully in the conduct of the hearing, including theopportunity to present evidence and cross-examine witnesses.

If a hearing is requested, the Commission will make a final determinationon the issue of no significant hazards consideration. The final determinationwill serve to decide when the hearing is held.

If the final determination is that the amendment request involves nosignificant hazards consideration, the Commission may issue the amendment andmake it immediately effective, notwithstanding the request for a hearing. Anyhearing held would take place after issuance of the amendment.

If the final determination is that the amendment request involves asignificant hazards consideration, any hearing held would take place beforethe issuance of any amendment.

Normally, the Commission will not issue the amendment until theexpiration of the 30-day notice period. However, should circumstances changeduring the notice period such that failure to act in a timely way wouldresult, for example, in derating or shutdown of the facility, the Commissionmay issue the license amendment before the expiration of the 30-day noticeperiod, provided that its final determination is that the amendment involvesno significant hazards consideration. The final determination will considerall public and State comments received before action is taken. Should theCommission take this action, it will publish in the **Federal Register** anotice of issuance and provide for opportunity for a hearing after issuance.The Commission expects that the need to take this action will occur veryinfrequently.

A request for a hearing or a petition for leave to intervene must befiled with the Secretary of the Commission, U.S. Nuclear RegulatoryCommission, Washington, DC 20555, Attention: Docketing and Services Branch, ormay be delivered to the Commission's Public Document Room, the GelmanBuilding, 2120 L Street, NW., Washington DC 20555, by the above date. Wherepetitions are filed during the last ten (10) days of the notice period, it isrequested that the petitioner promptly so inform the Commission by a toll-freetelephone call to Western Union at 1-(800) 325-6000 (in Missouri 1-(800) 342-6700). The Western Union operator should be given Datagram IdentificationNumber 3737 and the following message addressed to (Project Director):petitioner's name and telephone number, date petition was mailed, plant name,and publication date and page number of this **Federal Register** notice.A copy of the petition should also be sent to the Office of the GeneralCounsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555, and to theattorney for the licensee.

Nontimely filings of petitions for leave to intervene, amended petitions,supplemental petitions and/or requests for hearing will not be entertainedabsent a determination by the Commission, the presiding officer or the AtomicSafety and Licensing Board that the petition and/or request should be grantedbased upon a balancing of factors specified in 10 CFR 2.714(a)(1)(i)-(v) and2.714(d).

For further details with respect to this action, see the application foramendment which is available for public inspection at the Commission's PublicDocument Room, the Gelman Building, 2120 L Street, NW., Washington, DC 20555,and at the local public document room for the particular facility involved.

Carolina Power & Light Company, et al., Docket No. 50-400, Shearon Harris Nuclear Power Plant, Unit 1, Wake and Chatham Counties, North Carolina

Date of amendment request: March 10, 1992

Description of amendment request: The proposed TechnicalSpecification (TS) changes will (1) increase the limits for boronconcentration in the refueling water storage tank and the safety injectionsystem accumulators, (2) revise Figure 3.1-1, Shutdown Margin Versus RCS BoronConcentration, (3) increase the level of NaOH in the spray additive tank, (4)change the minimum level in the boric acid tank, and (5) provide forspecification of the boron concentration in the RCS and refueling canal viathe Core Operating Limits Report. Additionally, in the TS Bases, the proposedchanges will standardize and clarify the TS wording used for the boric acidtank, the safety injection accumulator, and the spray additive tank, and willclarify the relationship between volume and level.

Basis for proposed no significant hazards considerationdetermination: As required by 10 CFR 50.91(a), the licensee has providedits analysis of the issue of no significant hazards consideration, which ispresented below:

1. The proposed amendment does not involve a significant increase in theprobability or consequences of an accident previously evaluated.

(a) Increase in Boron Concentration in the RWST and Safety InjectionAccumulators: The higher boron concentration does not increase theaccident initiation probability for any of the Final Safety Analysis Report(FSAR) events. CP&L has determined that a) the higher boron concentration inthe RWST, SI System, and RCS will have no adverse effect on the stainlesssteel container materials, despite a slightly lower pH at 2600 ppmB than at2200 ppmB; b) there is no danger of boron precipitation; and c) corrosion ofcarbon steel by leakage of the more highly borated water will not be increasedsignificantly because the pH change is small and still in the range wherecorrosion rates are nearly independent of pH. Therefore, the probability of anaccident is not increased by the higher boron concentration.

The higher boron concentration in the RCS causes a very small increase intritium production rate in the coolant for a short period near the beginningof cycle. This does not contribute significantly to off-site doses or topersonnel doses. All radionuclide source terms used in the FSAR off-site dosecalculations remain unchanged because tritium is not currently modeled in theFSAR Chapter 15 off-site dose calculations. The post-LOCA hydrogen productionmay increase by about 3.5 percent (due to containment spray reacting withzinc) because of the higher boron concentration. This increase is consideredinsignificant. To ensure that the containment spray retains its capability ofremoving iodine from the containment atmosphere following a LOCA, and toensure that the sump solution will retain the iodine, it is proposed toincrease the NaOH volume in the Spray Additive Tank to maintain spray and sumppH between 8.5 and 11.0. Therefore, there will be no increase in theconsequences of an accident previously evaluated due to the higher boronconcentration.

(b) Increase in NaOH Volume: Neither the Spray Additive Tank(SAT), the NaOH solution, nor failure of the tank contributes to theinitiation of any FSAR Chapter 15 event. The proposed increase in NaOH volumedoes not increase any of the accident initiation probabilities. Therefore, theprobability of an accident is not increased by the larger NaOH volume.

The increase in NaOH volume compensates for the higher boronconcentration so that pH in the containment spray and sump remains between 8.5and 11.0 for effective iodine absorption by the containment spray and iodineretention in the sump. Thus, the proposed amendment does not involve asignificant increase in the consequences of any accidents due to the increasein boron concentration when the NaOH volume is also increased.

(c) Change in Minimum Level of Boric Acid in the Boric Acid Tank:Neither the Boric Acid Tank, the boric acid, nor failure of the tankcontributes to the initiation of any FSAR Chapter 15 event. The proposedchange in maximum level does not increase any of the accident initiationprobabilities. Therefore, the probability of each accident previouslyevaluated in the FSAR is not significantly increased by the proposed minimumboric acid volume.

The purpose of this proposed Technical Specification change is to ensureadequate shutdown during refueling. The consequences of the accidentspreviously evaluated in the FSAR are not increased by changing the TechnicalSpecifications to refer to the COLR for a potentially more restrictiverefueling boron concentration.

2. The proposed amendment does not create the possibility of a new ordifferent kind of accident from any accident previously evaluated.

(a) Increase in Boron Concentration in the RWST and Safety InjectionAccumulators: The proposed changes do not change normal plant operationsexcept as required to maintain the modified boron, lithium, and pH controlprogram. No changes are made to system functional requirements and no newaccident scenarios have been identified. Therefore, the proposed amendmentdoes not create the possibility of a new or different kind of accidentpreviously evaluated.

(b) Increase in NaOH Volume: The proposed change does not changeplant design or operation except to fill and maintain the SAT at the new levelrange. No new accidents have been identified. Therefore, the proposed increasein NaOH volume does not create the possibility of a new or different kind ofaccident from any accident previously evaluated.

(c) Change in Minimum Level of Boric Acid in the Boric Acid Tank:The proposed change does not change plant design or operation except tomaintain the proposed new minimum level. Therefore, the proposed increase inminimum boric acid level does not create the possibility of a new or differentkind of accident from any accident previously evaluated.

(d) Core Operating Limits Report: The proposed change does notchange plant design or refueling operations except to require a boronconcentration of [greater than or equal to] 2000 ppmB or as satisfied in theCore Operating Limits Report (COLR), which ever is more limiting (higher). Nonew or different accident scenario has been identified. Therefore, theproposed increase in minimum boron concentration does not create thepossibility of a new or different kind of accident from any accidentpreviously evaluated.

3. The proposed amendment does not involve a significant reduction in amargin of safety.

(a) Increase in Boron Concentration in the RWST and Safety InjectionAccumulators: The inadvertent boron dilution event in Modes 3, 4 and 5were reanalyzed and Technical Specification Figure 3.1-1 will be revised toensure that all shutdown margin criteria satisfy all Bases despite the higherboron concentration. The current analysis results for the inadvertent borondilution event in Modes 1, 2 and 6 remains valid since the analysis assumptionwith respect to boron concentrations delineated in FSAR Section 15.4.6 areunchanged due to the increase in boron concentration. Furthermore, aninadvertent boron dilution event in Mode 6 is precluded by administrativeprocedures. All acceptance criteria in the Bases of Technical Specificationsare satisfied without revision. The higher boron concentration together withthe proposed revision to Figure 3.1-1 ensures that the Limiting Conditions forOperation are retained. The Reload Safety Evaluation will confirm that allapplicable criteria are satisfied with no reduction in margins of safety.Therefore, the higher boron concentration does not involve a significantreduction in the margin of safety.

(b) Increase in NaOH Volume: The permissible range of theproposed NaOH volume is larger than before; thus margins to the maximum andminimum Technical Specification limits will be easier to maintain. Since thestructural and seismic analyses were based on the tank filled to capacity andthe proposed volume will be about 50 percent of capacity, these analysescontinue to have sufficient margin. The calculated containment spray and sumppH transients show ample margin within the required pH range, 8.5-11.0, forsolutions of 28-30 percent

NaOH. Therefore, the proposed change does notinvolve a significant reduction in the margin of safety.

(c) Change in Minimum Level of Boric Acid in the Boric Acid Tank:The margins of safety of interest are the shutdown margin criteria specifiedin the Technical Specification Bases 3/4.1.2. Those criteria are verified forthe final fuel design and final core loading pattern each cycle in the ReloadSafety Evaluation. The proposed minimum level, based on the Cycle 5 design,will provide adequate margin for future cycles. Therefore, the proposedminimum boric acid level does not involve a significant reduction in themargin of safety.

(d) Core Operating Limits Report: The margins of safety ofinterest are the shutdown margin criteria specified in the TechnicalSpecification Bases 3/4.9.1 and requires that [k effective is less than orequal to] 0.95. Since this criterion is not measurable, it is proposed tospecify the boron concentration necessary to achieve this criterion in theCOLR for each reload. The Technical Specification will require the morerestrictive of either the value in the COLR or 2000 ppmb. This change ensuresthat the shutdown margin specified in the Technical Specification Bases issatisfied. Therefore, the proposed change does not involve a significantreduction in the margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on thisreview, it appears that the three standards of 10 CFR 50.92(c) are satisfied.Therefore, the NRC staff proposes to determine that the amendment requestinvolves no significant hazards consideration.

Local Public Document Room location: Cameron Village RegionalLibrary, 1930 Clark Avenue, Raleigh, North Carolina 27605.

Attorney for licensee: R. E. Jones, General Counsel, CarolinaPower & Light Company, P. O. Box 1551, Raleigh, North Carolina 27602

NRC Project Director: Elinor G. Adensam

Duke Power Company, Docket Nos. 50-369 and 50-370, McGuire NuclearStation, Units 1 and 2, Mecklenburg County, North Carolina

Date of amendment request: February 5, 1992

Description of amendment request: The proposed amendments wouldrevise the methyl iodide penetration acceptance criteria requirement inTechnical Specification Surveillance Requirements 4.7.7.1a.(2) and 4.7.7.1b.from 90% to less than 10%. The proposed change is to correctly reflect thetest acceptance criteria documented in the Safety Evaluation Report (SER) for Amendment No. 113 and No. 95 to Facility Operating Licenses NPF-9 and NPF-17,respectively, on September 12, 1990.

Basis for proposed no significant hazards considerationdetermination: As required by 10 CFR 50.91(a), the licensee has providedits analysis of the issue of no significant hazards consideration, which ispresented below:

(1) The proposed amendment would not involve a significant increase inthe probability or consequences of an accident previously evaluated.

The proposed TS change from 90% to less than 10% for methyl iodidepenetration acceptance criterion is more conservative and is consistent withthe licensing basis. This amendment corrects a typographical error and doesnot alter the basis of the previously NRC approved design. This administrativechange itself is not considered to be an initiator or a contributer to anypreviously evaluated accidents. Therefore there is no increase in theprobability or consequences of an accident previously evaluated.

(2) The proposed amendment would not create the possibility of a new ordifferent kind of accident not previously evaluated.

The Auxiliary Building Filtered Ventilation Exhaust system is an accidentmitigation system and the proposed change merely corrects a typographicalerror in the Tech Spec Surveillance test criterion. There is no change tostructures, systems, components, or operating procedures. Therefore, thischange [cannot] create the possibility of a new or different kind of accidentfrom any accident previously evaluated.

(3) No significant reduction in a margin of safety will occur.

The revised acceptance values of the testing procedures continue toassure operability of the carbon filter as originally intended in theSeptember 12, 1990 Staff SER. This is an administrative change to correct atypographical error, therefore the margin of safety is not impacted. Note: Thestation's administrative acceptance criterion for methyl iodide penetrationhas been the proper amount (10%) since issuance of the previous licenseamendment containing the error (September 12, 1990).

The NRC staff has reviewed the licensee's analysis and, based on thisreview, it appears that the three standards of 10 CFR 50.92(c) are satisfied.Therefore, the NRC staff proposes to determine that the amendment requestinvolves no significant hazards consideration.

Local Public Document Room location: Atkins Library, Universityof North Carolina, Charlotte (UNCC Station), North Carolina 28223

Attorney for license: Mr. Albert Carr, Duke Power Company, 422South Church Street, Charlotte, North Carolina 28242

NRC Project Director: David B. Matthews

Florida Power Corporation, et al., Docket No. 50-302, Crystal River UnitNo. 3 Nuclear Generating Plant, Citrus County, Florida

Date of amendment request: February 27, 1992

Description of amendment request: The proposed amendment wouldsupport installation of a more reliable dual channel control rod positionindicator arrangement for Florida Power Corporation's (FPC) Crystal River Unit3 (CR-3). The Technical Specification (TS) changes delete the individualcontrol rod position accuracy requirement from TS 3.1.3.3 and add to theassociated Bases a description of what constitutes an operable positionindication channel. The amendment would also define a reed switch positionindicator channel and provide new acceptance criteria in TS 4.1.3.3 fordetermining agreement between the reed switch and pulse stepping indicatorchannels.

Basis for proposed no significant hazards considerationdetermination: As required by 10 CFR 50.91(a), the licensee has providedits analysis of the issue of no significant hazards consideration, which ispresented below:

FPC concludes this change will not:

1. Involve a significant increase in the probability or consequence of anaccident previously evaluated because the proposed requirements are consistentwith initial assumptions in the Design Basis Accident (DBA) analysis.

The CR-3 Technical Specifications and safety analysis were reviewedagainst the proposed requirements. The review also considered the core reloadanalysis which is the vehicle for relating the safety analysis to theTechnical Specifications. The reload analysis ensures the safety analysisassumptions reflected by the cycle-specific control rod position limit curvesare preserved and the cycle-specific limits ensure the consequences of anaccident are limited for those previously evaluated accidents. The methodologyfor the reload analysis includes a 1.5% uncertainty applied to group averageposition and has been previously reviewed and approved by the NRC. The 1.5%uncertainty accounts for the deviation of the indicated group average positionfrom the true average position and is the basis for the proposed requirements.Thus, a requirement based on reload analysis assumptions, such as this, doesnot result in an increase in the consequences of a previously analyzedaccident.

The ability to determine individual control rod position is not assumedas part of any safety analysis (other than to verify reactor trip). Thesafety analysis does assume reed switch position indication instrumentationwill detect an asymmetric rod condition and provide an input to the rodcontrol system to automatically decrease reactor power. Analysis performed forthe proposed position indicators considered this function of the system anddemonstrated that

the proposed indicators detect the asymmetric control rodconditions with a 95% probability and 95% confidence. Thus, the only activefunction associated with the reed switch position indication continues to beassured with this change and the probability of a previously analyzed accidentis not increased.

2. Create the possibility of a new or different kind of accident from anyaccident previously evaluated. The dual channel reed switch positionindication on whichthe proposed requirements are based, work on the sameprinciple of operation as the currently installed, single channel positionindication. The reed switch position indication is the only change to theinstalled plant hardware configuration. Therefore, the possibility of a new ordifferent kind of accident is not created.

3. Involve a significant reduction in the margin of safety because therod position indication LCO continues to require reed switch positionindicator channels for each control rod to be OPERABLE. The proposed amendmentchanges the surveillance requirement agreement criteria to provide alimitation (1.5% uncertainty on rod group average position) with a basis inthe CR-3 accident analysis. Therefore, the margin of safety provided by thisLCO is not significantly reduced.

The uncertainty assumed for rod group average position is currentlyreflected in other CR-3 Technical Specifications as a result of the cycle-specific reload analysis. Thus, the margin of safety provided by relatedTechnical Specifications is also unchanged.

The NRC staff has reviewed the licensee's analysis and, based on thisreview, it appears that the three standards of 50.92(c) are satisfied.Therefore, the NRC staff proposes to determine that the amendment requestinvolves no significant hazards consideration.

Local Public Document Room location: Coastal Region Library, 8619W. Crystal Street, Crystal River, Florida 32629

Attorney for licensee: A. H. Stephens, General Counsel, FloridaPower Corporation, MAC - A5D, P. O. Box 14042, St. Petersburg, Florida 33733

NRC Project Director: Herbert N. Berkow

Florida Power and Light Company, Docket Nos. 50-250 and 50-251, TurkeyPoint Plant Units 3 and 4, Dade County, Florida

Date of amendment request: February 25, 1992

Description of amendment request: The currently licensed term forTurkey Point Units 3 and 4 is 40 years commencing with issuance of theconstruction permits (April 27, 1967). The operating licenses currently expireon April 27, 2007. Accounting for the time that was required for plantconstruction, this represents an effective operating license term ofapproximately 34 and 3/4 years for Unit 3 and 34 years for Unit 4. Theproposed amendments would extend the expiration date of the operating licensesso that the 40-year term of each unit would begin with the date of issuance ofthe operating license, rather than the date of issuance of the constructionpermit. This would extend the operating license date for Turkey Point Unit 3to July 19, 2012 and for Turkey Point Unit 4 to April 10, 2013.

Basis for proposed no significant hazards considerationdetermination: As required by 10 CFR 50.91(a), the licensee has providedits analysis of the issue of no significant hazards consideration, which ispresented below:

(1) Operation of the facility in accordance with the proposedamendment[s] would not involve a significant increase in the probability orconsequences of an accident previously evaluated.

The proposed license amendments do not involve a change in theprobability or consequences of accidents previously evaluated since nophysical changes to the plants, their operation, nor their procedures areinvolved. The proposed changes merely involve the administrative activity ofrevising both units' operating license expiration dates.

Turkey Point Units 3 and 4 were designed and constructed assuming fortyyears of operation. The analyses contained in the Updated Final SafetyAnalysis Report (UFSAR) for Turkey Point Units 3 and 4 are also predicatedupon operation up to forty years. Surveillance and maintenance practices thatare implemented in accordance with the American Society of MechanicalEngineers (ASME) Code and the Turkey Point Units 3 and 4 TechnicalSpecifications provide assurance that any degradation in plant equipment willbe identified and corrected.

The design of the reactor vessels and their internals considered theeffects of forty years of operation at full power at a capacity factor of 80%(i.e., 32 effective full power years [EFPY]). Analyses have indicated thatexpected cumulative neutron fluences will not be a limiting consideration.Calculations, based on a forty year operating life, were made in accordancewith 10 CFR 50.61, "Fracture toughness requirements for protection againstpressurized thermal shock events," and found to be below the screeningcriteria.

The results of this analysis were submitted by FPL to the NRC by letterL-92-27 dated February 13, 1992, [and] demonstrate that the expected neutronfluences at Turkey Point Units 3 and 4 and resultant RT_{PTS} will notresult in either unit exceeding the RT_{PTS} screening criteria duringthe operating license recapture period through 32 EFPY. The Turkey Point Units3 and 4 analysis documented in the November 1991 BAW-2118P Report, **LowUpper-Shelf Toughness Fracture Analysis of Reactor Vessels of Turkey PointUnits 3 and 4 for Load Level A & B Conditions**, and submitted by FPL to theNRC by letter L-92-02 dated February 4, 1992, addresses the requirements of 10CFR 50 Appendix G, "Fracture Toughness Requirements." The analysis clearlyshows that the vessel material has excellent toughness and, although theupper-shelf energy of the Turkey Point vessels may drop below 50 ft-lbs, therewill be an adequate margin of safety against fracture through at least 40years of operation. In addition to these calculations, surveillance capsulesplaced inside the reactor vessels provide a means of monitoring the cumulativeeffects of power operation.

Aging analyses have been performed for all safety-related electricalequipment in accordance with the requirements of 10 CFR 50.49, "Environmentalqualification of electric equipment important to safety for nuclear powerplants," identifying qualified lifetimes for this equipment. These lifetimesare incorporated into equipment maintenance and replacement practices toensure that all safety-related electrical equipment remains qualified andavailable to perform its safety function throughout a forty year lifetime.

Additionally, analysis of operating experience at other facilities isroutinely conducted by FPL. This analysis, coupled with regulatory feedback,provides added assurance that emerging concerns are addressed in a timelymanner consistent with significance of the issue.

Based on the forty year design of the plant, coupled with the ongoingsurveillance of plant systems, structures, and components, FPL has concludedthat operation of Turkey Point Units 3 and 4 for the additional yearsrepresenting the time period between issuance of each unit's constructionpermit to issuance of its operating license will not involve an increase inthe probability or consequences of an accident previously evaluated.

(2) Operation of the facility in accordance with the proposedamendment[s] would not create the possibility of a new or different kind ofaccident from any accident previously evaluated

The proposed license amendments do not create the possibility of a new ordifferent kind of accident from any accident previously evaluated since nophysical changes to the plants, their operation, nor their procedures areinvolved. The proposed changes merely involve the administrative activity ofrevising both [units'] operating license expiration dates.

Based on the forty year design of the plant, coupled with the ongoingsurveillance of plant systems, structures, and components, FPL has concludedthat operation of Turkey Point Units 3 and 4 for the additional yearsrepresenting the time period between issuance of each unit's constructionpermit to issuance of its operating license will not create the possibility ofa new or different kind of accident from any accident previously evaluated.

(3) Operation of the facility in accordance with the proposedamendment[s] would not involve a significant reduction in margin of safety.

The proposed license amendments do not involve physical changes to theplants, their operation, or their procedures. The proposed

changes merelyinvolve the administrative activity of revising both units' operating licenseexpiration dates.

Since Turkey Point Units 3 and 4 were designed and constructed assumingan operating term of at least forty years, the proposed changes to theexpiration terms of the operating licenses will not affect, nor impact, theanalyses, Technical Specifications, or operation of either unit. Since thedesign, operation, maintenance, and surveillance of the units will continue tobe conducted in accordance with the UFSAR, operating licenses, FederalRegulations, and facility Technical Specifications, no reduction in margin ofsafety is involved in implementation of the proposed license amendments.

Based on the forty year design of the plant, coupled with the ongoingsurveillance of plant systems, structures, and components, FPL has concludedthat operation of Turkey Point Units 3 and 4 for the additional yearsrepresenting the time period between issuance of each unit's constructionpermit to issuance of its operating license will not result in a reduction ofany margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on thisreview, it appears that the three standards of 50.92(c) are satisfied.Therefore, the NRC staff proposes to determine that the amendment requestinvolves no significant hazards consideration.

Local Public Document Room location: Florida InternationalUniversity, University Park, Miami, Florida 33199

Attorney for licensee: Harold F. Reis, Esquire, Newman andHoltzer, P.C., 1615 L Street, N.W., Washington, D.C. 20036

NRC Project Director: Herbert N. Berkow

GPU Nuclear Corporation, et al., Docket No. 50-219, Oyster Creek NuclearGenerating Station, Ocean County, New Jersey

Date of amendment request: March 17, 1992

Description of amendment request: The amendment proposes torevise Technical Specification (TS) 4.2.E.5 and related bases. TS 4.2.E.5requires a B-10 enrichment surveillance of the Standby Liquid Control System(SLCS) at each refueling outage with analyses available within 30 days afterstartup. Since the Oyster Creek Nuclear Generating Station procures the sodiumpentaborate pre-enriched (B-10) and the B-10 is very stable, this TS undulyrestricts the performance of this surveillance to a plant shutdown. In orderto allow flexibility in the master surveillance schedule, the licenseeproposes to change the surveillance interval to once every 24 months.

Basis for proposed no significant hazards considerationdetermination: As required by 10 CFR 50.91(a), the licensee has providedits analysis of the issue of no significant hazards consideration, which ispresented below:

GPU Nuclear Corporation has determined that operation of Oyster Creek inaccordance with the proposed amendment will not:

1. Involve a significant increase in the probability or theconsequence of an accident previously evaluated.

The proposed changes reflect the use of preformulated and pre-enrichedsodium pentaborate in the SLCS. Since the sodium pentaborate is independentlyverified for the B-10 enrichment prior to shipment, an enrichment analysis ofthe SLCS tank once every twenty-four months is deemed adequate to ensure thatthe reactor can be brought to a cold shutdown condition from full power steadystate operating conditions at any time in core life independent of control rodsystem capabilities. The probability or the consequences of an accidentpreviously evaluated are unaltered by the proposed change.

2. Create the possibility of a new or different kind of accident fromany previously evaluated.

The proposed changes do not modify the system design for the SLCS nor the manner in which the SLCS would be operated. Since the SLCSretains the capability to shutdown the reactor, this change does not createthe possibility of a new or different kind of accident from any previouslyevaluated.

3. Involve a significant reduction in a margin of safety.

The proposed changes allow the performance of the B-10 enrichmentsurveillance during power operation or plant shutdown. Since the frequency ofthe surveillance stays the same, once per twenty-four months, there is nosignificant reduction in the margin of safety. The SLCS retains the capabilityto bring the reactor to a cold shutdown condition from full power steady stateoperating conditions at any time in core life independent of control rodsystem capabilities.

The NRC staff has reviewed the licensee's analysis and, based on thisreview, it appears that the three standards of 10 CFR 50.92(c) are satisfied.Therefore, the NRC staff proposes to determine that the amendment requestinvolves no significant hazards consideration.

Local Public Document Room location: Ocean County Library,Reference Department, 101 Washington Street, Toms River, New Jersey 08753

Attorney for licensee: Ernest L. Blake, Jr., Esquire. Shaw,Pittman, Potts & Trowbridge, 2300 N Street, NW., Washington, DC 20037.

NRC Project Director: John F. Stolz

Georgia Power Company, Oglethorpe Power Corporation, Municipal ElectricAuthority of Georgia, City of Dalton, Georgia, Docket Nos. 50-321 and 50-366,Edwin I. Hatch Nuclear Plant, Units 1 and 2, Appling County, Georgia

Date of amendment request: February 26, 1991, as supplementedFebruary 4, 1992

Description of amendment request: The proposed amendments wouldmodify various instrumentation surveillance requirements for both Hatch units.Specifically, action statements would be added to allow instrument channels tobe inoperable for the required surveillance testing without initiating morerestrictive actions. Also, the functional test intervals on selectedinstrumentation would be extended, based on NRC-approved methodology. Thus,the following Technical Specification (TS) changes have been proposed:

1. The channel functional test frequency of various emergency corecooling system (ECCS), control rod block, and isolation actuationinstrumentation has been changed from monthly to quarterly. Also, a 6-hourallowable outage time (AOT) for surveillance and a 12-hour AOT for repair havebeen provided in the action statements. This change is consistent with theNRC-approved Boiling Water Reactor Owners' Group (BWROG) TS Improvementmethodology as issued in General Electric (GE) Topical Reports NEDC-30936P-A,NEDC-30851P-A (Supplement 1), NEDC-31677P-A, and GENE-770-06-1.

2. Selected instrumentation tables in the Unit 1 TSs have beenreformatted to more closely resemble the Unit 2 TSs and the existing BWR-4Standard TSs.

3. Changes to other instrumentation channel specifications are alsoproposed to provide a 6-hour AOT in which an instrument can be inoperable sothat TS surveillances can be performed without entering the limiting conditionfor operation (LCO) action statements.

4. The channel functional test frequency of the reactor protection system(RPS) instrumentation surveillances are also proposed to be changed frommonthly to quarterly with a 6-hour AOT for required surveillance testing.

5. Minor editorial changes to various TS pages are also proposed.

Basis for proposed no significant hazards considerationdetermination: As required by 10 CFR 50.91(a), the licensee has providedits analysis of the issue of no significant hazards consideration, which ispresented below:

Proposed Change One:

Georgia Power Company (GPC) has reviewed the proposed change anddetermined it does not involve a significant hazards consideration based onthe following:

1. This change does not involve a significant increase in the probabilityor consequences of an accident. GE Topical Reports NEDC-30936P-A, NEDC-30851P-A (Supplement 1), NEDC-31677P-A and GENE-770-06-1 provide a probabilisticbasis for extending ECCS, rod block and isolation actuation instrumentationsurveillance intervals. These reports have been generically endorsed by theNRC, except for the GENE-770-06-1 report, which is still under NRC review.Adoption of these enhancements will provide a more consistent and correctsystem of ECCS, rod block and isolation actuation surveillances for both PlantHatch units. GPC has reviewed Plant Hatch's specific design and determined theGE Topical Reports envelope the Plant Hatch design. Therefore, the proposedchange does not involve a significant increase in the probability orconsequences of an accident.

2. The possibility of a different kind of accident from any analyzedpreviously is not created by this change, since no change is being made todegrade the design, operation, or maintenance of the plant and a new mode offailure is not created.

3. The proposed change does not involve a significant reduction in amargin of safety, since the referenced GE Topical Reports provide resultsindicating the requested interval extensions will not negatively affect thefunctional capability or reliability of the affected systems. Also, GPC hasdetermined existing setpoint calculations for the affected instrumentationwill not be affected by these changes.

Proposed Change Two:

Georgia Power Company has reviewed the proposed change and determined itdoes not involve a significant hazards consideration based on the following:

1. The change does not involve a significant increase in the probabilityor consequences of an accident, since the change is consistent with the GEBWR-4 STS and the Plant Hatch Unit 2 TS. No physical change to the facility orits operating parameters is being made. This change will clarify theidentification of the isolation actuation instrumentation.

2. The proposed change does not create the possibility of a differentkind of accident from any analyzed previously, since moving theinstrumentation which initiates isolation of the ECCS systems does not degradethe design, operation, or maintenance of the plant and a new mode of failureis not created.

3. Margins of safety are not significantly reduced by the proposedchange, since moving the affected instrumentation of Unit 1 Table 3.2-1 willresult in a more appropriate application of the Action Statements.

Also, the proposed change will result in the Plant Hatch Unit 1 TS ActionStatements being more consistent with the GE BWR-4 STS and the Plant HatchUnit 2 TS. Therefore, incorporating this change will not significantly reduceany margin of safety.

Proposed Change Three

Georgia Power Company has reviewed the proposed change and determined itdoes not involve a significant hazards consideration based on the following:

1. The proposed change does not involve a significant increase in theprobability or consequences of an accident, because the proposed surveillancesare already necessary to comply with TS, and adoption of this change merelyprovides for a reasonable AOT for the surveillance to be performed. Removal ofthis instrumentation from service for surveillance has been shown to have noeffect on the probability of an accident and an insignificant effect on theconsequences of an accident. For these reasons, the response of the plant topreviously evaluated accidents will remain unchanged.

2. The proposed change does not create the possibility of a new ordifferent kind of accident from any previously evaluated, since no change isbeing made to degrade the design, operation, or maintenance of the plant. Nonew modes of failure are created.

3. Margins of safety are not significantly reduced, since the proposedchange maintains reasonable AOTs for the instrumentation to perform designfunctions. In addition, the proposed change provides for conditions ofoperation which will preserve the ability of the system to perform itsintended function even during periods when instrument channels may be out ofservice for maintenance. Therefore, the proposed change does not reduce anymargin of safety.

Proposed Change Four:

Georgia Power Company has reviewed the proposed change and determined itdoes not involve a significant hazards consideration based on the following:

1. The proposed change does not involve a significant increase in theprobability or consequences of an accident, since the change is bounded by theNRC SER for methodology of NEDC-30851P-A. In addition, due to less frequenttesting of the RPS, there are fewer challenges to the safeguards system. Thisconservatively results in a decrease in core damage frequency. Also, since thecumulative effect of instrumentation tests does result in some radiationexposure, an increase in the required surveillance intervals would represent asavings in potential exposure.

2. The possibility of a different kind of accident from any analyzedpreviously is not created, since the RPS functions and reliabilities are notdegraded by this change. Also, no new modes of plant operation are involved.

3. Margins of safety are not significantly reduced, since the change hasbeen evaluated and found acceptable by the NRC and is bounded by the genericSER.

Proposed Change [Five]:

Georgia Power Company has reviewed the proposed change and determined itdoes not involve a significant hazards considerations based on the following:

1. This change does not involve a significant increase in the probabilityor consequences of an accident, since the plant analytical limits will remainunchanged. The changes are only editorial in nature and do not constitute anytechnical change to the TS.

2. The possibility of a different kind of accident from any anlayzedpreviously is not created by this change, since no system function orreliability is being degraded. No new modes of plant operation are involved.

3. The proposed change does not involve a significant reduction in amargin of safety, since the change is editorial in nature. Safety analysisassumptions and equipment performance are not changed in any way.

The NRC staff has reviewed the licensee's analysis and, based on thisreview, it appears that the three standards of 10 CFR 50.92(c) are satisfied.Therefore, the NRC staff proposes to determine that the amendment requestinvolves no significant hazards consideration.

Local Public Document Room location: Appling County PublicLibrary, 301 City Hall Drive, Baxley, Georgia 31513

Attorney for licensee: Ernest L. Blake, Jr., Esquire, Shaw,Pittman, Potts and Trowbridge, 2300 N Street, NW., Washington, DC 20037.

NRC Project Director: David B. Matthews

Georgia Power Company, Oglethorpe Power Corporation, Municipal ElectricAuthority of Georgia, City of Dalton, Georgia, Docket Nos. 50-321 and 50-366,Edwin I. Hatch Nuclear Plant, Units 1 and 2, Appling County, Georgia

Date of amendment request: October 14, 1991

Description of amendment request: The proposed amendments would:

(1) Delete the requirements for the Rod Sequence Control System (RSCS)from the Hatch Units 1 and 2 Technical Specifications (TSs). Banked PositionWithdrawal Sequence (BPWS) rod patterns at low power will be enforced by theRod Worth Minimizer (RWM). New operational constraints will be placed on theRWM.

(2) Revise the Unit 1 RWM TSs to match the Unit 2 TSs.

(3) Make administrative changes associated with the two changes above.

(4) Correct typographical errors and add clarifications to the Bases. Atlow power, the RSCS restricts rod movement to lessen the consequences of apostulated Rod Drop Accident (RDA). The RSCS was designed only for mitigationof the RDA and is required to be active only during low power operation. TheRSCS is a hard-wired redundant backup to the computer controlled RWM. OnDecember 27, 1987, the NRC issued a Safety Evaluation Report approving theelimination of the RSCS while retaining the RWM as a backup to the operatorsfor control rod pattern control. The NRC's SER was in response to Amendment 17of General Electric Topical Report NEDE-24011-P-A, "General Electric StandardApplication for Reactor Fuel."

Section 3.3.B.1 of the Unit 1 TSs referred to an incorrect surveillancerequirement which should be 4.3.A., not 4.3.B.

The Unit 1 Bases 3.3.G.1 incorrectly stated that the RWM minimizes theprobability, instead of the consequences, of an RDA. This statement is beingdeleted to be consistent with the RWM design basis. This change alsoexplicitly identifies BPWS as the correct rod pattern sequence that is to beloaded into the RWM and that BPWS is only required below 10% of RTP (RatedThermal Power). Above that power level, BPWS rod patterns are not required tomitigate the consequences of an RDA; therefore, they do not have to be inputinto the RWM.

Basis for proposed no significant hazards considerationdetermination: As required by 10 CFR 50.91(a), the licensee has providedits analysis of the issue of no significant hazards consideration, parts of which are presented below for the above changes:

1. The proposed amendment does not involve a significantincrease in the probability or consequences of anaccident previously evaluated.

a. The Rod Sequence Control System (RSCS) and Rod Worth Minimizer (RWM)are separate systems and are not required for, nor do they support, the properoperation of any other system. Hence, deleting the RSCS has no significanteffect on the probability of failure of equipment in other systems or withinthe RWM.

The probability of occurrence of an accident is not significantlyaffected by this change. These changes could only affect the consequences ofthe rod drop accident (RDA), since the probability of an RDA is dependent onlyon the control rod drive system and mechanisms themselves, and not in any wayon the RSCS or RWM.

The consequences of an RDA as evaluated in the Hatch Units 1 and 2 FSARs[Final Safety Analysis Reports] will not be significantly effected by thesechanges. Improvements in the RDA analysis methods (e.g., BNL-NUREG 28109,"Thermal Hydraulic Effects on Control Rod Drop Accident in a BWR," October1980) indicated that the peak fuel enthalpies resulting from an RDA aresignificantly lower than previously determined by less refined methodologies.

* * * *

b. Entry into the startup mode to demonstrate RWM operability will beperformed in accordance with approved procedures. Normally, RWM will beoperable and the selection of an erroneous rod, as well as its withdrawal,will be blocked by RWM. If [the] RWM is inoperable, [and] ... the operatorinadvertently withdraw[s] the wrong rod, and should the rod "drop", theconsequences would be bounded by the existing rod drop accident analysis. Notethat this specification already exists in the Unit 2 specifications. Theprobability of a rod drop is unaffected by this change since the assumptionscontained in the original analysis are unchanged (i.e., the rod is fullyinserted in the core, becomes uncoupled, the drive is withdrawn and the rodsubsequently drops).

The current Unit 2 Technical Specifications surveillance for RWM requiresthe BPWS input be verified only once after a sequence is loaded into the RWM.Therefore, the RWM enforces those BPWS rod patterns. ...

Bypassing the RWM is necessary to allow the performance of special testsrequired by other Technical Specification requirements. These tests includescram time testing and shutdown margin testing. This change does not representany additional bypassing of rod pattern controls than already exists under thepresent Technical Specifications.

c. The proposed administrative changes and the correction oftypographical errors and statements do not result in modifications of plantcomponents or systems nor do they result in changes in plant operation.Therefore, there is no significant increase in the probability or consequencesof an accident previously evaluated due to this change.

2. The proposed amendment does not create the possibility of a new ordifferent kind of accident from any accident previously evaluated.

a. Operation of the RSCS and RWM cannot cause or prevent an accident.These systems function to minimize the consequences of an RDA. These eventsare already evaluated in the FSARs, and the effect of this proposed change onthe analyses is discussed in Item 1 above.

Elimination of the RSCS and the changes to the Unit 1 RWM specificationwill have no impact on the operation of any other systems, and therefore wouldnot contribute to a malfunction in any other equipment nor create thepossibility for any accident which has not already been evaluated.

b. Proposed administrative changes, and the correction of typographicalerrors and statements do not result in modifications of plant components nordo they result in changes in plant operation. These changes, therefore, do notcreate the possibility of a new or different kind of accident than previouslyevaluated.

3. The proposed amendment does not involve a significant reduction in themargin of safety.

Elimination of the RSCS will not result in a significant reduction in themargin of safety for the following reasons:

a. An NRC probability study (letter and enclosure fromB. C. Rusche, NRR, to R. Fraley, ACRS, dated June 1, 1976, "Generic Item IIA-2 Control Rod Drop Accident (BWRs)>) has determined that the probability of anRDA resulting in unacceptable consequences was so small that backfit of theRSCS was not needed.

The RSCS is a redundant backup to the RWM. Eliminating the RSCS does noteliminate the control rod pattern monitoring function performed by the RWM.Furthermore, to ensure that the RWM will be in service when required, theproposed RWM Technical Specification allows only one startup per unit percalendar year with the RWM out of service prior to or during the withdrawal ofthe first 12 control rods. If the RWM is out of service below 10% of ratedthermal power, control rod movement and compliance with prescribed BPWScontrol rod patterns will be verified by a second licensed operator ortechnically qualified member of the plant technical staff.

* * * *

GE has provided technical justification for the proposed changes in theTopical Report NEDE-24011-P-A and associated references which justify theacceptability of the proposed change. The NRC has reviewed and accepted the GEanalysis and provided guidelines for licensees to follow when requesting thechanges proposed in NEDE-24011-P-A and approved in the NRC's SER issuedDecember 27, 1987, to J. S. Charnley of General Electric. The proposed changeis consistent with those approved in the NRC's SER and the guidelines setforth therein. Therefore, there is not significant reduction in a margin ofsafety.

The changes being made to make the Unit 1 Technical Specificationsconsistent with the Unit 2 Technical Specifications do not reduce the marginof safety since the affected plant systems are the same and the margins ofsafety are identical for the two units.

b. The proposed administrative changes and the correction oftypographical errors and statements do not result in modifications of plantcomponents or systems nor do they result in changes in plant operation. Thus,this change does not result in a significant reduction in the margin ofsafety.

The NRC staff has reviewed the licensee's analysis and, based on thisreview, it appears that the three standards of 10 CFR 50.92(c) are satisfied.Therefore, the NRC staff proposes to determine that the amendment requestinvolves no significant hazards consideration.

Local Public Document Room location: Appling County PublicLibrary, 301 City Hall Drive, Baxley, Georgia 31513

Attorney for licensee: Ernest L. Blake, Jr., Esquire, Shaw,Pittman, Potts and Trowbridge, 2300 N Street, NW., Washington, DC 20037.

NRC Project Director: David B. Matthews

Niagara Mohawk Power Corporation, Docket No. 50-220, Nine Mile PointNuclear Station Unit No. 1, Oswego County, New York

Date of amendment request: March 10, 1992

Description of amendment request: The proposed amendment wouldddelete the current requirement to demonstrate, by test, that a redundantsystem/component is operable when a system/component is declared inoperable.In lieu of demonstrating (by testing) operability of the redundantsystem/component, the technical specifications (TS) would be changed torequire an administrative check of plant records to verify operability of theredundant system/

component. The TS affected by this proposed change are: 4.1.2(Liquid Poison System), 3.1.3 and 4.1.3 (Emergency Cooling System), 4.1.4(Core Spray System), 4.1.6 (Control Rod Drive Pump Coolant Injection), 4.1.8(High Pressure Coolant Injection (HPCI)), 3.3.7 and 4.3.7 (Containment SpraySystem), and 4.4.4 (Emergency Ventilation System). Conforming changes would bemade to the Bases for TS 4.4.4 and to Definition 1.2. The proposed amendmentwould also make administrative changes to TS 3.1.3, 4.1.3, 3.3.7, and 4.3.7 todelete superseded material and renumber paragraphs.

Basis for proposed no significant hazards considerationdetermination: As required by 10 CFR 50.91(a), the licensee has providedits analysis of the issue of no significant hazards consideration, which ispresented below:

The operation of Nine Mile Point Unit 1 [NMP1], in accordance withthe proposed amendment, will not involve a significant increase in theprobability or consequences of an accident previously evaluated.

The present testing requirements for the liquid poison, core spray,control rod drive pump coolant injection, HPCI, containment spray, emergencycooling, and emergency ventilation systems requires when a component or systembecomes inoperable, its redundant component or system shall be demonstratedoperable immediately and daily thereafter. This represents requirements beyondthose necessary to adequately demonstrate system operability. Other testingrequirements in place not affected by this proposed amendment provide adequateassurance that remaining redundant systems are operable and capable ofperforming their design function. Verifying the operability of redundantsystems/components are administrative checks that will assure theiravailability. The proposed deletion of multiple system testing will conformNMP1 to current BWR plant operating practices. Because changing testingrequirements will not change the probability of accident precursors, thisproposed amendment does not affect the probability of an accident previouslyevaluated. The proposed amendment does not involve a significant increase inthe consequences of an accident previously evaluated because normalsurveillance testing ensures that the operability for the above systems ismaintained.

Furthermore, the removal of the additional surveillance testing from thetechnical specifications would decrease the probability of equipment failurebecause the excessive testing causes unnecessary wear on the safety relatedequipment and unnecessary challenges to the safety systems. Also, theprobability of human error will decrease as a result of removing the excessivetesting. The potential misdirection of the operators' attention frommonitoring and directing plant operations becomes less probable if thistesting is not performed. Removing the excessive scope and frequency ofsurveillance testing, many of which are required on a daily basis during LCO's[limiting conditions for operation], will actually decrease the probability ofequipment failure which could require plant shutdown.

Changes/Deletions were made to 3.1.3 and 4.1.3 to remove references toFuel Cycle 8 and Fuel Cycle 9. NMP1 is currently in Fuel Cycle 11, makingthese references inapplicable. [TS] 4.3.7.e requires checks be made to assurethe "conditions listed in 3.3.7.f are met". Technical Specification 3.3.7.fwas deleted by Amendment No. 105 which was issued on May 16, 1989. Therefore,4.3.7.e is not applicable and will be deleted. [TS] 3.3.7.e also refers to3.3.7.f and will be revised to reflect Amendment No. 105. These changes areadministrative in nature and will not increase the probability or consequencesof an accident.

The operation of Nine Mile Point Unit 1, in accordance with theproposed amendment, will not create the possibility of a new or different kindof accident from any accident previously evaluated.

The change deletes excessive testing requirements for the liquid poison,core spray, control rod drive pump coolant injection, HPCI, containment spray,emergency cooling, and emergency ventilation systems. Verifying theoperability of redundant systems/components are administrative checks thatwill assure their availability. These changes do not introduce any new modesof operation which could initiate a new or different kind of accident.Therefore, the proposed amendment will not introduce any new types ofequipment failure that could cause a new or different kind of accident.

Changes/Deletions were made to 3.1.3 and 4.1.3 to remove references toFuel Cycle 8 and Fuel Cycle 9. NMP1 is currently in Fuel Cycle 11, makingthese references inapplicable. [TS] 4.3.7.e requires checks be made to assurethe "conditions listed in 3.3.7.f are met". Technical Specification 3.3.7.fwas deleted by Amendment No. 105 which was issued on May 16, 1989. Therefore,4.3.7.e is not applicable and will be deleted. [TS] 3.3.7.e also refers to3.3.7.f and will be revised to reflect Amendment No. 105. These changes areadministrative in nature and will not create possibility of a new or differentkind of accident.

The operation of Nine Mile Point Unit 1, in accordance with theproposed amendment, will not involve a significant reduction in a margin ofsafety.

The proposed Technical Specification changes will not reduce theequipment required by the Technical Specifications during an LCO or normaloperation conditions for the liquid poison, core spray, control rod drive pumpcoolant injection, HPCI, containment spray, emergency cooling, and emergencyventilation systems. The testing that will remain in the TechnicalSpecifications provides adequate assurance of system performance. Thereduction in testing will decrease the probability of equipment failure andhuman error. Verifying the operability of redundant system/components areadministrative checks that will assure their availability. Therefore, theproposed changes do not represent a significant reduction in a margin ofsafety.

Changes/Deletions were made to 3.1.3 and 4.1.3 to remove references toFuel Cycle 8 and Fuel Cycle 9. NMP1 is currently in Fuel Cycle 11, makingthese references inapplicable. [TS] 4.3.7.e requires checks be made to assurethe "conditions listed in 3.3.7.f are met". Technical Specification 3.3.7.fwas deleted by Amendment No. 105 which was issued on May 16, 1989. Therefore,4.3.7.e is not applicable and will be deleted. [TS] 3.3.7.e also refers to3.3.7.f and will be revised to reflect Amendment No. 105. These changes areadministrative in nature and will not involve a significant reduction in amargin of safety.

The NRC staff has reviewed the licensee's analysis and, based on thisreview, it appears that the three standards of 50.92(c) are satisfied.Therefore, the NRC staff proposes to determine that the amendment requestinvolves no significant hazards consideration.

Local Public Document Room location: Reference and DocumentsDepartment, Penfield Library, State University of New York, Oswego, New York13126.

Attorney for licensee: Mark J. Wetterhahn, Esquire, Winston &Strawn, 1400 L Street, NW., Washington, DC 20005-3502.

NRC Project Director: Robert A. Capra

Northern States Power Company, Docket Nos. 50-282 and 50-306, PrairieIsland Nuclear Generating Plant Generating Plant, Goodhue County, Minnesota

Date of amendment request: March 20, 1992

Description of amendment request: The proposed amendment wouldrevise the Technical Specifications to reflect the station blackout/electricalsafeguards upgrade (SBO/ESU) project. The SBO/ESU project provides twoadditional emergency diesel generators located in a new building. The twooriginal diesel generators, presently shared by Units 1 and 2 will bededicated to Unit 1 and selected equipment common to both units. The two newdiesel generators will be dedicated to Unit 2 and selected common equipment.Each pair will be capable of providing alternate power to the other unit inevent of a unit blackout. Also as part of the project, the 4160 VAC and 480VAC safeguards electrical distribution systems will be modified, auxiliarysupport systems for the new diesel generators will be installed, and anexisting cooling water pump will be qualified for safeguards classification.The proposed amendments will provide appropriate TS Limiting Conditions for Operation

and Surveillance Requirementsreflecting the SBO/ESU modifications.

Basis for proposed no significant hazards considerationdetermination: As required by 10 CFR 50.91(a), the licensee has providedan analysis of the issue of no significant hazards consideration. The NRCstaff has reviewed the licensee's analysis against the standards of 10 CFR50.92(c). The NRC staff's review is presented below.

(1) Does the proposed change involve a significant increase in theprobability or consequences of an accident previously evaluated?

The SBO/ESU project modifications were analyzed to determine their impacton the transients and design basis accidents evaluated in the Updated SafetyAnalysis Report (USAR) to determine if they (a) changed, degraded or preventedprotective actions described or assumed in the USAR, (b) altered anyassumptions made in evaluating the radiological consequences of an accident,(c) played a direct part in mitigating the radiological consequences of anaccident, or (d) affected any fission product barrier. The analysesdemonstrated that the USAR transient and accident analyses remain valid andbounding. Therefore, the proposed TS change would thus not involve asignificant increase in the probability or consequences of an accidentpreviously evaluated.

(2) Does the proposed amendment create the possibility of a new ordifferent kind of accident from any accident previously evaluated?

The SBP/ESU project modifications were analyzed to determine the types ofaccidents which could result from malfunction of the new and modified systems,structures, and components. Considered in this analysis were the effects ofradiator cooling for the new diesel engines and the use of solid stateprogrammable load sequencers and voltage regulators. The analysis hasdetermined that radiators can perform their diesel engine support function.The new load sequencers will be subjected to a validation and verificationprogram and be appropriately tested. Failure of the programmable solid statevoltage regulators is enveloped by the event of a complete loss of asafeguards train. Therefore, the proposed modifications and new TS do notcreate the possibility of a new or different kind of accident.

(3) Does the proposed amendment involve a significant reduction in amargin of safety?

The SBO/ESU modifications improve the margin of safety for each unit andfor the entire site by providing increased onsite power availability andproviding sources of power which are not dependent on an external coolingwater supply. The new equipment will provide improved voltage regulation andimproved motor control center feeder circuit coordination. Set points and timedelays for the safeguards buses will maintain the existing margin of safetyfor degraded voltage events. Therefore, the proposed amendment does notinvolve a significant reduction in a margin of safety.

Based on this review, it appears that the three standards of 10 CFR50.92(c) are satisfied. Therefore, the NRC staff proposes to determine thatthe amendment request involves no significant hazards consideration.

Local Public Document Room location: Minneapolis Public Library,Technology and Science Department, 300 Nicollet Mall, Minneapolis, Minnesota 55401.

Attorney for licensee: Gerald Charnoff, Esq., Shaw, Pittman,Potts and Trowbridge, 2300 N Street, NW., Washington, DC 20037.

NRC Project Director: Ledyard B. Marsh.

Pacific Gas and Electric Company, Docket Nos. 50-275 and 50-323, DiabloCanyon Nuclear Power Plant, Unit Nos. 1 and 2, San Luis Obispo County, California

Date of amendment requests: December 26, 1991 (Reference LAR 91-08)

Description of amendment requests: The proposed amendments wouldrevise the combined Technical Specifications (TS) for the Diablo CanyonNuclear Power Plant Unit Nos. 1 and 2 to relocate TS Table 3.6-1,"Containment Isolation Valves," to Diablo Canyon Power Plant (DCPP)procedures, which are subject to the change control provisions in theAdministrative Controls Section of the TS. This license amendment request isbeing made in accordance with the guidance provided in Generic Letter (GL) 91-08. The specific TS changes proposed are as follows: (1) TS 1.8, "ContainmentIntegrity," and Surveillance Requirement 4.6.1.1 a. would be revised to allowfor valves to be opened under administrative control as permitted by TS 3.6.3and would delete reference to TS Table 3.6-1. (2) TS 3/4.6.3 would be revisedby adding a note that locked or sealed closed valves may be opened on anintermittent basis under administrative control and removing reference to TSTable 3.6-1. The associated Bases would also be appropriately revised.

Basis for proposed no significant hazards considerationdetermination: As required by 10 CFR 50.91(a), the licensee has providedits analysis of the issue of no significant hazards consideration, which ispresented below:

1. Does the change involve a significant increase in the probability orconsequences of an accident previously evaluated?

The proposed changes simplify the Technical Specifications, meet theregulatory requirements for control of containment isolation, and areconsistent with the recommendations of NUREG 1024 and with GL 91-08. Theprocedural details of the containment isolation valve table have not beenchanged, but only relocated to a different controlling document. The proposedchanges are administrative in nature, should result in improved administrativepractices, and do not affect plant operations.

Therefore, the proposed changes do not involve a significant increase inthe probability or consequences of an accident previously evaluated.

2. Does the change create the possibility of a new or different kind ofaccident from any accident previously evaluated?

The proposed changes are administrative in nature, do not result inphysical alterations or changes to the operation of the plant, and cause nochange in the method by which any safety-related system performs its function.

Therefore, the proposed changes do not create the possibility of a new ordifferent kind of accident from any accident previously evaluated.

3. Does the change involve a significant reduction in a margin of safety?

The administrative change to relocate TS Table 3.6-1 to the DCPP plantprocedures does not alter the basic regulatory requirements and does notaffect any safety analyses. Adequate control of the content of the table isassured by existing administrative procedures.

The proposed relocation of TS Table 3.6-1 does not alter the requirementsfor containment isolation valve operability currently in the TS. The LCO andSurveillance Requirements would beretained in the revised TS. Therefore, theproposed changes would not affect the meaning, application, and function ofthe TS requirements.

Therefore, the proposed changes do not involve a significant reduction ina margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on thisreview, it appears that the three standards of 50.92(c) are satisfied.Therefore, the NRC staff proposes to determine that the amendment requestsinvolve no significant hazards consideration.

Local Public Document Room location: California Polytechnic StateUniversity, Robert E. Kennedy Library, Government Documents and MapsDepartment, San Luis Obispo, California 93407

Attorney for licensee: Richard F. Locke, Esq., Pacific Gas andElectric

Company, P.O. Box 7442, San Francisco, California 94120

NRC Project Director: James E. Gagliardo, Acting

Pacific Gas and Electric Company, Docket Nos. 50-275 and 50-323, DiabloCanyon Nuclear Power Plant, Unit Nos. 1 and 2, San Luis Obispo County,California

Date of amendment requests: February 4, 1992 (LAR 92-02)

Description of amendment requests: The proposed amendments wouldrevise the combined Technical Specifications (TS) for the Diablo CanyonNuclear Power Plant Unit Nos. 1 and 2 to remove cycle-specific informationthat is no longer necessary and correct table notations. The specific TSchanges proposed are as follows: (1) As Diablo Canyon Power Plant, Unit 2,begins cycle 5 operation, several cycle specific TS for Units 1 and 2, willbecome outdated. Proposed administrative changes would be made to TS 3.1.1.1,3.1.1.2, 4.1.2.1 (and 3/4.1.2 Bases), 4.1.2.2, 3.1.2.5, 3.1.2.6, 3.1.3.4,3.4.2.2, 3.5.1, 4.5.2, 3/4.5.4 (and 3/4.5.4 Bases), 3.7.1.6, 3.9.1, and 3.10.1to remove cycle specific information that is no longer necessary.Administrative changes would also be made to TS Tables 2.2-1, 3.2-1, 3.3-1,3.3-2, 3.3-4, 3.3-5, and 4.3-1, that would remove cycle-specific information;and, (2) administrative changes would be made to Table 3.3-5 to correct tablenotations. Table 3.3-5, "Engineered Safety Features Response Times,"provides required response times for various initiating signals. Pacific Gasand Electric (PG&E) intended to change the Table notations as part of LicenseAmendments [LA] 51 and 50. However, due to an administrative error, PG&Eomitted the respective changes. The response time for item 9.a of Table 3.3-5currently does not reference the table notation which includes time delays forassociated diesel generator to start and load. Current Diablo Canyon PowerPlant response time testing for the motor driven auxiliary feedwater pumpconservatively includes these delays. Therefore, PG&E proposes toadministratively add a table notation to include time delays for theassociated diesel generator to start and load.

Basis for proposed no significant hazards considerationdetermination: As required by 10 CFR 50.91(a), the licensee has providedits analysis of the issue of no significant hazards consideration, which ispresented below:

a. Does the change involve a significant increase in the probability orconsequences of an accident previously evaluated?

The TS revisions proposed in this LAR [License Amendment Request] do notchange the operating methodology of DCPP [Diablo Canyon Power Plant]. Theproposed administrative changes delete cycle-specific TS and correct Tablenotations.

Therefore, the proposed changes do not involve a significant increase inthe probability or consequences of an accident previously evaluated.

b. Does the change create the possibility of a new or different kind ofaccident from any accident previously evaluated?

The proposed revisions to the DCPP TS are administrative in nature.Further, the proposed changes would not result in any physical alteration toany plant system, and there would not be a change in the method by which anysafety-related system performs its function.

Therefore, the proposed changes do not create the possibility of a new ordifferent kind of accident from any accident previously evaluated.

c. Does the change involve a significant reduction in a margin of safety?

The proposed administrative changes clarify the DCPP TS by deletingcycle-specific TS and correcting Table notations. In addition, the proposedchanges have no effect on the current operating methodologies or actions whichgovern plant performance.

Therefore, the proposed changes do not involve a significant reduction ina margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on thisreview, it appears that the three standards of 50.92(c) are satisfied.Therefore, the NRC staff proposes to determine that the amendment requestsinvolve no significant hazards consideration.

Local Public Document Room location: California Polytechnic StateUniversity, Robert E. Kennedy Library, Government Documents and MapsDepartment, San Luis Obispo, California 93407

Attorney for licensee: Richard F. Locke, Esq., Pacific Gas andElectric Company, P.O. Box 7442, San Francisco, California 94120

NRC Project Director: James E. Gagliardo, Acting

Power Authority of The State of New York, Docket No. 50-286, Indian PointNuclear Generating Unit No. 3, Westchester County, New York

Date of amendment request: February 6, 1992

Description of amendment request: The licensee requests anamendment to the technical specifications to change the frequency of controlrod drop time testing (specified in Table 4.1-3) and calibration of the analogrod position indication system (specified in Table 4.1-1) to accommodateoperation with a 24-month operating cycle. The licensee intends to begin a 24-month operating cycle starting with cycle nine (scheduled to start in June1992). The proposed changes are in accordance with the guidance provided inGeneric Letter 91-04, "Changes in Technical Specification SurveillanceIntervals to Accommodate a 24-Month Fuel Cycle."

Basis for proposed no significant hazards considerationdetermination: As required by 10 CFR 50.91(a), the licensee has providedits analysis of the issue of no significant hazards consideration, which ispresented below:

(1) Does the proposed license amendment involve a significant increase inthe probability or consequences of an accident previously evaluated?

Response:

The proposed changes do not involve a significant increase in theprobability or consequences of a previously-analyzed accident. The changespropose extending the surveillance intervals for rod drop time testing and rodposition indication calibration. The changes do not involve any physicalchanges to the plant, nor do they alter the way any equipment functions. On-line surveillance and testing assure equipment operability, and also assurethat any control rod misalignment will be detected. A review of significantoccurrence reports from 1985 through mid 1991 indicates that equipmentproblems are being identified and corrected without relying on the once perrefueling outage tests to identify performance problems. [For the controlrods, on-line surveillance and testing includes movement of all control rodson a monthly basis, enabling the detection of any mechanically bound controlrod. For the analog rod position indication system, on-line surveillance andtesting includes a channel check performed each shift and a functional testperformed on a monthly basis, thus ensuring system operability and enablingthe detection of misaligned control rods.]

(2) Does the proposed license amendment create the possibility of a newor different kind of accident from any accident previously evaluated?

Response:

The proposed license amendment does not create the possibility of a newor different kind of accident. The changes propose extending the surveillanceintervals for rod drop time testing and rod position indication calibration.The changes do not involve any physical changes to the plant, nor do theyalter the way any equipment functions. On-line surveillance and testing assureequipment operability, and also assure that any control rod misalignment willbe detected.

(3) Does the proposed amendment involve a significant reduction in amargin of safety?

Response:

The proposed amendment does not involve a significant reduction in amargin of safety. The changes propose extending the surveillance intervals forrod drop time testing and rod position indication calibration. The changes donot involve any physical changes to the plant, nor do they alter the way anyequipment functions. On-line surveillance and testing assure equipmentoperability, and also assure that any control rod misalignment

will bedetected. A review of significant occurrence reports from 1985 through mid1991 indicates that equipment problems are being identified and correctedwithout relying on the once per refueling outage tests to identify performanceproblems. [For the control rods, on-line surveillance and testing includesmovement of all control rods on a monthly basis, enabling the detection ofany mechanically bound control rod. For the analog rod position indicationsystem, on-line surveillance and testing includes a channel check performedeach shift and a functional test performed on a monthly basis, thus ensuringsystem operability and enabling the detection of misaligned control rods.]

The NRC staff has reviewed the licensee's analysis and, based on thisreview, it appears that the three standards of 50.92(c) are satisfied.Therefore, the NRC staff proposes to determine that the amendment requestinvolves no significant hazards consideration.

Local Public Document Room location: White Plains Public Library,100 Martine Avenue, White Plains, New York 10601.

Attorney for licensee: Mr. Charles M. Pratt, 10 Columbus Circle,New York, New York 10019.

NRC Project Director: Robert A. Capra

Saxton Nuclear Experimental Corporation, Docket No. 50-146, SaxtonNuclear Facility, Bedford County, Pennsylvania

Date of amendment request: September 22, 1987, as supplemented onFebruary 25, 1988, April 27, 1988, April 26, 1990, September 6, 1990, January31, 1991, July 16, 1991, March 3, 1992, and March 6, 1992.

Description of amendment request: This proposed amendment wouldrevise the description of the facility site by removing the Control andAuxiliary Building, the Radioactive Waste Disposal Facility, the RefuelingWater Storage Tank, the earthen Filled Drum Storage Area, and the Pipe Tunnel(the outbuildings) from the license. The proposed amendment would make minoreditorial changes to the technical specifications to update the reportingrequirements the licensee must follow in making certain reports to the NRC.The technical specifications would also be amended to reflect a change in themethod used for water analysis for radionuclides employed by the licensee.

Basis for proposed no significant hazards considerationdetermination: The Commission has provided standards for determiningwhether a significant hazards consideration exists as stated in 10 CFR50.92(c). A proposed amendment to an operating license for a facility involvesno significant hazards consideration if operation of the facility inaccordance with the amendment would not: (1) involve a significant increase inthe probability or consequences of an accident previously evaluated; or (2)create the possibility of a new or different kind of accident from anyaccident previously evaluated; or (3) involve a significant reduction in amargin of safety.

The Saxton Nuclear Experimental Corporation (SNEC) has submitted a nosignificant hazards consideration analysis in accordance with the requirementsof 10 CFR 50.91 and 50.92. SNEC's submittal and analysis is summarized asfollows: the proposed amendment to remove the outbuildings from the licensedoes not involve a significant hazards consideration because the areasinvolved have been decontaminated to established limits acceptable fortermination of a facility license. The amount of radionuclides on site is farless than those used for accident analysis of the reactor. Therefore, theremoval of decontaminated buildings from the license does not increase theprobability or consequences of an accident previously evaluated; or create thepossibility of a new or different kind of accident from any accidentpreviously evaluated; or involve a significant reduction in a margin ofsafety. The staff has determined that other proposed changes are admini-strative in nature or are an improvement in counting methodology forradionuclides and therefore, do not increase accident probability orconsequences, do not involve any new or different type of accidents and do notreduce any margin of safety.

The staff has reviewed the licensee's submittal and it's no significanthazards consideration and based on it's review proposes to determine that theproposed changes do not involve a significant hazards considerations.

Local Public Document Room location: Saxton Community Library,911 Church Street, Saxton, Pennsylvania 16678

Attorney for licensee: Ernest L. Blake, Jr. Esquire, Shaw,Pittman, Potts and Trowbridge, 2300 N Street, N.W., Washington, D.C. 20037

NRC Project Director: Seymour H. Weiss

Tennessee Valley Authority, Docket Nos. 50-259, 50-260, and 50-296,Browns Ferry Nuclear Plant, Units 1, 2, and 3, Limestone County, Alabama

Date of amendment request: January 10, 1992 (TS 304)

Description of amendment request: The proposed amendment wouldreplace the present Browns Ferry (BFN) Technical Specifications (TS) for Units2 and 3 with revised operability and surveillance requirements (Section3.9.D/4.9D) for emergency diesel generators (EDG) that syupply power to plantshared systems. Similar requirements will be added to the Unit 1 TechnicalSpecifications. Proposed Limiting Condition for Operation 3.9.D will require applicable EDG power sources to be operable whenever particular trains of theStandby Gas Treatment (SBGT) System and/or the Control Room EmergencyVentilation System (CREVS) are required operable by any Browns Ferry unit'sTechnical Specifications. Proposed changes to Surveillance Requirement 4.9.Dretain the present intent of the Unit 2 and 3 requirements, and clarifiestesting provisions to make them applicable to all three units.

Surveillance Requirement 4.9.C will be added to Unit 1 to clarifyrequirements for cold shutdown operations. Similar requirements are already inplace for Units 2 and 3.

The Bases for 3.9 and 4.9 are revised to describe the changes proposed tothe corresponding technical specifications.

Basis for proposed no significant hazards considerationdetermination: As required by 10 CFR 50.91(a), the licensee has providedits analysis of the issue of no significant hazards consideration, which ispresented below:

1. The proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

The safety design basis of the offsite power supplies is to provideadequate power to start the BFN [Browns Ferry Nuclear Plant] Units, carrycommon plant auxiliary loads and, when necessary, to carry the emergency loadsof equipment in engineered safeguards systems for a unit in a design basisaccident while also supplying auxiliary power requirements. The safetyobjective of the onsite power supplies is to provide a self-contained andhighly reliable source of power to the required loads for the safe shutdownand cooldown of all three units in the event of a loss of offsite power andloss of coolant accident in any one unit.

The safety functions of the onsite and offsite power supplies aremaintained by this change to the Technical Specifications. There are nophysical changes to the plant as a result of this amendment. The presentprovisions that address Unit 3 EDGs [Emergency Diesel Generators] requiredoperable for Unit 2 operation are being revised to address Units 1, 2, and 3diesel power supply requirements for the plant shared systems of SBGT [StandbyGas Treatment] and CREVS [Control Room Emergency Ventilation System]. This TS[Technical Specification] change recognizes the interdependency of

powersupplies, from a unit that is in Cold Shutdown, Refuel, or defueled to a unitthat is operating, for shared plant systems.

The SBGT system provides a means for minimizing the release ofradioactive material from the containment to the environs by filtering andexhausting the air from the three Reactor Building areas and the commonrefueling area and maintaining the areas at a negative pressure duringcontainment isolation conditions. The ability to fulfill the safety functionsof the SBGT system is not changed by this proposed TS amendment. The proposedchange will require that when one or more units require operability of theSBGT system, that corresponding diesel generator emergency power supplies forSBGT Trains A, B, and C be operable. As in present Unit 2 and 3 TSs, theallowed out-of-service time of 30 days is retained for an inoperable powersupply provided the redundant train(s) of equipment and their normal andemergency power supplies are operable. If these conditions are not met, theaffected equipment is declared inoperable.

Each of the three 50 percent capacity trains of the SBGT system issupplied with emergency power from separate emergency power supplies to ensurethat two trains are always available in case of loss of offsite power and theloss of any one train or EDG. Control logic for the SBGT automatically andconcurrently starts all three trains upon receipt of an accident signal (lowreactor water level, high drywell pressure or high activity in a ventilationexhaust duct). Should one train fail, the two remaining trains will continueto provide the required flow.

CREVS consists of two 100 percent capacity trains with each being capableof pressurizing the control room under isolated conditions. The ability tomeet the safety functions of the CREVS is assured by this amendment to theTSs. The intent of present Unit 2 and 3 TSs is retained such that when CREVSis required operable by one or more BFN Units' TSs, the associated dieselgenerator emergency power supplies are also required to be operable.

The proposed changes do not affect accident precursors and, as such, thischange does not involve a significant increase in the probability of anaccident previously evaluated. The proposed changes follow the intent ofpresent provisions in Units 2 and 3 TSs and apply the intent of theseprovisions for plant shared systems to Units 1, 2, and 3. The proposed changesassure that at least the present level of operability for the SBGT system andCREVS is maintained; therefore, the changes do not involve a significantincrease in the consequences of an accident previously evaluated.

2. The proposed change to the technical specifications does not createthe possibility of a new or different kind of accident from any accidentpreviously evaluated.

The proposed changes to the TSs do not involve any physical changes tothe facility. The effect of the proposed changes is to require operability ofthe diesel generator emergency power supplies for the plant shared systems ofSBGT and/or CREVS when these systems are required operable by any unit,regardless of whether another unit is operating, shutdown, in refuel or isdefueled. Since at least the present level of operability is maintained forthese systems and no new modes of operation are introduced, the proposedchange does not create the possibility of a new or different kind of accidentfrom any accident previously evaluated.

3. The proposed change does not involve a significant reduction in amargin of safety.

The present TSs for Units 2 and 3 address the operability of the Unit 3emergency diesel generators required for Unit 2 operation. The proposedchanges use the intent of present requirements to place similar operabilityrequirements on Unit 1/2 emergency diesel generators required for Unit 3operation, and also on Unit 3 emergency diesel generators required for Unit 1operation. Since at least the present level of operability for these systemsis being maintained, the proposed changes do not involve a significantreduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on thisreview, it appears that the three standards of 10 CFR 50.92(c) are satisfied.Therefore, the NRC staff proposes to determine that the amendment requestinvolves no significant hazards consideration.

Local Public Document Room location: Athens Public Library, SouthStreet, Athens, Alabama 35611

Attorney for licensee: General Counsel, Tennessee ValleyAuthority, 400 West Summit Hill Drive, Ell B33, Knoxville, Tennessee 37902

NRC Project Director: Frederick J. Hebdon

Tennessee Valley Authority, Docket Nos. 50-259, 50-260, and 50-296,Browns Ferry Nuclear Plant, Units 1, 2, and 3, Limestone County, Alabama

Date of amendment request: January 14, 1992 (TS 300)

Description of proposed amendment: The proposed amendment wouldadd provisions for core thermal-hydraulic stability in Technical Specification3.5.M/4.5.M, 3.6.F/4.6.F, Technical Specification Bases 3.5.M and 3.6.F/4.6.Ffor Browns Ferry Units 1 and 3. These changes implement the requirements ofNRC Bulletin 88-07, Supplement 1 by defining allowable operating regions forcore flow and power. For Browns Ferry Units 1, 2, and 3 the proposed changesupdate Technical Specification Bases 4.2 to clarify testing provisions forHigh Pressure Coolant Injection (HPCI) and Reactor Core Isolation Cooling(RCIC).

Basis for proposed no significant hazards considerationdetermination: As required by 10 CFR 50.91(a), the license has providedits analysis of the issue of no significant hazards consideration, which ispresented below:

1. The proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

Implementation of the proposed TS [Technical Specification] changedecreases the probability of core thermal-hydraulic oscillations by precludingoperation in regions where instabilities may occur. In addition, the proposedchange will provide additional assurance that core oscillations that do occurwill be suppressed prior to exceeding fuel integrity limits. The proposedchange does not have an adverse safety effect on any affected safety systemnor are the assumptions of the safety analyses affected by restrictingoperation to outside of Regions I and II. [Region I is equivalent to Region Aas described in NRC Bulletin No. 88-07, Supplement 1, December 30, 1988.Region II is equivalent to the combined Regions B and C as described in NRCBulletin No. 88-07, Supplement 1.] Therefore, the proposed change reduces theprobability and consequences of potential core oscillations and does notincrease the probability or consequences of any other previously analyzedevent.

[The proposed change to the Browns Ferry Technical Specification Basesdoes not affect plant operations or equipment. Therefore, the Bases changedoes not increase the probability or consequences of an accident previouslyevaluated.]

2. The proposed change to the technical specifications does not createthe possibility of a new or different kind of accident from any accidentpreviously evaluated.

Restricting operation to outside of Regions I and II does not create anynew failure mechanisms. Plant procedures will preclude normal operation inthose regions. Emergency entry into a restricted region is permitted toprotect plant safety equipment provided that the prescribed actions (i.e.,scram or exit) for the region entered are performed. Operator actions to exitRegion II will be performed in compliance with plant procedures, fuelpreconditioning restrictions, and technical specifications. Therefore, thechanges do not create the possibility of a new or different kind of accidentfrom any previously evaluated.

[The proposed change to the Browns Ferry Technical Specification Basesdoes not affect plant operations or equipment. Therefore, the Bases changedoes not create the possibility of a new or different kind of accident.]

3. The proposed change does not involve a significant reduction in amargin of safety.

The proposed changes are conservative in nature and provide increasedassurance that the fuel safety limit MCPR [Minimum Critical Power Ratio] willnot be violated due to core oscillations. These changes are consistent withNRC and GE [General Electric] guidelines. [NRC guidelines are described by NRCBulletin No. 88-07, Supplement 1, December 30, 1988.] The implementation ofthis technical specification will actually increase this margin of safety at BFN [Browns Ferry Nuclear Plant] by not allowing the plant to operate inRegions I or II. If one of these Regions is

entered, specific operatoractions are required which will place the plant in a more conservative andsafe condition than current BFN Units 1 and 3 Technical Specifications require.

[The proposed change to the Browns Ferry Technical specification Basesdoes not affect plant operations or equipment. Therefore, the Bases changedoes not reduce any safety margin.]

The NRC staff has reviewed the licensee's analysis and, based on thisreview, it appears that the three standards of 10 CFR 50.92(c) are satisfied.Therefore, the NRC staff proposes to determine that the amendment requestinvolves no significant hazards consideration.

Local Public Document Room location: Athens Public Library, SouthStreet, Athens, Alabama 35611

Attorney for licensee: General Counsel, Tennessee ValleyAuthority, 400 West Summit Hill Drive, Ell B33, Knoxville, Tennessee 37902

NRC Project Director: Frederick J. Hebdon

Union Electric Company, Docket No. 50-483, Callaway Plant, Unit 1,Callaway County, Missouri

Date of amendment request: December 4, 1991 and March 11, 1992

Description of amendment request: The proposed amendment revisesTechnical Specifications 3/4.4.4 and 3.4.9.3 to address NRC staffrecommendations provided in Generic Letter 90-06, Resolution of "Power-Operated Relief Valve and Block Valve Reliability," and "Additional Low-Temperature Overpressure Protection for Light-Water Reactors."

Basis for proposed no significant hazards considerationdetermination: As required by 10 CFR 50.91(a), the licensee has providedits analysis of the issue of no significant hazards consideration which ispresented below:

The proposed changes to Technical Specification 3/4.4.4 and its Bases donot involve a significant hazards consideration because operation of CallawayPlant with these changes would not:

1. Involve a significant increase in the probability or consequences ofan accident previously evaluated. No credit is taken for operation of thePORVs in the FSAR Chapter 15 accident analyses if their operation mitigatesthe result of the accident. Turbine trips are evaluated in FSAR Section 15.2.3with and without the pressurizer PORVs. The loss of offsite AC power and lossof normal feedwater analyses (FSAR Sections 15.2.6 and 15.2.7) assume thePORVs are operable only because their operation maximizes the transientpressurizer water volume caused by condensation of steam that would have beenrelieved through the safety valves. The proposed changes to TechnicalSpecification 3/4.4.4 Action a. requires that with the block valve(s) closed,power be maintained to the valve(s) so they can be readily opened from thecontrol room. This change would decrease the amount of time needed to initiatefeed and bleed capabilities in the event an alternative measure to removedecay heat from the reactor core is necessary. The proposed change to TS3/4.4.4 Action d. is a clarification for potential situation where anautomatic signal to the PORVs is inoperable but the PORV is mechanicallyfunctional. Since the PORV is still mechanically functional, it would enhancesafe operation to not close and remove power from the block valve, and allowhe PORV to remain in a condition where it could easily be manually opened fromthe control room if required. This clarification is consistent with theoperability requirements for the PORVs in Modes 1, 2 and 3. Therefore, theproposed changes to Technical Specification 3/4.4.4, and its associated Basesare intended to increase the reliability and availability of the PORVs, and donot involve a significant increase in the probability or consequences of anaccident previously evaluated.

2. Create the possibility of a new or different kind of accident from anypreviously evaluated. There is no new type of accident or malfunction beingcreated and the method and manner of plant operation remains unchanged. Nochange in testing methodology is being proposed, and the equipment is notbeing operated in a new or different manner. Changes incorporate the staffpositions delineated in GL 90-06.

3. Involve a significant reduction in a margin of safety. There are noplant design changes involved and no changes are being made to the safetylimits or safety system settings that would adversely impact plant safety. Theproposed changes to Technical Specification 3/4.4.4 increase the availabilityand reliability of the power-operated relief valves (PORVs) and block valvesto perform their intended function. The changes do not reduce any technicalspecification margin of safety.

The proposed changes to Technical Specification 3.4.9.3 do not involve asignificant hazards consideration because operation of Callaway Plant withthese changes would not:

1. Involve a significant increase in the probability or consequences ofan accident previously evaluated. There is no change being proposed in thecontrol designed to limit the occurrence of an overpressure transient. Theproposed changes to Technical Specification 3.4.9.3 only serve to limit theamount of time the plant is vulnerable to a potentially damaging overpressuretransient with limited overpressure protection available. Therefore, theproposed changes to Technical Specification 3.4.9.3 increases flexibility andavailability of the low-temperature overpressure protection system with aresultant increase in the level of plant safety and do not involve asignificant increase in the probability or consequences of an accidentpreviously evaluated.

2. Create the possibility of a new or different kind of accident from anypreviously evaluated. There is no new type of accident or malfunction beingcreated and the method and manner of plant operation remains unchanged. Thereare no changes being proposed to the level of surveillance required todemonstrate compliance with the LCO. The installed overpressure mitigationdevices will continue to be operated and tested in a manner consistent withtheir design and installation. The proposed changes are intended to enhancethe level of overpressure protection during periods of vulnerability. Changesincorporate the staff positions delineated in GL 90-06.

3. Involve a significant reduction in a margin of safety. There are noplant design changes involved and no changes are being made to the safetylimits or safety system settings that would adversely impact plant safety. Theproposed changes to Technical Specification 3.4.9.3 increases the flexibilityand availability of the overpressure protection system to mitigate a low-temperature overpressurization event. The changes do not reduce any technicalspecifications margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on thisreview, it appears that the three standards of 50.92(c) are satisfied.Therefore, the NRC staff proposes to determine that the amendment requestinvolves no significant hazards consideration.

Local Public Document Room location: Callaway County PublicLibrary, 710 Court Street, Fulton, Missouri 65251.

Attorney for licensee: Gerald Charnoff, Esq., Shaw, Pittman,Potts & Trowbridge, 2300 N Street, N.W., Washington, DC 20037.

NRC Project Director: John N. Hannon

Washington Public Power Supply System, Docket No. 50-397, Nuclear ProjectNo. 2, Benton County, Washington

Date of amendment request: February 21, 1992

Description of amendment request: The proposed amendment revisesthe operability requirements for the safety/relief valves and accident monitoring instrumentation to reflect the additional safety grade positionindication instrumentation installed by the licensee.

Basis for proposed no significant hazards considerationdetermination: As required by 10 CFR 50.91(a), the licensee has providedits analysis of the issue of no significant hazards consideration, which ispresented below:

The Supply System has evaluated this amendment request per 10 CFR 50.92and determined it does not represent a significant hazard because it does not:

1) Involve a significant increase in the probability or consequences ofan accident previously evaluated because no credit is taken for SRV positionindication functioning

in the initiation or mitigation of any analyzedaccident. Although no credit is taken for operator action as a result of SRVposition indication alarm and annunciation, the addition of a second qualifiedinstrument increases the probability that the Operator will be alerted to anopen SRV well before the point that the accident analysis presently recognizes(high suppression pool temperature). Hence, the addition of the stem positionindicator represents a decrease in the probability or consequences of anaccident previously evaluated. The change in REQUIRED NUMBER OF CHANNELS from"2" to "1" for movement into Operational Conditions is offset by enhancedoverall plant safety in the avoidance of forced shutdowns and the exposure topotential transient events in the shutdown and startup maneuvers. Further, theproposed change preserves at least the same level of SRV position indicationreliability as presently provided. Therefore, this change does not involve asignificant increase in the probability or consequences of an accidentpreviously evaluated.

2) Create the possibility of a new or different kind of accident from anyaccident previously evaluated because SRV operation, including the ADSfunction, remains unaffected. No new modes of operation of any equipmentresult due to this change. The addition of the SRV stem position indication isa non-intrusive design that does not affect the operation of the SRV.Therefore, this change does not create the possibility of a new or differentkind of accident from any accident previously evaluated.

3) Involve a significant reduction in a margin of safety because, asdiscussed above, the changes preserve at least the same level of SRV positionindication reliability as presently required by the Technical Specifications.Further, the addition of a second qualified instrument and the flexibilityprovided by this change avoids possible forced shutdown situations (on failureof one instrument). Startup and shutdown maneuvers expose the plant to moretransient conditions than steady state operation does. Hence, avoidance of anunnecessary shutdown enhances the margin of safety. The change in REQUIREDNUMBER OF CHANNELS from "2" to "1" for movement into OperationalConditions is offset by the above enhancement to overall plant safety.Therefore, this change does not involve a significant reduction in the marginof safety.

The NRC staff has reviewed the licensee's analysis and, based on thisreview, it appears that the three standards of 50.92(c) are satisfied.Therefore, the NRC staff proposes to determine that the amendment requestinvolves no significant hazards consideration.

Local Public Document Room location: Richland Public Library, 955Northgate Street, Richland, Washington 99352

Attorney for licensee: Nicholas S. Reynolds, Esq., Winston &Strawn, 1400 L Street, N.W., Washington, D.C. 20005-3502

NRC Project Director: James E. Gagliardo, Acting Director

Yankee Atomic Electric Company, Docket No. 50-029, Yankee Nuclear PowerStation, Franklin County, Massachusetts

Date of amendment request: March 27, 1992

Description of amendment request: The proposed amendment wouldmodify the operating license to remove authorization for reactor poweroperation and replace it with a possession-only license.

Basis for proposed no significant hazards considerationdetermination: As required by 10 CFR 50.92(a), the licensee has providedits analysis of the issue of no significant hazards consideration, which ispresented below:

These proposed modifications to the YNPS Operating License prohibit the power operation of the reactor while still retaining theauthorization to use systems, structures, and components necessary to ensurecontinued public health and safety. Maintenance of the facility in apermanently shutdown condition with the special nuclear material used asreactor fuel restricted from the Vapor Container is addressed by current NRC-approved analyses contained in YNPS's Final Safety Analysis Report. As such,the proposed modifications to the license of YNPS will not:

1. Involve a significant increase in the probability or consequences ofan accident previously evaluated. These modifications do not affect thepresent plant's systems, structures, or components currently associated withthe integrity of the spent fuel and spent fuel pit.

2. Create the possibility of a new or different kind of accident fromany accident previously evaluated. These modifications only restrict thelocation of spent fuel to previously analyzed locations.

3. Involve a significant reduction of safety. These modifications to thelicense do not reduce any plant safety margins.

Based on the discussion above, it is concluded that (1) there isreasonable assurance that the health and safety of the public will not beendangered by the maintenance of YNPS consistent with the proposedmodifications, (2) that activities authorized by the amended facility licensewill continue to be conducted in compliance with the Commission's regulationsand (3) the issuance of this amendment will not be inimical to the commondefense and security or the health and safety of the public. These proposedmodifications have been reviewed by the Plant Operation Review Committee andthe Nuclear Safety Audit and Review Committee.

The NRC staff has reviewed the licensee's analysis, and based on thisreview, it appears that the three standards of 50.92(c) are satisfied.Therefore, the NRC staff proposes to determine that the amendment requestinvolves no significant hazards consideration.

Local Public DocumentRoom location: Greenfield Community College, 1 College Drive, Greenfield,Massachusetts 01301

Attorney for licensee: Thomas Dignan, Esquire, Ropes and Gray,One International Place, Boston, Massachusetts 02110-2624

NRC Project Director: Seymour H. Weiss

Previously Published Notices Of Consideration of Issuance of AmendmentsTo Operating Licenses and Proposed No Significant Hazards ConsiderationDetermination and Opportunity For Hearing

The following notices were previously published as separate individualnotices. The notice content was the same as above. They were published asindividual notices either because time did not allow the Commission to waitfor this biweekly notice or because the action involved exigent circumstances.They are repeated here because the biweekly notice lists all amendments issuedor proposed to be issued involving no significant hazards consideration. Fordetails, see the individual notice in the **Federal Register** on the dayand page cited. This notice does not extend the notice period of the originalnotice.

Carolina Power & Light Company, Docket No. 50-261, H. B. Robinson SteamElectric Plant, Unit No. 2, Darlington County, South Carolina

Date of amendment request: March 5, 1992, as supplemented March6, 1992

Brief description of amendment request: The amendment will add afootnote to Technical Specifications (TS) 3.14.3.2.a and 3.14.4.2.a which willsuspend the requirements of these fire protection TS for the duration of thecontainment Integrated Leak Rate Test and the Structural Integrity Test.

Date of publication of individual notice in **Federal Register**:March 13, 1992 (57 FR 8938)

Expiration date of individual notice: Comment period expiredMarch 30, 1992.

Local Public Document Room location: Hartsville Memorial Library,Home and Fifth Avenues, Hartsville, South Carolina 29535

Illinois Power Company and Soyland Power Cooperative, Inc., Docket No. 50-461, Clinton Power Station, Unit No. 1, DeWitt County, Illinois

Date of application for amendment: February 28, 1992

Brief description of amendment request: The amendment wouldremove redundant wording regarding "Radiation Protection Manager"qualification requirement from Technical Specifications.

Date of individual notice in **Federal Register:** March 5, 1992(57 FR 7943)

Expiration date of individual notice: April 6, 1992

Local Public Document Room location: Vespasian Warner PublicLibrary, 120 West Johnson Street, Clinton, Illinois 61727

TU Electric Company, Docket No. 50-445, Comanche Peak Steam ElectricStation, Unit 1, Somervell County, Texas

Date of amendment request: February 28, 1992

Brief description of amendment request: The proposed amendmentwould remove the Boron Dilution Mitigation System (BDMS) from the TechnicalSpecifications.

Date of individual notice in **Federal Register:** March 13, 1992(57 FR 8941)

Expiration date of individual notice: April 13, 1992

Local Public Document Room location: University of Texas atArlington Library, Government Publications/Maps, 701 South Cooper, P. O. Box19497, Arlington, Texas 76019

Wisconsin Public Service Corporation, Docket No. 50-305, Kewaunee NuclearPower Plant, Kewaunee County, Wisconsin

Date of application for amendment: January 27, 1992

Brief description of amendment request: The amendment would allowuse of Combusion Engineering Nuclear Services sleeves and plugs for tuberepair in the Kewaunee plant steam generators.

Date of individual notice in **Federal Register:** February 14,1992 (57 FR 5495)

Expiration date of individual notice: March 16, 1992

Local Public Document Room location: Government Document Section,Library Learning Center, University of Wisconsin, 2420 Nicolet Drive, GreenBay, Wisconsin 54301.

Notice of Issuance of Amendment to Facility Operating License

During the period since publication of the last biweekly notice, theCommission has issued the following amendments. The Commission has determinedfor each of these amendments that the application complies with the standardsand requirements of the Atomic Energy Act of 1954, as amended (the Act), andthe Commission's rules and regulations. The Commission has made appropriatefindings as required by the Act and the Commission's rules and regulations in10 CFR Chapter I, which are set forth in the license amendment.

Notice of Consideration of Issuance of Amendment to Facility OperatingLicense and Proposed No Significant Hazards Consideration Determination andOpportunity for Hearing in connection with these actions was published in theFederal Register as indicated. No request for a hearing or petitionfor leave to intervene was filed following this notice.

Unless otherwise indicated, the Commission has determined that theseamendments satisfy the criteria for categorical exclusion in accordance with10 CFR 51.22. Therefore, pursuant to 10 CFR 51.22(b), no environmental impactstatement or environmental assessment need be prepared for these amendments.If the Commission has prepared an environmental assessment under the specialcircumstances provision in 10 CFR 51.12(b) and has made a determination basedon that assessment, it is so indicated.

For further details with respect to the action see (1) the applicationsfor amendments, (2) the amendments, and (3) the Commission's related letters,Safety Evaluations and/or Environmental Assessments as indicated. All of theseitems are available for public inspection at the Commission's Public DocumentRoom, the Gelman Building, 2120 L Street, NW., Washington, D.C., and at thelocal public document rooms for the particular facilities involved. A copy ofitems (2) and (3) may be obtained upon request addressed to the U.S. NuclearRegulatory Commission, Washington, DC 20555, Attention: Director, Division ofReactor Projects.

Arizona Public Service Company, et al., Docket Nos. STN 50-528, STN 50-529, and STN 50-530, Palo Verde Nuclear Generating Station, Units 1, 2, and 3,Maricopa County, Arizona

Date of application for amendments: November 20, 1990

Brief description of amendments: These amendments revise theminimum shutdown cooling flowrate for Mode 5 (cold shutdown) and Mode 6(refueling).

Date of issuance: March 31, 1992

Effective date: March 31, 1992

Amendment Nos.: 60, 47, and 33

Facility Operating License Nos. NPF-41, NPF-51, and NPF-74:

Theamendments revised the Technical Specifications.

Date of initial notice in **Federal Register:** December 21, 1990(55 FR 52337) In response, on January 21, 1991, and on January 22, 1991,respectively, Allan L. Mitchell and Linda E. Mitchell, and Myron L. Scott,Barbara S. Bush and the Coalition for Responsible Energy Education ("CREE")filed petitions for leave to intervene and requested a hearing on theamendment. An Atomic Safety and Licensing Board was established, which orderedthat supplemental petitions be filed by April 12, 1991, and scheduled aprehearing conference for May 29, 1991. However, on April 11, 1991,petitioners Allan and Linda Mitchell filed a Notice of Voluntary Withdrawal oftheir petition, and petitioners Scott/Bush/CREE failed to file the requiredsupplemental petition. Accordingly, the proceeding was terminated by orderissued on May 14, 1991.The Commission's related evaluation of the amendments is contained in a SafetyEvaluation dated March 31, 1992.No significant hazards consideration comments received: No.

Local Public Document Room location: Phoenix Public Library, 12East McDowell Road, Phoenix, Arizona 85004

Carolina Power & Light Company, et al., Docket Nos. 50-325 and 50-324,Brunswick Steam Electric Plant, Units 1 and 2, Brunswick County, North Carolina

Date of application for amendments: October 16, 1991

Brief description of amendments: The amendments change theTechnical Specification requirements for the high pressure coolant injectionsystem to be operable when reactor pressure is at or above 150 psig instead ofthe present requirement of 113 psig.

Date of issuance: March 30, 1992

Effective date: March 30, 1992

Amendment Nos.: 157, 188

Facility Operating License Nos. DPR-71 and DPR-62. Amendmentsrevise the Technical Specifications.

Date of initial notice in **Federal Register:** November 13, 1991(56 FR 57691) The Commission's related evaluation of the amendments iscontained in a Safety Evaluation dated March 30, 1992.No significant hazards consideration comments received: No.

Local Public Document Room location: University of North Carolinaat Wilmington, William Madison Randall Library, 601 S. College Road,Wilmington, North Carolina 28403-3297.

Cleveland Electric Illuminating Company, Duquesne Light Company, OhioEdison Company, Pennsylvania Power Company, Toledo Edison Company, Docket No.50-440, Perry Nuclear Power Plant, Unit No.1, Lake County, Ohio

Date of application for amendment: September 13, 1990,supplemented October 16, 1990.

Brief description of amendment: This amendment revised the TS bymaking several administrative corrections related to previous amendments, toapply certain existing surveillance requirements to all appropriateoperational conditions, and to make changes to the Administrative ControlsSection to reflect recent organizational changes. In addition, other minoreditorial corrections to the TS and Bases were made.

Date of issuance: March 20, 1992

Effective date: March 20, 1992

Amendment No. 42

Facility Operating License No. NPF-58.

Date of initial notice in **Federal Register:** June 26, 1991 (56FR 29271)No significant hazards consideration comments received: No

Local Public Document Room location: Perry Public Library, 3753Main Street, Perry, Ohio 44081.

Commonwealth Edison Company, Docket No. STN 50-454, Byron Station, Unit No. 1, Ogle County, IllinoisDocket No. STN 50-456, Braidwood Station, Unit No. 1, Will County, Illinois

Date of application for amendments: October 26, 1990, assupplemented April 23, 1991, November 18, 1991, and February 6, 1992

Brief description of amendments: These amendments were submittedto change a portion of the Technical Specification Tables 2.2-1 and 3.3-4,Reactor Trip System Instrumentation Trip Setpoints and Engineered SafetyFeatures Actuation System Instrumentation Trip Setpoints, respectively. Newsetpoints were specified for the low-low steam generator water level reactortrip and feedwater initiation for the Unit 1 Model D-4 steam generators.Results from the recently completed CECo setpoint study were also incorporatedin determining the new setpoints.

Date of issuance: March 25, 1992

Effective date: March 25, 1992

Amendment Nos.: 45 and 34

Facility Operating License Nos. NPF-37 and NPF-72: The amendmentsrevised the Technical Specifications.

Date of initial notice in **Federal Register:** January 22, 1992(57 FR 2588)The February 6, 1992, submittal provided additional clarifying informationthat did not change the initial proposed no significant hazards considerationdetermination. The Commission's related evaluation of the amendments iscontained in a Safety Evaluation dated March 25, 1992. No significant hazards consideration comments received: No

Local Public Document Room location: For Byron, the Byron PublicLibrary, 109 N. Franklin, P.O. Box 434, Byron, Illinois 61010; for Braidwood,the Wilmington Township Public Library, 201 S. Kankakee Street, Wilmington,Illinois 60481.

Consumers Power Company, Docket No. 50-255, Palisades Plant, Van Buren County, Michigan

Date of application for amendment: November 12, 1991

Brief description of amendment: This amendment removes theschedule for withdrawal of the reactor vessel material specimens from theTechnical Specifications. A revised reactor vessel surveillance coupon removalschedule has been submitted for approval which reflects the actual operatingcycle that will be included in the next revision of the FSAR.

Date of issuance: March 27, 1992

Effective date: March 27, 1992

Amendment No.: 142

Facility Operating License No. DPR-20. The amendment revises theTechnical Specifications.

Date of initial notice in **Federal Register:** February 5, 1992(57 FR 4486) The Commission's related evaluation of the amendment is containedin a Safety Evaluation dated March 27, 1992.No significant hazards consideration comments received: No.

Local Public Document Room location: Van Zoeren Library, HopeCollege, Holland, Michigan 49423.

Consumers Power Company, Docket No. 50-255, Palisades Plant, Van Buren County, Michigan

Date of application for amendment: November 1, 1991

Brief description of amendment: This amendment revises thePalisades Technical Specifications in support of Cycle 10 operations.Additionally, changes are allowed to the upper limit of the boronconcentration for the safety injection tanks and the refueling water storagetank.

Date of issuance: March 27, 1992

Effective date: March 27, 1992

Amendment No.: 143

Facility Operating License No. DPR-20. The amendment revises theTechnical Specifications.

Date of initial notice in **Federal Register:** December 11, 1991(56 FR 64653) The Commission's related evaluation of the amendment iscontained in a Safety Evaluation dated March 27, 1992. No significant hazardsconsideration comments received: No.

Local Public Document Room location: Van Zoeren Library, HopeCollege, Holland, Michigan 49423.

Duke Power Company, Docket Nos. 50-269, 50-270 and 50-287, Oconee NuclearStation, Units 1, 2 and 3, Oconee County, South Carolina

Date of application for amendments: August 12, 1991

Brief description of amendments: The amendments revised TS 3.8.1affecting the radiation monitoring system in the reactor building refuelingarea and the spent fuel storage area. In addition, an editorial correction toTS 3.8.4 revised the character representing the term "less than or equal to"in the k_{eff} value.

Date of issuance: March 31, 1992

Effective date: March 31, 1992

Amendment Nos.: 192, 192, and 189

Facility Operating License Nos. DPR-38, DPR-47 and DPR-55:Amendments revised the Technical Specifications.

Date of initial notice in **Federal Register:** October 16, 1991(56 FR 51923) The Commission's related evaluation of the amendments iscontained in a Safety Evaluation dated March 31, 1992. No significant hazardsconsideration comments received: No

Local Public Document Room location: Oconee County Library, 501West South Broad Street, Walhalla, South Carolina 29691

Duquesne Light Company, et al., Docket Nos. 50-334 and 50-412, Beaver Valley Power Station, Unit Nos. 1 and 2, Shippingport, Pennsylvania

Date of application for amendments: December 21, 1989.

Brief description of amendments: The amendments modify Technical Specification 4.5.1 relating to Emergency Core Cooling Systems (ECCS).Specifically, the amendments delete Surveillance Requirement 4.5.1.d whichrequired periodic verification of automatic opening of the accumulatorisolation valves. Additionally, a typographical error was corrected inSurveillance Requirement 4.5.1.c (Unit 1 only).

Date of issuance: March 25, 1992

Effective date: March 25, 1992

Amendment Nos.: 164 for Unit 1; 44 for Unit 2

Facility Operating License Nos. DPR-66 and NPF-73. Amendmentsrevised the Technical Specifications.

Date of initial notice in **Federal Register:** February 7, 1990(55 FR 4269). The Commission's related evaluation of the amendments iscontained in a Safety Evaluation dated March 25, 1992. No significant hazardsconsideration comments received: No.

Local Public Document Room location: B. F. Jones MemorialLibrary, 663 Franklin Avenue, Aliquippa, Pennsylvania 15001.

Entergy Operations, Inc., Docket Nos. 50-313 and 50-368, Arkansas Nuclear One, Unit Nos. 1 and 2, Pope County, Arkansas

Date of amendment request: October 15, 1991, as supplementedMarch 13, 1992

Brief description of amendments: The amendments revised theOperating Licenses (OLs) and the Technical Specifications (TSs) for ArkansasNuclear One, Units 1 and 2. The changes to the OLs added the NRC's standard OLcondition for Fire Protection. The changes to the TSs relocated the FireProtection requirements from the TSs to the respective Safety Analysis Reportsverbatim. These changes were prepared in accordance with Generic Letters 86-10and 88-12.

Date of issuance: March 31, 1992

Effective date: 90 days from the date of issuance

Amendment Nos.: 158 & 132

Facility Operating License Nos. DPR-51 and NPF-6. Amendmentsrevised the Technical Specifications and licenses.

Date of initial notice in **Federal Register:** November 27, 1991(56 FR 60116). The additional information contained in the supplemental letterdated March 13, 1992, was clarifying in nature and, thus, within the scope of the initial notice and did not affect the staff's proposed no significanthazards consideration determination.The Commission's related evaluation of the amendments is contained in a SafetyEvaluation dated March 31, 1992. No significant hazards consideration commentsreceived: No.

Local Public Document Room location: Tomlinson Library, ArkansasTech University, Russellville, Arkansas 72801

Entergy Operations, Inc., System Energy Resources, Inc., SouthMississippi Electric Power Association, and Mississippi Power & Light Company,Docket No. 50-416, Grand Gulf Nuclear Station, Unit 1, Claiborne County, Mississippi

Date of application for amendment: February 27, 1991

Brief description of amendment: The amendment replaced currentLicense Condition 2.C(36), Attachment 1, Item (c)(4), which requiredimplementation of the requirements of Regulatory Guide (RG) 1.97 for fluxmonitoring prior to startup following the fifth refueling outage. The proposednew license condition allows implementation of the RG 1.97 flux monitoring tobe deferred until after the NRC staff completes its review of the BWR Owners'Group appeal of the NRC staff's RG 1.97 requirements.

Date of issuance: March 23, 1992

Effective date: March 23, 1992Amendment No: 94

Facility Operating License No. NPF-29. Amendment revises thelicense.

Date of initial notice in **Federal Register:** February 19, 1992(57 FR 6037) The Commission's related evaluation of the amendment is containedin a Safety Evaluation dated March 23, 1992. No significant hazardsconsideration comments received: No

Local Public Document Room location: Judge George W. ArmstrongLibrary, Post Office Box 1406, S. Commerce at Washington, Natchez, Mississippi39120.

GPU Nuclear Corporation, Docket No. 50-320, Three Mile Island NuclearStation, Unit No. 2, (TMI-2), Dauphin County, Pennsylvania

Date of application for amendment: June 27, 1989

Brief description of amendment: The amendment modifies Appendix ATechnical Specifications by deleting the TMI-2 Deputy Director position.

Date of issuance: March 2, 1992

Effective date: March 2, 1992

Amendment No.: 41

Facility Operating License No. DPR-73. Amendment revised theTechnical Specifications.

Date of initial notice in **Federal Register.** March 20, 1991(56 FR 11780) The Commission' related evaluation of this amendment iscontained in a Safety Evaluation dated March 2, 1992. No significant hazardsconsideration comments received: No

Local Public Document Room location: Government PublicationsSection, State Library of Pennsylvania, Walnut Street and Commonwealth Avenue,Box 1601, Harrisburg, Pennsylvania 17105.

Houston Lighting & Power Company, City Public Service Board of SanAntonio, Central Power and Light Company, City of Austin, Texas, Docket Nos.50-498 and 50-499, South Texas Project, Units 1 and 2, Matagorda County, Texas

Date of amendment request: April 15, 1991, as supplemented byletter dated January 24, 1992.

Brief description of amendments: The amendments eliminate therequirement for a Power Range, Neutron Flux High Negative Rate Trip (NFRT).

Date of issuance: March 12, 1992

Effective date: March 12, 1992, to be implemented within 30 daysof issuance.

Amendment Nos.: Amendments Nos. 34 and 25

Facility Operating License Nos. NPF-76 and NPF-80. Amendmentrevised the Technical Specifications.

Date of initial notice in **Federal Register:** August 7, 1991(56 FR 37584). The January 24, 1992, supplement provided an implementationdate and did not change the initial no significant hazards considerationdetermination. The Commission's related evaluation of the amendments iscontained in a Safety Evaluation dated March 12, 1992. No significant hazards consideration comments received: No.

Local Public Document Room location: Wharton County JuniorCollege, J. M. Hodges Learning Center, 911 Boling Highway, Wharton, Texas 77488

Indiana Michigan Power Company, Docket Nos. 50-315 and 50-316, Donald C. Cook Nuclear Plant, Unit Nos. 1 and 2, Berrien County, Michigan

Date of application for amendments: February 15, 1991, assupplemented October 8, 1991 and January 14, 1992.

Brief description of amendments: These amendments reviseTechnical Specification 5.6.1.1 "Criticality-Spent Fuel," for both units.Specifically, the current requirement to store Westinghouse fuel assemblieswith fuel enrichments of greater than 3.95 weight percent U-235 and burnup ofless than 5,500 MWD/MTU in Region I of the spent fuel pool in a 3-out-of-4array (one storage cell in each symmetrical array empty) is modified to allowan array of highly reactive fuel "checkerboarded" with adequately burnt fuelwith no empty storage locations. Additionally, minor administrative changes,i.e., page renumbering, correcting Table titles are being made.

Date of issuance: March 12, 1992

Effective date: March 12, 1992

Amendments Nos.: 163 & 147

Facility Operating Licenses Nos. DPR-58 and DPR-74.
Amendmentsrevised the Technical Specifications.

Date of initial notice in **Federal Register:** January 22, 1992(57 FR 2596). By letters dated October 8, 1991, and January 14, 1992, thelicensee submitted additional information that did not change the initialproposed no significant hazards consideration determination. The Commission's related evaluation of the amendments is contained in anEnvironmental Assessment dated March 12, 1992 and in a Safety Evaluation datedMarch 12, 1992. No significant hazards consideration comments received: No.

Local Public Document Room location: Maude Preston PalenskeMemorial Library, 500 Market Street, St. Joseph, Michigan 49085.

Niagara Mohawk Power Corporation, Docket No. 50-410, Nine Mile PointNuclear Station, Unit 2, Scriba, New York

Date of application for amendment: January 29, 1992

Brief description of amendment: The amendment revises TechnicalSpecification Sections 1.31, "Primary Containment Integrity;" 3/4.6.1,"Primary Containment;" 3/4.6.3 "Primary Containment Isolation Valves;"3/4.8.4, Electrical Equipment Protective Devices;" and delete associatedTables 3.6.3-1, 3.8.4.1-1, and 3.8.4.3-1. The removal of the equipment listscontained in the tables allows for administrative control of any future changes to the lists without processing a license amendment. This is inaccordance with Generic Letter 91-08.

Date of issuance: March 24, 1992

Effective date: March 24, 1992

Amendment No.: 37

Facility Operating License No. NPF-69: Amendment revises theTechnical Specifications.

Date of initial notice in **Federal Register:** February 19, 1992(57 FR 6038) The Commission's related evaluation of the amendment iscontained in a Safety Evaluation dated March 24, 1992. No significant hazardsconsideration comments received: No

Local Public Document Room location: Reference and DocumentsDepartment, Penfield Library, State University of New York, Oswego, New York 13126.

Niagara Mohawk Power Corporation, Docket No. 50-410, Nine Mile PointNuclear Station, Unit 2, Scriba, New York

Date of application for amendment: January 17, 1992

Brief description of amendment: The amendment increases thenumber of fuel assemblies allowed out of approved storage locations in thespent fuel pool from one to three. This allows simultaneous use of both fuelpreparation machines.

Date of issuance: March 24, 1992

Effective date: March 24, 1992

Amendment No.: 38

Facility Operating License No. NPF-69: Amendment revises theFacility Operating License.

Date of initial notice in **Federal Register:** February 19, 1992(57 FR 6038) The Commission's related evaluation of the amendment is containedin a Safety Evaluation dated March 24, 1992. No significant hazardsconsideration comments received: No

Northeast Nuclear Energy Company, et al., Docket No. 50-336, Millstone Nuclear Power Station, Unit No. 2, New London County, Connecticut

Date of application for amendment: June 14, 1991

Brief description of amendment: The amendment changes theTechnical Specifications to clarify the requirement for an explicit azimuthalpower tilt correction to the total unrodded integrated radial peaking factor.These changes will allow either full-core or octant-symmetric based incoredetector monitoring system power distribution analyses.

Date of issuance: March 30, 1992

Effective date: March 30, 1992

Amendment No.: 155

Facility Operating License No. DPR-65. Amendment revised theTechnical Specifications.

Date of initial notice in **Federal Register:** July 10, 1991 (56FR 31440) The Commission's related evaluation of the amendment is contained in a SafetyEvaluation dated March 30, 1992. No significant hazards consideration comments received: No.

Local Public Document Room location: Learning Resources Center,Thames Valley State Technical College, 574 New London Turnpike, Norwich,Connecticut 06360.

Omaha Public Power District, Docket No. 50-285, Fort Calhoun Station,Unit No. 1, Washington County, Nebraska

Date of amendment request: November 27, 1991, as supplementedFebruary 12, March 6, and March 10, 1992

Brief description of amendment: The amendment revised theTechnical Specification to change the negative limit for the ModeratorTemperature Coefficient (MTC) of reactivity for the Cycle 14 Reload.

Date of issuance: April 2, 1992

Effective date: April 2, 1992

Amendment No.: 143

Facility Operating License No. DPR-40. Amendment revised theTechnical Specifications.

Date of initial notice in **Federal Register:** January 8, 1992(57 FR 713) The additional information contained in the supplemental lettersdated February 12, March 6, and March 10, 1992, was clarifying in nature and thus, within the scope of the initial notice and did not affect the staff'sproposed no significant hazards consideration determination. The Commission'srelated evaluation of the amendment is contained in a Safety Evaluation datedApril 2, 1992. No significant hazards consideration comments received: No.

Local Public Document Room location: W. Dale Clark Library, 215South 15th Street, Omaha, Nebraska 68102

Portland General Electric Company, et al., Docket No. 50-344, Trojan Nuclear Plant, Columbia County, Oregon

Date of application for amendment: January 25, 1990, and revisedJuly 15, 1991

Brief description of amendment: This amendment removes Table 3.6-1, "Containment Isolation Valves," from the Trojan Technical Specifications(TS) in accordance with guidance in Generic Letter 91-08, "Removal ofComponent Lists from Technical Specifications," dated May 6, 1991. Otherassociated specifications and associated Bases are modified to reflect thechanges. This is a TS line-item improvement.

Date of issuance: March 30, 1992

Effective date: March 30, 1992

Amendment No.: 182

Facility Operating License No. NPF-1: The amendment revised theTechnical Specifications.

Date of initial notice in **Federal Register:** December 26, 1991(56 FR 66926) The Commission's related evaluation of the amendment iscontained in a Safety Evaluation dated March 30, 1992. No significant hazardsconsideration comments received: No.

Local Public Document Room location: Branford Price MillarLibrary, Portland State University, 934 S.W. Harrison Street, P.O. Box 1151,Portland, Oregon 97207

Portland General Electric Company, et al., Docket No. 50-344, Trojan Nuclear Plant, Columbia County, Oregon

Date of application for amenament: April 24, 1991, andsupplemented January 27, 1992, and February 21, 1992

Brief description of amendment: The amendment revises thesurveillance requirement of Trojan Technical Specification (TTS) 3/4.6.1.5,"Containment Systems - Air Temperature." This change would allow theprimary containment average air temperature to be measured at five of eightdesignated locations within the containment.

Date of issuance: March 31, 1992

Effective date: March 31, 1992

Amendment No.: 183

Facility Operating License No. NPF-1: The amendment revised theTechnical Specifications.

Date of initial notice in **Federal Register:** December 11, 1991(56 FR 64661) The Commission's related evaluation of the amendment iscontained in a Safety Evaluation dated March 31, 1992. The supplementalmaterial was provided at the request of the Nuclear Regulatory Commission anddid not affect the proposed determination of no significant hazardsconsideration. No significant hazards consideration comments received: No.

Local Public Document Room location: Branford Price MillarLibrary, Portland State University, 934 S.W. Harrison Street, P.O. Box 1151,Portland, Oregon 97207

Power Authority of The State of New York, Docket No. 50-286, Indian PointNuclear Generating Unit No. 3, Westchester County, New York

Date of application for amendment: August 30, 1991

Brief description of amendment: The amendment revises TechnicalSpecifications Section 3.10 (Control Rod and Power Distribution Limits), andthe Bases to allow the shutdown margin to be a constant value of 1.3 percentdelta k/k. In addition, the amendment also revises Technical Specifications1.0 (Definitions) to add a definition for shutdown margin.

Date of issuance: March 24, 1992

Effective date: March 24, 1992

Amendment No.: 112

Facility Operating License No. DPR-64: Amendment revised theTechnical Specifications.

Date of initial notice in **Federal Register:** October 2, 1991(56 FR 49925) The Commission's related evaluation of the amendment iscontained in a Safety Evaluation dated March 24, 1992. No significant hazardsconsideration comments received: No

Local Public Document Room location: White Plains Public Library,100 Martine Avenue, White Plains, New York, 10610.

Power Authority of The State of New York, Docket No. 50-286, Indian PointNuclear Generating Unit No. 3, Westchester County, New York

Date of application for amendment: June 8, 1990, as supplemented January 22, 1992

Brief description of amendment: The amendment revises TechnicalSpecifications Section 3.5 to reduce the minimum number of operable channelsrequired for the high steam flow safety injection signal to 1 channel persteam line in each of 3 steam lines and changes the associated minimum degree of redundancy to 1 channel per steam line in each of 3 steamlines. The amendment also reformats Table 3.5-3.

Date of issuance: March 30, 1992

Effective date: March 30, 1992

Amendment No.: 113

Facility Operating License No. DPR-64: Amendment revised theTechnical Specifications.

Date of initial notice in **Federal Register:** July 11, 1990 (55FR 28481) The Commission's related evaluation of the amendment is contained ina Safety Evaluation dated March 30, 1992. No significant hazards considerationcomments received: No

Local Public Document Room location: White Plains Public Library,100 Martine Avenue, White Plains, New York, 10610.

Public Service Electric & Gas Company, Docket No. 50-354, Hope CreekGenerating Station, Salem County, New Jersey

Date of application for amendment: October 17, 1991

Brief description of amendment: This amendment revises theExplosive Gas Mixture and the Radioactive Gaseous and Liquid EffluentMonitoring Instrumentation section in the TS. Specifically, TS 3.11.2.6,ACTION b has been revised to agree with the corresponding ACTION b of TS3.3.7.11 and ACTION 124 of Table 3.3.7.11-1.

Date of issuance: April 1, 1992

Effective date: As of date of issuance and shall be implementedwithin sixty days of the date of issuance.

Amendment No.: 49

Facility Operating License No. NPF-57: This amendment revised theTechnical Specifications.

Date of initial notice in **Federal Register:** November 13, 1991(56 FR 57702) The Commission's related evaluation of the amendment iscontained in a Safety Evaluation dated April 1, 1992. No significant hazards consideration comments received: No

Local Public Document Room location: Pennsville Public Library,190 S. Broadway, Pennsville, New Jersey 08070

Sacramento Municipal Utility District, Docket No. 50-312, Rancho SecoNuclear Generating Station, Sacramento County, California

Date of application for amendment: August 13, 1991

Brief description of amendment: This amendment consists ofadministrative changes to the radiological effluent technical specifications(RETS) at Rancho Seco and changes to some technical specifications that nolonger are required at Rancho Seco.

Date of issuance: March 17, 1992

Effective date: March 17, 1992

Amendment No. 118

Facility Operating License No. DPR-54. This amendment revised theTechnical Specifications.

Date of initial notice in **Federal Register:** October 2, 1991(56 FR 49925) The Commission's related evaluation of the amendment iscontained in a Safety Evaluation dated March 17, 1992. No significant hazardsconsideration comments received: No

Local Public Document Room location: Martin Luther King RegionalLibrary, 7340 24th Street Bypass, Sacramento, California 95822

Sacramento Municipal Utility District, Docket No. 50-312, Rancho SecoNuclear Generating Power Station, Sacramento County, California

Date of application for amendment: December 28, 1989 andsupplemented by letters dated October 2, October 28, and November 19, 1991.

Brief description of amendment: Replace Appendix A TechnicalSpecifications in its entirety with a set of Permanently Defueled TechnicalSpecifications.

Date of issuance: March 19, 1992

Effective date: On the date that Amendment No. 117 becomeseffective

Amendment No.: 119

Facility Operating License No. DPR-54. This amendment revised theTechnical Specifications.

Date of initial notice in **Federal Register:** July 25, 1990 (55FR 30311) The Commission's related evaluation of the amendment is contained ina Safety Evaluation dated March 19, 1992. No significant hazards considerationcomments received: No

Local Public Document Room location: Martin Luther King RegionalLibrary, 7340 24th Street Bypass, Sacramento, California 95822

Southern Nuclear Operating Company, Inc., Docket Nos. 50-348 and 50-364, Joseph M. Farley Nuclear Plant, Units 1 and 2, Houston County, Alabama.

Date of amendments request: July 15, 1991, as supplementedSeptember 10, 1991, and January 10, 1992

Brief description of amendments: The amendments change theTechnical Specifications to (1) allow the use of Vantage 5 fuel assemblies inboth units, and (2) allow the removal of the resistance temperature detector(RTD) bypass manifold system in Unit 2 and its replacement with fast responseRTDs in the reactor coolant hot and cold leg piping.

Date of issuance: March 11, 1992

Effective date: March 11, 1992

Amendment Nos.: 92 and 85

Facility Operating License Nos. NPF-2 and NPF-8. Amendmentsrevise the Technical Specifications.

Date of initial notice in **Federal Register:** December 26, 1991(56 FR 66914) and January 31, 1992 (57 FR 3803) The Commission's relatedevaluation of the amendments is contained in a Safety Evaluation dated March11, 1992. No significant hazards consideration comments received: No

Local Public Document Room location: Houston-Love MemorialLibrary, 212 W. Burdeshaw Street, P. O. Box 1369, Dothan, Alabama 36302

Southern Nuclear Operating Company, Inc., Docket Nos. 50-348 and 50-364, Joseph M. Farley Nuclear Plant, Units 1 and 2, Houston County, Alabama.

Date of amendments request: December 11, 1991

Brief description of amendments: The amendments remove the 3.25limitation for three consecutive surveillance intervals from TechnicalSpecification (TS) 4.0.2. It also clarifies the Bases for TS 4.0.2 to reflectthe increased flexibility for scheduling surveillances.

Date of issuance: March 31, 1992

Effective date: March 31, 1992

Amendment Nos.: 93, 86

Facility Operating License Nos. NPF-2 and NPF-8. Amendmentsrevise the Technical Specifications.

Date of initial notice in **Federal Register:** January 22, 1992(57 FR 2600) The Commission's related evaluation of the amendments iscontained in a Safety Evaluation dated March 31, 1992. No significant hazardsconsideration comments received: No

Local Public Document Room location: Houston-Love MemorialLibrary, 212 W. Burdeshaw Street, P. O. Box 1369, Dothan, Alabama 36302

Southern Nuclear Operating Company, Inc., Joseph M. Farley Nuclear Plant, Unit 2, Houston County, Alabama.

Date of application for amendment: February 20, 1992, assupplemented on March 27, 1992

Brief description of amendment: The amendment modifies TechnicalSpecifications 4.4.6.4 and 3.4.7.2, and Bases 3/4.4.6, to allow theimplementation of interim steam generator tube plugging criteria for the tubesupport plate elevations. The amendment also reduces the allowed primary-to-secondary operational leakage from any one steam generator from 500 gallonsper day to 150 gallons per day. The total allowed primary-to-secondaryoperational leakage through all steam generators is reduced from one gallonper minute (1440 gallons per day) to 450 gallons per day. This amendment isonly applicable for the ninth operating cycle.

Date of issuance: April 1, 1992

Effective date: April 1, 1992

Amendment No.: 87

Facility Operating License No. NPF-8. Amendment revises theTechnical Specifications.

Date of initial notice in **Federal Register:** March 2, 1992 (57FR 7405) The March 27, 1992, letter provided clarifying information that didnot change the proposed initial determination of no significant hazardsconsideration as published in the **Federal Register.** The Commission'srelated evaluation of the amendment is contained in a Safety Evaluation datedApril 1, 1992. No significant hazards consideration comments received: No

Local Public Document Room location: Houston-Love MemorialLibrary, 212 W. Burdeshaw Street, P. O. Box 1369, Dothan, Alabama 36302

Tennessee Valley Authority, Docket Nos. 50-328, Sequoyah Nuclear Plant,Unit 2, Hamilton County, Tennessee

Date of application for amendment: May 24, 1991; SupplementedAugust 23, 1991 (TS 91-08 and 91-11).

Brief description of amendment: The change replaces certaincycle-specific parameter limit values in the Technical Specifications withreferences to a Core Operating Limits Report, in accordance with GenericLetter 88-16. In addition, changes to the Bases sections are alsoincorporated.

Date of issuance: March 30, 1992

Effective date: March 30, 1992

Amendment No.: 146

Facility Operating License No. DPR-79: Amendment revises thetechnical specifications.

Date of initial notice in **Federal Register:** July 10, 1991 -56 FR 31443 The Commission's related evaluation of the amendment is containedin a Safety Evaluation dated March 30, 1992. No significant hazardsconsideration comments received:

Local Public Document Room location: Chattanooga-Hamilton CountyLibrary, 1101 Broad Street, Chattanooga, Tennessee 37402

Tennessee Valley Authority, Docket Nos. 50-327 and 50-328, SequoyahNuclear Plant, Units 1 and 2, Hamilton County, Tennessee

Date of application for amendment: August 10, 1999; supplementedMay 18, November 16, 1989; December 21, 1990; March 22, 1991; and November 21,1991.

Brief description of amendment: The amendment incorporateschanges related to low-temperature overpressure protection (LTOP) and poweroperated relief valve (PORV) reliability in accordance with the guidanceprovided in Generic Letter 90-06.

Date of issuance: March 30, 1992

Effective date: March 30, 1992

Amendment No.: 157 - Unit 1; 147 - Unit 2

Facility Operating License Nos. DPR-77 and DPR-79: Amendmentsrevise the Technical Specifications.

Date of initial notice in **Federal Register:** September 7,1988, 53 FR 34612 and renoticed on December 26, 1991, 56 FR 66929. TheCommission's related evaluation of the amendment is contained in a SafetyEvaluation dated March 30, 1992. No significant hazards consideration commentsreceived: No.

Local Public Document Room location: Chattanooga-Hamilton CountyLibrary, 1101 Broad Street, Chattanooga, Tennessee 37402

Tennessee Valley Authority, Docket Nos. 50-327 and 50-328, SequoyahNuclear Plant, Units 1 and 2, Hamilton County, Tennessee

Date of application for amendment: March 31, 1991; supersededSeptember 6, 1991 (TS 90-01)

Brief description of amendment: The amendment incorporates newreactor coolant system pressure-temperature limit curves that are applicableup to 16 effective full power years.

Date of issuance: March 31, 1992

Effective date: March 31, 1992

Amendment No.: 158 - Unit 1; 148 - Unit 2

Facility Operating License Nos. DPR-77 and DPR-79: Amendmentsrevise the technical specifications.

Date of initial notice in **Federal Register:** April 3, 1991 (56FR 13669);

renoticed October 2, 1991 (56 FR 49928). The Commission's relatedevaluation of the amendment is contained in a Safety Evaluation dated March31, 1992. No significant hazards consideration comments received: None

Local Public Document Room location: Chattanooga-Hamilton CountyLibrary,1101 Broad Street, Chattanooga, Tennessee 37402

Union Electric Company, Docket No. 50-483, Callaway Plant, Unit 1,Callaway Count, Missouri

Date of application for amendment: December 16, 1991

Brief description of amendment: The amendment revised TechnicalSpecification 4.5.2.h. and the associated bases to reflect the reanalysis ofacceptable Emergency Core Cooling System (ECCS) subsystem pump flow rates. Inaddition, the specific ECCS subsystem flow balance test requirement wereclarified.

Date of issuance: March 24, 1992

Effective date: March 24, 1992

Amendment No.: 68

Facility Operating License No. NPF-30: Amendment revised theTechnical Specifications.Date of initial notice in **Federal Register:** January 22, 1992 (57 FR2602) The Commission's related evaluation of the amendment is contained in aSafety Evaluation dated March 24, 1992. No significant hazards considerationcomments received: No.

Local Public Document Room location: Callaway County PublicLibrary, 710 Court Street, Fulton, Missouri 65251 and the John M. OlinLibrary, Washington University, Skinker and Lindell Boulevards, St. Louis,Missouri 63130.

Union Electric Company, Docket No. 50-483, Callaway Plant, Unit 1,Callaway County, Missouri

Date of application for amendment: November 22, 1991

Brief description of amendment: The amendment revised TS 3/4.3.2and 3/4.7.6 to take exception to TS 3.0 which prevents entry into anoperational mode unless the conditions for the Limiting Condition forOperation (LOCO) are met. The revision allowed operational mode changes whilecertain control room ventilation TS action statements are in effect.

Date of issuance: March 26, 1992

Effective date: March 26, 1992

Amendment No.: 69

Facility Operating License No. NPF-30. Amendment revised theTechnical Specifications.

Date of initial notice in **Federal Register:** January 22, 1992(57 FR 2602) The Commission's related evaluation of the amendment iscontained in a Safety Evaluation dated March 26, 1992. No significant hazardsconsideration comments received: No.

Local Public Document Room location: Callaway County PublicLibrary, 710 Court Street, Fulton, Missouri 65251.

Virginia Electric and Power Company, Docket Nos. 50-280 and 50-281, SurryPower Station, Unit Nos. 1 and 2, Surry County, Virginia.

Date of application for amendments: January 22, 1992, assupplemented March 9, 1992.

Brief description of amendments: These amendments permit anupgrade of the main control room and emergency switchgear room airconditioning system by allowing the non-outage installation of chilled waterconnections for future installations of two new 50% capacity chillers.

Date of issuance: April 1, 1992

Effective date: April 1, 1992

Amendment Nos. 168 & 167

Facility Operating License Nos. DPR-32 and DPR-37: Amendmentsrevised the Technical Specifications.

Date of initial notice in **Federal Register:** February 19, 1992(57 FR 6041) The March 9, 1992 letter provided supplemental information whichdid not change the initial proposed no significant hazard considerationdetermination. The Commission's related evaluation of the amendment iscontained in a Safety Evaluation dated April 1, 1992. No significant hazardsconsideration comments received: No

Local Public Document Room location: Swem Library, College ofWilliam and Mary, Williamsburg, Virginia 23185

Notice of Issuance Of Amendment To Facility Operating License and FinalDetermination Of No Significant Hazards Consideration and Opportunity forHearing (Exigent Or Emergency Circumstances)

During the period since publication of the last biweekly notice, theCommission has issued the following amendments. The Commission has determinedfor each of these amendments that the application for the amendment complieswith the standards and requirements of the Atomic Energy Act of 1954, asamended (the Act), and the Commission's rules and regulations. The Commissionhas made appropriate findings as required by the Act and the Commission'srules and regulations in 10 CFR Chapter I, which are set forth in the licenseamendment.

Because of exigent or emergency circumstances associated with the datethe amendment was needed, there was not time for the Commission to publish,for public comment before issuance, its usual 30-day Notice of Considerationof Issuance of Amendment and Proposed No Significant Hazards ConsiderationDetermination and Opportunity for a Hearing. For exigent circumstances, theCommission has either issued a **Federal Register** notice providingopportunity for public comment or has used local media to provide notice tothe public in the area surrounding a licensee's facility of the licensee'sapplication and of the Commission's proposed determination of no significanthazards consideration. The Commission has provided a reasonable opportunityfor the public to comment, using its best efforts to make available to thepublic means of communication for the public to respond quickly, and in thecase of telephone comments, the comments have been recorded or transcribed asappropriate and the licensee has been informed of the public comments.

In circumstances where failure to act in a timely way would haveresulted, for example, in derating or shutdown of a nuclear power plant or inprevention of either resumption of operation or of increase in power output upto the plant's licensed power level, the Commission may not have had anopportunity to provide for public comment on its no significant hazardsdetermination. In such case, the license amendment has been issued withoutopportunity for comment. If there has been some time for public comment butless than 30 days, the Commission may provide an opportunity for publiccomment. If comments have been requested, it is so stated. In either event,the State has been consulted by telephone whenever possible.

Under its regulations, the Commission may issue and make an amendmentimmediately effective, notwithstanding the pendency before it of a request fora hearing from any person, in advance of the holding and completion of anyrequired hearing, where it has determined that no significant hazardsconsideration is involved.

The Commission has applied the standards of 10 CFR 50.92 and has made afinal determination that the amendment involves no significant hazardsconsideration. The basis for this determination is contained in the documentsrelated to this action.

Accordingly, the amendments have been issued and madeeffective as indicated.

Unless otherwise indicated, the Commission has determined that theseamendments satisfy the criteria for categorical exclusion in accordance with10 CFR 51.22. Therefore, pursuant to 10 CFR 51.22(b), no environmental impactstatement or environmental assessment need be prepared for these amendments.If the Commission has prepared an environmental assessment under the specialcircumstances provision in 10 CFR 51.12(b) and has made a determination basedon that assessment, it is so indicated.

For further details with respect to the action see (1) the applicationfor amendment, (2) the amendment to Facility Operating License, and (3) theCommission's related letter, Safety Evaluation and/or EnvironmentalAssessment, as indicated. All of these items are available for publicinspection at the Commission's Public Document Room, the Gelman Building, 2120L Street, NW., Washington, DC 20555, and at the local public document room forthe particular facility involved.

A copy of items (2) and (3) may be obtained upon request addressed to theU. S. Nuclear Regulatory Commission, Washington, DC 20555, Attention:Director, Division of Reactor Projects.

The Commission is also offering an opportunity for a hearing with respectto the issuance of the amendment. By May 15, 1992, the licensee may file arequest for a hearing with respect to issuance of the amendment to the subjectfacility operating license and any person whose interest may be affected bythis proceeding and who wishes to participate as a party in the proceedingmust file a written request for a hearing and a petition for leave tointervene. Requests for a hearing and a petition for leave to intervene shallbe filed in accordance with the Commission's "Rules of Practice for DomesticLicensing Proceedings" in 10 CFR Part 2. Interested persons should consult acurrent copy of 10 CFR 2.714 which is available at the Commission's PublicDocument Room, the Gelman Building, 2120 L Street, NW., Washington, DC 20555and at the local public document room for the particular facility involved. Ifa request for a hearing or petition for leave to intervene is filed by theabove date, the Commission or an Atomic Safety and Licensing Board, designatedby the Commission or by the Chairman of the Atomic Safety and Licensing BoardPanel, will rule on the request and/or petition; and the Secretary or thedesignated Atomic Safety and Licensing Board will issue a notice of hearing oran appropriate order.

As required by 10 CFR 2.714, a petition for leave to intervene shall setforth with particularity the interest of the petitioner in the proceeding, andhow that interest may be affected by the results of the proceeding. Thepetition should specifically explain the reasons why intervention should bepermitted with particular reference to the following factors: (1) the natureof the petitioner's right under the Act to be made a party to the proceeding;(2) the nature and extent of the petitioner's property, financial, or otherinterest in the proceeding; and (3) the possible effect of any order which maybe entered in the proceeding on the petitioner's interest. The petition shouldalso identify the specific aspect(s) of the subject matter of the proceedingas to which petitioner wishes to intervene. Any person who has filed apetition for leave to intervene or who has been admitted as a party may amendthe petition without requesting leave of the Board up to fifteen (15) daysprior to the first prehearing conference scheduled in the proceeding, but suchan amended petition must satisfy the specificity requirements described above.

Not later than fifteen (15) days prior to the first prehearing conferencescheduled in the proceeding, a petitioner shall file a supplement to thepetition to intervene which must include a list of the contentions which aresought to be litigated in the matter. Each contention must consist of aspecific statement of the issue of law or fact to be raised or controverted.In addition, the petitioner shall provide a brief explanation of the bases ofthe contention and a concise statement of the alleged facts or expert opinionwhich support the contention and on which the petitioner intends to rely inproving the contention at the hearing. The petitioner must also providereferences to those specific sources and documents of which the petitioner isaware and on which the petitioner intends to rely to establish those facts orexpert opinion. Petitioner must provide sufficient information to show that agenuine dispute exists with the applicant on a material issue of law or fact.Contentions shall be limited to matters within the scope of the amendmentunder consideration. The contention must be one which, if proven, wouldentitle the petitioner to relief. A petitioner who fails to file such asupplement which satisfies these requirements with respect to at least onecontention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject toany limitations in the order granting leave to intervene, and have theopportunity to participate fully in the conduct of the hearing, including theopportunity to present evidence and cross-examine witnesses. Since theCommission has made a final determination that the amendment involves nosignificant hazards consideration, if a hearing is requested, it will not staythe effectiveness of the amendment. Any hearing held would take place whilethe amendment is in effect.

A request for a hearing or a petition for leave to intervene must befiled with the Secretary of the Commission, U.S. Nuclear RegulatoryCommission, Washington, DC 20555, Attention: Docketing and Services Branch, ormay be delivered to the Commission's Public Document Room, the GelmanBuilding, 2120 L Street, NW., Washington, DC 20555, by the above date. Wherepetitions are filed during the last ten (10) days of the notice period, it isrequested that the petitioner promptly so inform the Commission by a toll-freetelephone call to Western Union at 1-(800) 325-6000 (in Missouri 1-(800) 342-6700). The Western Union operator should be given Datagram IdentificationNumber 3737 and the following message addressed to (Project Director):petitioner's name and telephone number, date petition was mailed, plantname, and publication date and page number of this Federal Registernotice. A copy of the petition should also be sent to the Office of theGeneral Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555, andto the attorney for the licensee.

Nontimely filings of petitions for leave to intervene, amended petitions,supplemental petitions and/or requests for hearing will not be entertainedabsent a determination by the Commission, the presiding officer or the AtomicSafety and Licensing Board that the petition and/or request should be grantedbased upon a balancing of the factors specified in 10 CFR 2.714(a)(1)(i)-(v)and 2.714(d).

Baltimore Gas and Electric Company, Docket No. 50-318, Calvert CliffsNuclear Power Plant, Unit No. 2, Calvert County, Maryland

Date of application for amendment: March 25, 1992

Brief description of amendment: The amendment revises TechnicalSpecifications (TS) 4.6.2.1.b.1, 4.6.2.1.b.2, 4.6.2.2.b, and 4.6.3.1.d.2. Theprevious TS identified the specific

test signal to be used when testingcontainment spray valves and pumps, the containment air coolers, and thecontainment iodine filters trains. This revision changes the specific testsignal to indicate that the appropriate Engineered Safety Feature ActuationSystem test signal be used during the required surveillance testing.

Date of issuance: March 27, 1992

Effective date: March 27, 1992

Amendment No.: 148

Facility Operating License No. DPR-69: Amendment revised theTechnical Specifications. Public comments requested as to proposed nosignificant hazards consideration: No. The Commission's related evaluation ofthe amendment, finding of emergency circumstances, and final determination ofno significant hazards consideration are contained in a Safety Evaluationdated March 27, 1992.

Local Public Document Room location: Calvert County Library,Prince Frederick, Maryland 20678.

Attorney for licensee: Mr. Jay E. Silbert, Esquire, Shaw,Pittman, Potts and Trowbridge, 2300 N Street, NW., Washington, DC 20037.

NRC Project Director: Robert A. Capra

Dated at Rockville, Maryland, this 7th day of April 1992.

For the Nuclear Regulatory Commission

Steven A. Varga,

Director, Division of Reactor Projects - I/II,Office of Nuclear Reactor Regulation

[FR Doc. 92-8571 Filed 4-14-92; 8:45 am]

BILLING CODE 7590-01-F

[Docket No. 50-348-CivP, 50-364-CivP and ASLBP No. 91-626-02-CivP]

Alabama Power Co.; (Joseph M. Farley Nuclear Plant, Units 1 and 2); Hearing (Second Phase of Evidentiary Hearing in Civil Penalty Proceeding)

April 9, 1992.

On August 21, 1990, the NRC staff issued an Order Imposing Civil Monetary Penalty to Alabama Power Company (APCo). (55 FR 35,230 (1990)). The order alleges that APCo violated certain of the requirements of 10 CFR 5049, which mandates that nuclear facility electrical equipment important to safety must be qualified to remain functional during the harsh environmental conditions that will exist during and after a design basis accident. The order imposed a fine of $450,000 for the alleged violations. Acting pursuant to 10 CFR 2.205(d), APCo challenged the validity of the staff's order and requested a hearing.

In a January 23, 1992 order, the Licensing Board declared that the evidentiary hearing for this proceeding would be conducted in two phases. During the first phase, the staff and APCo could present direct testimony regarding the validity of the civil penalty order and conduct cross-examination relative to that testimony. The order also established that at the second (and concluding) phase of the hearing, the Board would receive staff rebuttal testimony and APCo surrebuttal testimony and provide the parties with the opportunity to cross-examine the sponsoring witnesses. Thereafter, on February 11–14, 18–21, 1992, the Licensing Board conducted the first phase of the evidentiary hearing.

Please take notice that the Board will conduct the second phase of the evidentiary hearing in this proceeding beginning at 9 a.m. on Monday, May 18, 1992, in the NRC Hearing Room, Fifth Floor, West Tower, East-West Towers Building, 4350 East-West Highway, Bethesda, Maryland. The hearing will continue each weekday (holidays excepted) until concluded.

Bethesda, Maryland, April 9, 1992.

For the Atomic Safety and Licensing Board.

G. Paul Bollwerk, III,

Chairman, Administrative Judge.

[FR Doc. 92-8700 Filed 4-14-92; 8:45 am]

BILLING CODE 7510-01-M

[Docket No. 50-220]

Niagara Mohawk Power Corporation; Consideration of Issuance of Amendment to Facility Operating License, Proposed No Significant Hazards Consideration Determination, and Opportunity for Hearing

The U.S. Nuclear Regulatory Commission (the Commission) is considering issuance of an amendment to Facility Operating License No. DPR-63 issued to Niagara Mohawk Power Corporation (the licensee) for operation of the Nine Mile Nuclear Station, Unit No. 1, located in Oswego County, New York.

The proposed amendment would change sections 3.1.1b(1) and 4.1.1b(1) to allow operation with control rod 22-31 potentially uncoupled for the remainder of cycle 10, which is scheduled to end in September 1992. The proposed amendment specifies conditions under which control rod 22-31 may be operated and modifies existing surveillance requirements to require rod position verficiation by use of neutron instrumentation. Conforming changes would be made to the Bases.

Before issuance of the proposed license amendment, the Commission will have made findings required by the Atomic Energy Act of 1954, as amended (the Act) and the Commission's regulations.

The Commission has made a proposed determination that the amendment request involves no significant hazards consideration. Under the Commission's regulations in 10 CFR 50.92, this means that operation of the facility in accordance with the proposed amendment would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety. As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

The operation of Nine Mile Point Unit 1, in accordance with the proposed amendment, will not involve a significant increase in the probability or consequences of an accident previously evaluated.

The only accident evaluated in the Safety Analysis Report (SAR) which could be impacted by the withdrawal of potentially uncoupled control rod 22-31, is the Control Rod Drop Accident (CRDA). For the CRDA, the faulty control rod is assumed uncoupled from the CRD, (Control Rod Drive) that it sticks in an inserted position, that it does not follow the CRD during withdrawal, and then becomes unstuck and drops to the position of the withdrawn CRD. The other control rods and CRDs are assumed to operate properly and remain coupled for the duration of the accident. For control rod 22-31, because its coupling with the control rod drive cannot be confirmed, it must be assumed that they are uncoupled and could therefore potentially affect the CRDA analysis conclusions unless adequate restrictions and compensatory provisions are instituted to preclude such a possibility.

Above 20% of rated thermal power, a Niagara Mohawk calculation concludes that the consequences of a CRDA are negligible and no constraints on control rod sequences are required. Therefore, pursuant to Niagara Mohawk's calculation, the proposed amendment requires control rod 22-31 to remain inserted and not be withdrawn whenever rated thermal power is below 20%. When at greater than 20% rated thermal power, control rod 22-31 may be withdrawn up to position 46 with the requirement that its position be verified by neutron instrumentation (LPRM or TIP) response as the control rod is withdrawn. Although the current overtravel test data and friction test data indicates that control rod 22-31 is coupled, the adequacy of its coupling cannot be ascertained. The restriction on operation of CRD 22-31 to above position 46 provides additional conservatism that an inadvertent uncoupling by the postulated mechanism whereby the uncoupling rod is installed in the wrong hole in the CRD spud, does not occur.

The existing Technical Specifications prohibit continued operation with any other uncoupled rod withdrawn. During the withdrawal of control rod 22–31 above 20% rated thermal power, neutron instrumentation enables monitoring of the neutron flux in the vicinity of the control rod thereby verifying that the control rod blade tracks with the drive movement. This ensures that the rod is not sticking and separated from the CRD. If such verification cannot be accomplished, the proposed amendment requires that control rod 22–31 be fully inserted and valved out of service.

The compensatory actions of the proposed amendment assuring that the position of the affected control rod 22–31 corresponds to the position of CRD 22–31, in conjunction with the proposed requirement for full insertion of CRD 22–31 when below 20% rated thermal power results in the probability and/or consequences of a CRDA not being increased by the proposed changes.

The operation of Nine Mile Point Unit 1, in accordance with the proposed amendment, will not create the possibility of a new or different kind of accident from any accident previously evaluated.

The possibility of an accident of a different type than previously evaluated has not been created by the proposed amendment. The most severe consequence of an improperly coupled control rod is the CRDA, and as was shown above, the CRDA analysis conclusions are unaffected by the proposed changes. The Niagara Mohawk calculation previously referenced addresses the possibility of equipment damage from scram loadings. Mechanism damage could occur during the declaration phase of the scram stroke. If the rod were indeed uncoupled, it would continue to move upward and the velocity limiter would strike the bottom of the fuel support casting. However, analysis shows that although damage might occur to the velocity limiter or, upon rebound, to the spud and the lock plug, there is insufficient energy to dislodge the fuel support and fuel. Furthermore, the Niagara Mohawk calculation of possible deformation within the coupling assembly does not indicate any adverse scram performance for the rod. The Niagara Mohawk calculation concludes that the scram and insertion performance are not degraded nor are other reactivity control functions adversely affected. In fact, since the rod will be operated at a slightly inserted position for full withdrawal, it should have slightly better scram reactivity insertion characteristics.

With the proposed Technical Specification changes, it is therefore reasonable to conclude that operation with control rod 22–31 potentially uncoupled will not lead to any condition adverse to reactor safety and will therefore not create the possibility of a new or different kind of accident from any accident previously evaluated.

The operation of Nine Mile Point Unit 1, in accordance with the proposed amendment, will not involve a significant reduction in a margin of safety.

The proposed amendment does not involve a significant reduction in the margin of safety as the limiting event associated with an uncoupled control rod is the CRDA and all fuel limits stipulated in that analysis will be met when the compensatory measures included in the Technical Specification changes are implemented.

Therefore, based on the above evaluation, Niagara Mohawk has concluded that these changes do not involve significant hazards consideration.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

The Commission is seeking public comments on this proposed determination. Any comments received within thirty (30) days after the date of publication of this notice will be considered in making any final determination. The Commission will not normally make a final determination unless it receives a request for a hearing.

Written comments may be submitted by mail to the Rules and Directives Review Branch, Division of Freedom of Information and Publications Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555, and should cite the publication date and page number of this **Federal Register** notice. Written comments may also be delivered to room P–223, Phillips Building, 7920 Norfolk Avenue, Bethesda, Maryland, from 7:30 a.m. to 4:15 p.m. Federal workdays. Copies of written comments received may be examined at the NRC Public Document Room, The Gelman Building, 2120 L Street, NW., Washington, DC 20555. The filing of requests for hearing and petitions for leave to intervene is discussed below.

By May 15, 1992, the licensee may file a request for a hearing with respect to issuance of the amendment to the subject facility operating license and any person whose interest may be affected by this proceeding and who wishes to participate as a party in the proceeding must file a written request for a hearing and a petition for leave to intervene. Requests for a hearing and a petition for leave to intervene shall be filed in accordance with the Commission's "Rules of Practice for Domestic Licensing Proceedings" in 10 CFR part 2. Interested persons should consult a current copy of 10 CFR 2.714 which is available of the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC 20555 and at the local public document room located at Reference and Documents Department, Penfield Library, State University of New York, Oswego, New York 13126. If a request for a hearing or petition for leave to intervene is filed by the above date, the Commission or an Atomic Safety and Licensing Board, designated by the Commission or by the Chairman of the Atomic Safety and Licensing Board, will rule on the request and/or petition; and the Secretary or the designated Atomic Safety and Licensing Board will issue a notice of hearing or an appropriate order.

As required by 10 CFR 2.714, a petition for leave to intervene shall set forth with particularity the interest of the petitioner in the proceeding, and how that interest may be affected by the results of the proceeding. The petition should specifically explain the reasons why intervention should be permitted with particular reference to the following factors: (1) The nature of the petitioner's right under the Act to be made party to the proceeding; (2) the nature and extent of the petitioner's property, financial, or other interest in the proceeding; and (3) the possible effect of any order which may be entered in the proceeding on the petitioner's interest. The petition should also identify the specific aspect(s) of the subject matter of the proceeding as to which petitioner wishes to intervene. Any person who has filed a petition for leave to intervene or who has been admitted as a party may amend the petition without requesting leave of the Board up to fifteen (15) days prior to the first prehearing conference scheduled in the proceeding, buth such an amended petition must satisfy the specificity requirements described above.

Not later than fifteen (15) days prior to the first prehearing conference scheduled in the proceeding, a petitioner shall file a supplement to the petition to intervene which must include a list of the contentions which are sought to be litigated in the matter. Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the petitioner shall provide a brief explantion of the bases of the contention and a concise statement of the alleged facts or expert opinion which support the contention and on which the petitioner intends to rely in proving the contention at the hearing. The petitioner must also provide references to those specific sources and documents of which the petitioner is aware and on which the petitioner intends to rely to establish those facts or expert opinion. Petitioner must provide sufficient information to show that a genuine dispute exists with the applicant on a material issue of law or fact. Contentions shall be limited to

matters within the scope of the amendment under consideration. The contention must be one which, if proven, would entitle the petitioner to relief. A petitioner who fails to file such a supplement which satisfies these requirements with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportuity to participate fully in the conduct of the hearing, including the opportunity to present evidence and cross-examine witnesses.

If a hearing is requested, the Commission will make a final determination on the issue of no significant hazards consideration. The final determination will serve to decide when the hearing is held.

If the final determination is that the amendment request involves no significant hazards consideration, the Commission may issue the amendment and make it immediately effective, notwithstanding the request for a hearing. Any hearing held would take place after issuance of the amendment.

If the final determination is that the amendment request involves a significant hazards consideration, any hearing held would take place before the issuance of any amendment.

Normally, the Commission will not issue the amendment until the expiration of the 30-day notice period. However, should circumstances change during the notice period such that failure to act in a timely way would result, for example, in derating or shutdown of the facility, the Commission may issue the license amendment before the expiration of the 30-day notice period, provided that its final determination is that the amendment involves no significant hazards consideration. The final determination will consider all public and State comments received. Should the Commission take this action, it will publish in the **Federal Register** a notice of issuance and provide for opportunity for a hearing after issuance. The Commission expects that the need to take this action will occur very infrequently.

A request for a hearing or a petition for leave to intervene must be filed with the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Docketing and Services Branch, or may be delivered to the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC 20555, by the above date. Where petitions are filed during the last ten (10) days of the notice period, it is requested that the peititioner promptly so inform the Commission by a toll-free telephone call to Western Union at 1—(800) 325–6000 (in Missouri 1—(800) 342–6700). The Western Union operator should be given Datagram Identification Number 3737 and the following message addressed to Robert A. Capra: petitioner's name and telephone number, date petition was mailed, plant name, and publication date and page number of this **Federal Register** notice. A copy of the petition should also be sent to the Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555, and to Mark J. Wetterhahn, Esquire, Winston and Straw, 1400 L Street, NW., Washington, DC 20005–3502, attorney for the licensee.

Nontimely filings of petitions for leave to intervene, amended petitions, supplemental petitions and/or requests for hearing will not be entertained absent a determination by the Commission, the presiding officer or the presiding Atomic Safety and Licensing Board that the petition and/or request should be granted based upon a balancing of the factors specified in 20 CFR 2.714(a)(1)(i)–(v) and 2.714(d).

For further details with respect to this action, see the application for amendment dated March 31, 1992, which is available for public inspection at the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC 20555 and at the local public document room located at Reference and Documents Department, Penfield Library, State University of New York, Oswego, New York 13126.

Dated at Rockville, Maryland, this 7th day of April.

Donald S. Brinkman,

Senior Project Manager, Project Directorate I–1, Division of Reactor Projects—I/II, Office of Nuclear Reactor Regulation.

[FR Doc. 92–8702 Filed 4–14–92; 8:45am]

BILLING CODE 7590–01–M

[Docket No. 030–29626–OM; Re: License Suspension; ASLBP No. 92–653–02–OM]

Piping Specialists, Inc.; (Byproduct Material License No. 24–24826–01 EA 91–136); Memorandum and Order

A public evidentiary hearing will commence April 28, 1992, at the U.S. Court of Appeals, Courtroom 829, 811 Grand Ave., Kansas City, MO 64106. The first session will start at 1:30 p.m. local time; subsequent times will be announced. The hearing should conclude by May 1, 1992.

For the Atomic Safety and Licensing Board, Bethesda, Maryland.

Peter B. Bloch,

Chair.

[FR Doc. 92–8699 Filed 4–14–92; 8:45 am]

BILLING CODE 7590–01–M

[Docket No. 50–333]

Power Authority of the State of New York Withdrawal of Application for Amendment to Facility Operating License

The United States Nuclear Regulatory Commission (the Commission) has granted the request of the Power Authority of the State of New York (the licensee) to withdraw its January 16, 1990, application for proposed amendment to Facility Operating License No. DPR–59 for the James A. FitzPatrick Nuclear Power Plant, located in Oswego County, New York.

The proposed amendment would have revised the containment leak rate testing requirements at the FitzPatrick plant.

The Commission has previously issued a Notice of Consideration of Issuance of Amendment published in the **Federal Register** on March 21, 1990, (55 FR 10545). However, by letter dated March 31, 1992, the licensee withdrew the proposed change.

For further details with respect to this action, see the application for amendment dated January 16, 1990, and the licensee's letter dated March 31, 1992, which withdrew the application for license amendment. The above documents are available for public inspection at the Commission's Public Document Room, 2120 L Street, NW., Washington, DC, and the State University of New York, Penfield Library, Reference and Documents Department, Oswego, New York.

Dated at Rockville, Maryland, this 7th day of April 1992.

For The Nuclear Regulatory Commission.

Brian C. McCabe,

Project Manager, Project Directorate I–1, Division of Reactor Projects—I/II, Office of Nuclear Reactor Regulation.

[FR Doc. 92–8701 Filed 4–14–92; 8:45 am]

BILLING CODE 7590–01–M

OFFICE OF MANAGEMENT AND BUDGET

Budget Rescissions and Deferrals

On April 8, 1992, the President transmitted a Special Message proposing the rescission of FY 1992 budgetary resources. The Special Message transmitted to the House and

Senate contained a Presidential transmittal memorandum, proposed changes in appropriations language, and other technical information. For additional information on this Special Message, contact: OMB: Budget Review and Concepts Division, room 6202, New Executive Office Building, Washington, DC 20503, (202) 395–4632

The rescission proposal would eliminate all remaining FY 1992 funding for the Office of the Federal Inspector (OFI) for the Alaska Natural Gas Transportation System. The OFI was established in 1979 to expedite construction of an Alaskan natural gas pipeline that was to connect through Canadian gas pipelines to gas pipelines in the lower 48 states. This pipeline has never been built, its construction is not expected in the near future, and the FY 1993 Budget proposes no new funding for the OFI. Legislation to abolish the OFI and to dispose of its various functions will be submitted to Congress by the Department of Energy. The amount proposed for rescission is as follows:

Rescission Number	Rescission Proposal	Budgetary resources proposed for rescission (in thousands of dollars)
	Department of Energy:	
	Energy Programs:	
R92–34	Fossil energy research and development (OMB identification code 89–0213–0–1–271)	145

James C. Murr,

Associate Director for Legislative Reference and Administration.

[FR Doc. 92–8725 Filed 4–14–92; 8:45 am]

BILLING CODE 3110–01–F

Office of Federal Procurement Policy

Revision of the Office of Management and Budget (OMB) Circular No. A–119, Extension of Public Comment Period

AGENCY: Office of Federal Procurement Policy (OFPP), OMB.

ACTION: OMB is extending the deadline for public comments on Circular No. A–119, "Federal Participation in the Development and Use of Voluntary Standards." This Circular is being reviewed and revised, as appropriate, to foster greater agency use of voluntary standards, particularly in light of recently stated national objectives, and to increase the effectiveness of the Circular. The revised Circular was originally published for comment on March 20, 1992 with a deadline for receiving comments of April 20, 1992. The deadline is hereby extended to May 20, 1992.

DATES: Comments must be received on or before May 20, 1992.

ADDRESSES: Written comments should be sent to Office of Management and Budget, Office of Federal Procurement Policy, 725 17th Street, NW., Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Chris Jordan, Policy Analyst, Office of Federal Procurement Policy, 725 17th Street, NW., Washington, DC 20503. Telephone (202) 395–6810.

Dated: April 10, 1992.

Allan V. Burman.

Administrator.

[FR Doc. 92–8727 Filed 4–14–92; 8:45 am]

BILLING CODE 3110–01–M

DEPARTMENT OF STATE

[Public Notice 1603]

Delegation of Authority Number 195 Soviet Nuclear Risk Reduction Act

By virtue of the authority vested in me as Secretary of State, including the authority of section 4 of the Act of May 26, 1946 (22 U.S.C. 2658) and Presidential Delegation of Authority dated March 20, 1992, I hereby delegate to the Deputy Secretary of State in his capacity as the Coordinator for U.S. Assistance to the new Independent States the functions vested in the President under section 211(b) of H.R. 3807, as passed by the Senate on November 25, 1991, and referred to in section 108 of the Dire Emergency Supplemental Appropriations and Transfers for Relief From the Effects of Natural Disasters, for other Urgent Needs, and for Incremental Cost of "Operation Desert Shield/Desert Storm" Act of 1992 (Pub. L. 102–229).

Notwithstanding this delegation of authority, the Secretary of State may exercise the functions herein delegated at any time.

This Delegation of Authority shall be published in the **Federal Register**.

Dated: April 3, 1992.

James A. Baker III,

Secretary of State.

[FR Doc. 92–8665 Filed 4–14–92; 8:45 am]

BILLING CODE 4710–10–M

Office of Defense Trade Controls

[Public Notice 1607]

Munitions Exports to A. Rosenthal (PTY) LTD. Located in Namibia and South Africa, and Two of its Employees, Karl Cording and Ian Ace

AGENCY: Department of State.

ACTION: Notice.

SUMMARY: Notice is hereby given that all existing licenses and other approvals, granted pursuant to section 38 of the Arms Export Control Act, that authorize the export or transfer of defense articles or defense services by, for, or to, A. ROSENTHAL (PTY) LTD. [located in Namibia and South Africa], and two of its employees, KARL CORDING and IAN ACE, and any other subsidiaries or associated companies, of defense articles or defense services are suspended. In addition, it shall be the policy of the Department of State to deny all export license applications and other requests for approval involving, directly or indirectly, the above cited entities. This action also precludes the use in connection with such entities of any exemptions from license or other approval included in the ITAR (22 C.F.R. Parts 120–130).

EFFECTIVE DATE: March 19, 1992.

FOR FURTHER INFORMATION CONTACT: Clyde G. Bryant, Jr., Chief, Compliance Analysis Division, Office of Defense Trade Controls, Center for Defense Trade, Bureau of Politico-Military Affairs, Department of State (703: 875–6650).

SUPPLEMENTARY INFORMATION: On March 19, 1992, the U.S. Department of

Commerce revoked all export licenses and other written approvals in which A. ROSENTHAL (PTY) LTD. (with locations in Namibia and South Africa) and two of its employees, Karl Cording and Ian Ace appear or participate in any manner or capacity.

The defendants, A. Rosenthal (PTY) LTD., and two of its employees, Karl Cording and Ian Ace have allegedly violated the Export Administration Regulations (codified at 15 CFR parts 768–799 (1991), issued pursuant to the Export Administration Act of 1979, as amended (50 U.S.C. App. 2410–2420)). All privileges and outstanding licenses in which the defendants appear or participated were revoked by Commerce.

This action has been taken pursuant to section 38(g)(4)(B) of the Arms Export Control Act (AECA), (22 U.S.C. 2778(g)(4)(B)) and § 126.7(a)(1), 126.7(a)(2), and 126.7(a)(6) of the International Traffic in Arms Regulations (22 CFR 126.7(a)(1) (2) & (6)), and the Department of Commerce Order Denying Export Privileges to A. Resenthal (PTY) LTD. [Located in Namibia and South Africa], and two of its employees, Karl Cording and Ian Ace (March 19, 1992). It shall be the policy of the Department of State to deny all export license applications involving, directly or indirectly, A. Rosenthal (PTY) LTD. [located in Numibia and South Africa], Karl Cording and Ian Ace. This action also precludes the use in connection with such entities of any exemptions from license or other approval requirements included in the ITAR (22 CFR parts 120–130). It will remain in effect until the Commerce Department denial order is lifted.

Dated: April 8, 1992.

William B. Robinson,

Director Office of Defense Trade Controls, Department of State.

[FR Doc. 92–8840 Filed 4–14–92; 8:45 am]

BILLING CODE 4710–25–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Proposed Advisory Circular; Airplane Flight Manual

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed advisory circular and requests for comments.

SUMMARY: This notice announces the availability of and requests comments on a proposed advisory circular (AC) concerning the form and content of the approved and unapproved portions of the FAA-approved Airplane Flight Manual (AFM).

DATES: Comments must be received on or before August 3, 1992.

ADDRESSES: Send all comments on the proposed AC to the Federal Aviation Administration, attention: Don Stimson, Flight Test and Systems Branch, ANM–111, Transport Airplane Directorate, Aircraft Certification Service, 1601 Lind Avenue SW., Renton, Washington, 98055–4056. Comments may be inspected at the above address between 7:30 a.m. and 4 p.m. weekdays, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Patricia Siegrist, Regulations Branch, ANM–114, at the above address, telephone (206) 227–2126.

SUPPLEMENTARY INFORMATION

Comments Invited

A copy of the subject AC may be obtained by contacting the person named above under **"FOR FURTHER INFORMATION CONTACT."** Interested persons are invited to comment on the proposed AC by submitting such written data, views, or arguments as they may desire. Commenters must identify the subject of the AC and submit comments in duplicate to the address specified above. All communications received on or before the closing date for comments will be considered by the Transport Standards Staff before issuing the final AC.

Discussion

The primary purpose of the FAA-approved Airplane Flight Manual is to provide an authoritative source of information considered to be necessary for or likely to promote safe operation of an airplane. The AFM provides a variety of information necessary for safe operation of an airplane under normal and emergency conditions. Operating limitations and procedures, and performance and loading information constitute the normal makeup of the AFM. Historically, the AFM was directed to the needs and convenience of the flightcrew. The language and presentations in the manual were in consideration of the user. As the commercial transport aircraft industry continued to develop, becoming more technologically sophisticated and complex, so did the AFM. Because of this complexity, a number of manufacturers have modified the presentation of data available in the AFM to enhance its utility for the flightcrew. In this case, the AFM, rather than being a document directly used by the flightcrew, has developed into a reference document whose presentation is substantially modified to improve utilization in the format of the flightcrew operations manual.

The purpose of the proposed AC is to define the information required in the AFM by the applicable airworthiness regulations and to provide further guidance as to the form and content of both the approved and unapproved portions of the AFM.

Notice of this proposed AC was first published on February 2, 1989. Since that time, the AC has been extensively revised to harmonize with similar advisory material expected to be issued by the European Joint Aviation Authorities (JAA), and to add an appendix addressing computerized versions of the AFM. These revisions are considered to be extensive enough to warrant republication of the AC for public comment. Relevant comments received in response to the prior notice have been retained. Those comments will be considered along with any additional comments received on or before the closing date for comments specified in this notice.

Issued in Renton, Washington, on April 6, 1992.

Donald L. Riggin,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 92–8673 Filed 4–14–92; 8:45 am]

BILLING CODE 4910–13–M

Noise Exposure Map Notice; Receipt of Noise Compatibility Program Update and Request for Review, Baton Rouge Metropolitan Airport, Baton Rouge, LA

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice.

SUMMARY: The Federal Aviation Administration (FAA) announces its determination that the noise exposure maps submitted by the Greater Baton Rouge Airport District for Baton Rouge Metropolitan Airport under the provisions of title I of the Aviation Safety and Noise Abatement Act of 1979 (Pub. L. 96–193) and 14 CFR part 150 are in compliance with applicable requirements. The FAA also announces that it is reviewing a proposed noise compatibility program update that was submitted for Baton Rouge Metropolitan Airport under part 150 in conjunction with the noise exposure maps and that this program will be approved or disapproved on or before September 27, 1992.

EFFECTIVE DATE: The effective date of the FAA's determination on the noise

exposure maps and the start of its review of the associated noise compatibility program is March 31, 1992. The public comment period ends May 30, 1992.

FOR FURTHER INFORMATION CONTACT: Dean A. McMath, Department of Transportation, Federal Aviation Administration, Fort Worth, Texas, 76193–0610, (817) 624–5594. Comments on the proposed noise compatibility program update should also be submitted to the above office.

SUPPLEMENTARY INFORMATION: This notice announces that the FAA finds that the noise exposure maps submitted for Baton Rouge Metropolitan Airport are in compliance with applicable requirements of part 150, effective March 31, 1992. Further, FAA is reviewing a proposed noise compatibility program update for that airport which will be approved or disapproved on or before September 27, 1992. This notice also announces the availability of this program update for public review and comment.

Under section 103 of title I of the Aviation Safety and Noise Abatement Act of 1979 (hereinafter referred to as "the Act"), an airport operator may submit to the FAA noise exposure maps which meet applicable regulations and which depict noncompatible land uses as of the date of submission of such maps, a description of projected aircraft operations, and the ways in which such operations will affect such maps. The Act requires such maps to be developed in consultation with interested and affected parties in the local community, government agencies, and persons using the airport.

An airport operator who has submitted noise exposure maps that are found by the FAA to be in compliance with the requirements of Federal Aviation Regulations (FAR) part 150, promulgated pursuant to title I of the Act, may submit a noise compatibility program for FAA approval which sets forth the measures the operator has taken or proposes for the reduction of existing noncompatible uses and for the prevention of the introduction of additional noncompatible uses.

The Greater Baton Rouge Airport District submitted to the FAA on December 4, 1991 noise exposure maps, descriptions and other documentation which were produced during development of the Airport Noise Compatibility Study Update—1991. It was requested that the FAA review this material as the noise exposure maps, as described in section 103(a)(1) of the Act, and that the noise mitigation measures, to be implemented jointly by the airport and surrounding communities, be approved as a noise compatibility program update under section 104(b) of the Act.

The FAA has completed its review of the noise exposure maps and related descriptions submitted by the Greater Baton Rouge Airport District. The specific maps under consideration are 1991 Noise Exposure Map and 1996 Noise Exposure Map found as attachments to the study in the submission.

The FAA has determined that these maps for Baton Rouge Metropolitan Airport are in compliance with applicable requirements. This determination is effective on March 31, 1992. FAA's determination on an airport operator's noise exposure maps is limited to a finding that the maps were developed in accordance with the procedures contained in appendix A of FAR part 150. Such determination does not constitute approval of the applicant's data, information, or plans, or a commitment to approve a noise compatibility program or to fund the implementation of that program.

If questions arise concerning the precise relationship of specific properties to noise exposure contours depicted on a noise exposure map submitted under section 103 of the Act, it should be noted that the FAA is not involved in any way in determining the relative locations of specific properties with regard to the depicted noise contours, or in interpreting the noise exposure maps to resolve questions concerning, for example, which properties should be covered by the provisions of section 107 of the Act. These functions are inseparable from the ultimate land use control and planning responsibilities of local government. These local responsibilities are not changed in any way under part 150 or through FAA's review of noise exposure maps. Therefore, the responsibility for the detailed overlaying of noise exposure contours onto the map depicting properties on the surface rests exclusively with the airport operator which submitted those maps, or with those public agencies and planning agencies with which consultation is required under section 103 of the Act. The FAA has relied on the certification by the airport operator, under § 150.21 of FAR part 150, that the statutorily required consultation has been accomplished.

The FAA has formally received the noise compatibility program update for the Baton Rouge Metropolitan Airport, also effective on March 31, 1992. Preliminary review of the submitted material indicates that it conforms to the requirements for the submittal of noise compatibility programs, but that further review will be necessary prior to approval or disapproval of the program. The formal review period, limited by law to a maximum of 180 days, will be completed on or before September 27, 1992.

The FAA's detailed evaluation will be conducted under the provisions of 14 CFR 150.33. The primary considerations in the evaluation process are whether the proposed measures may reduce the level of aviation safety, create an undue burden on interstate or foreign commerce, or be reasonably consistent with obtaining the goal of reducing existing noncompatible land uses and preventing the introduction of additional noncompatible land uses.

Interested persons are invited to comment on the proposed program with specific reference to these factors. All comments, other than those properly addressed to local land use authorities, will be considered by the FAA to the extent practicable. Copies of the noise exposure maps, the FAA's evaluation of the maps, and the proposed noise compatibility program are available for examination at the following locations:

Federal Aviation Administration, Airports Division, ASW–600, Fort Worth, Texas 76193–0600.

Greater Baton Rouge Airport District, suite 212, Ryan Terminal Building, Baton Rouge, Louisiana 70807.

Questions may be directed to the individual named above under the heading, **FOR FURTHER INFORMATION CONTACT.**

Issued in Fort Worth, Texas, March 31, 1992.

Donald J. Guffey,

Manager, Arkansas/Louisiana Airport Development Office.

[FR Doc. 92–8677 Filed 4–14–92; 8:45 am]

BILLING CODE 4910–13–M

Receipt of Noise Compatibility Program/Request for Review, Greater Peoria Regional Airport, Peoria, IL

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice.

SUMMARY: The Federal Aviation Administration (FAA) announces that it is reviewing a proposed noise compatibility program (NCP) and that was submitted for Greater Peoria Regional Airport under the provisions of title I of the Aviation Safety and Noise Abatement Act of 1979 (Public Law 96–193) (hereinafter referred to as "the Act") and 14 CFR part 150 by the

Greater Peoria Airport Authority. This program was submitted subsequent to a determination by FAA that associated noise exposure maps submitted under 14 CFR part 150 for Greater Peoria Regional Airport were in compliance with applicable requirements effective April 12, 1991. The proposed noise compatibility program will be approved or disapproved on or before September 23, 1992.

EFFECTIVE DATE: The effective date of the FAA's start of its review of the associated noise compatibility program is March 27, 1992. The public comment period ends May 26, 1992.

FOR FURTHER INFORMATION CONTACT: Jerry R. Mork, Federal Aviation Administration, Great Lakes Region, Chicago Airports District Office, CHI–ADO–630.5, 2300 East Devon Avenue, room 258, Des Plaines, Illinois 60018, (312) 694–7522. Comments on the proposed noise compatibility program should also be submitted to the above office.

SUPPLEMENTARY INFORMATION: This notice announces that the FAA is reviewing a proposed noise compatibility program at Greater Peoria Regional Airport. The program will be approved or disapproved on or before September 23, 1992. This notice also announces the availability of this program for public review and comment.

An airport operator who has submitted noise exposure maps that are found by FAA to be in compliance with the requirements of Federal Aviation Regulations (FAR) part 150, promulgated pursuant to title I of the Act, may submit a noise compatibility program for FAA approval which sets forth the measures the operator has taken or proposes for the reduction of existing noncompatible uses and for the prevention of the introduction of additional noncompatible uses.

The FAA has formally received the Noise Compatibility Program for the Greater Peoria Regional Airport, effective March 27, 1992, after reviewing and accepting the errata and revised exhibits submitted on March 20, 1992. These errata and revised exhibits were submitted in response to our February 12, 1992, review, based on the sponsor's original submittal of May 20, 1991. It was requested that the FAA review this material and that the noise mitigation measure, to be implemented jointly by the airport and surrounding communities, be approved as a noise compatibility program under section 104(b) of the Act. Preliminary review of the submitted material indicates that it conforms to the requirements for the submittal of noise compatibility programs, but that further review will be necessary prior to approval or disapproval of the program. The formal review period, limited by law to a maximum of 180 days, will be completed on or before September 23, 1992.

The FAA's detailed evaluation will be conducted under the provisions of 14 CFR part 150, § 150.33. The primary considerations in the evaluation process are whether the proposed measures may reduce the level of aviation safety, create an undue burden on interstate or foreign commerce, or be reasonably consistent with obtaining the goal of reducing existing noncompatible land uses and preventing the introduction of additional noncompatible land uses.

Interested persons are invited to comment on the proposed program with specific reference to these factors. All comments, other than those properly addressed to local land use authorities, will be considered by the FAA to the extent practicable. Copies of the noise exposure maps, the FAA's evaluation of the maps, and the proposed noise compatibility program are available for examination at the following locations:

Federal Aviation Administration, 800 Independence Avenue, SW., room 617, Washington, DC 20591.

Federal Aviation Administration, Great Lakes Region, Airports Division, 2300 East Devon Avenue, room 269, Des Plaines, Illinois 60018.

Federal Aviation Administration, Chicago Airports Division Office, 2300 East Devon Avenue, room 258, Des Plaines, Illinois 60018.

Greater Peoria Airport Authority, Greater Peoria Regional Airport, 1900 South Maxwell Road, Fourth Floor, Peoria, Illinois 61607.

Division of Aeronautics, Illinois Department of Transportation, Capital Airport, Springfield, Illinois 62706.

Questions may be directed to the individual named above under the heading, **FOR FURTHER INFORMATION CONTACT.**

Issued in Des Plaines, Illinois, March 27, 1992.

Louis H. Yates,

Manager, Chicago Airports District Office, Great Lakes Region.

[FR Doc. 92–8679 Filed 4–14–92; 8:45 am]

BILLING CODE 4910–13–M

Approval of Noise Compatibility Program Portland International Airport Portland, OR

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice

SUMMARY: The Federal Aviation Administration (FAA) announces its findings on the noise compatibility program submitted by the Director of Aviation of the Portland International Airport under the provisions of title I of the Aviation Safety and Noise Abatement Act of 1979 (Pub. L. 96–193) and 14 CFR part 150. These findings are made in recognition of the description of Federal and non-Federal responsibilities in Senate Report No. 96–52 (1980).

On September 16, 1991, the FAA determined that the noise exposure maps submitted by the Director of Aviation under part 150 were in compliance with applicable requirements. On March 4, 1992, the Assistant Administrator for Airports approved the Portland International Airport noise compatibility program. All but two of the program elements were approved.

EFFECTIVE DATE: The effective date of the FAA's approval of the Portland International Airport noise compatibility program is March 4, 1992.

FOR FURTHER INFORMATION CONTACT: Dennis G. Ossenkop; Federal Aviation Administration; Northwest Mountain Region; Airports Division, ANM–611; 1601 Lind Avenue, SW., Renton, WA, 98055–4056. Documents reflecting this FAA action may be reviewed at this same location.

SUPPLEMENTARY INFORMATION: This notice announces that the FAA has given its overall approval to the noise compatibility program for Portland International Airport, effective March 4 1992. Under section 104(a) of the Aviation Safety and Noise Abatement Act of 1979 (hereinafter referred to as "the Act"), an airport operator who has previously submitted a noise exposure map may submit to the FAA a noise compatibility program which sets forth the measures taken or proposed by the airport operator for the reduction of existing noncompatible land uses and prevention of additional noncompatible land uses within the area covered by the noise exposure maps. The Act requires such a program to be developed in consultation with interested and affected parties including the State, local communities, government agencies, airport users, and FAA personnel.

Each airport noise compatibility program developed in accordance with Federal Aviation Regulation (FAR) part 150 is a local program, not a Federal program. The FAA does not substitute its judgment for that of the airport proprietor with respect to which measures should be recommended for

action. The FAA's approval or disapproval of FAR part 150 program recommendations is measured according to the standards expressed in part 150 and the Act and is limited to the following determinations:.

a. The noise compatibility program was developed in accordance with the provisions and procedures of FAR part 150;

b. Program measures are reasonably consistent with achieving the goals of reducing existing noncompatible land uses around the airport and preventing the introduction of additional noncompatible land uses;

c. Program measures would not create an undue burden on interstate or foreign commerce, unjustly discriminate against types or classes of aeronautical uses, violate the terms of airport grant agreements, or intrude into areas preempted by the Federal Government; and

b. Program measures relating to the use of flight procedures can be implemented within the period covered by the program without derogating safety, adversely affecting the efficient use and management of the navigable airspace and air traffic control systems, or adversely affecting other powers and responsibilities of the Administrator prescribed by law.

Specific limitations with respect to FAA's approval of an airport noise compatibility program are delineated in FAR part 150, § 150.5. Approval is not a determination concerning the acceptability of land uses under Federal, State, or local law. Approval does not by itself constitute an FAA implementing action. A request for Federal Action or approval to implement specific noise compatibility measures may be required, and an FAA decision on the request may require an environmental assessment of the proposed action. Approval does not constitute a commitment by the FAA to financially assist in the implementation of the program nor a determination that all measures covered by the program are eligible for grant-in-aid funding from the FAA. Where Federal funding is sought, requests for project grants must be submitted to the FAA Airports District Office in Renton, Washington.

The Port of Portland submitted to the FAA the noise exposure maps, descriptions, and other documentation produced during the noise compatibility planning study conducted at Portland International Airport. The Portland International Airport noise exposure maps were determined by FAA to be in compliance with applicable requirements on September 16, 1991. Notice of this determination was published in the **Federal Register** on October 8, 1991.

The Portland International Airport noise compatibility program contains a proposed noise compatibility program comprised of actions designed for phased implementation by airport management and adjacent jurisdictions from the date of study completion to the year 1995. It was requested that the FAA evaluate and approve this material as a noise compatibility program as described in section 104(b) of the Act. The FAA began its review of the program on September 16, 1991 and was required by a provision of the Act to approve or disapprove the program within 180 days (other than the use of new flight procedures for noise control). Failure to approve or disapprove such program within the 180-day period shall be deemed to be an approval of such program.

The submitted program contained proposed actions for noise mitigation on and off the airport. The FAA completed its review and determined that the procedural and substantive requirements of the Act and FAR part 150 have been satisfied. The overall program, therefore, was approved by the Assistant Administrator for Airports effective March 4, 1992.

Outright approval was granted for all program elements except elements I.A.5 and I.B.7. Program Element I.A.5 was disapproved for purposes of part 150 because it can not be shown that this element provides any noise mitigation benefit. Program Element I.B.7 was disapproved because it can not be shown that construction of high-speed exit taxiways provides any noise mitigation benefit.

These determinations are set forth in detail in a Record of Approval endorsed by the Assistant Administrator for Airports on March 4, 1992. The Record of Approval, as well as other evaluation materials and the documents comprising the submittal, are available for review at the FAA office listed above and at the administrative offices of the Portland International Airport.

Issued in Renton, Washington on March 23, 1992.

David A. Field,

Acting Manager, Airports Division, Northwest Mountain Region.

[FR Doc. 92-8678 Filed 4-14-92; 8:45 am]

BILLING CODE 4910-13-M

Intent To Prepare an Environmental Impact Statement and To Hold Environmental Scoping Meetings for Runway Safety Area Improvements and Taxiway Extension at Tweed-New Haven Airport, New Haven, CT

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of public environmental scoping meetings.

SUMMARY: The Federal Aviation Administration, (FAA) is issuing notice to advise the public that an Environmental Impact Statement (EIS) will be prepared for a proposal by the City of New Haven to construct runway safety area improvements at the southerly end of Runway 02–20 and to extend the existing parallel taxiway to the southerly end of this runway. To ensure that all significant issues related to the proposed action are identified, public scoping meetings will be held.

FOR FURTHER INFORMATION CONTACT: John Silva, Manager, Environmental Programs, Airports Division, New England Region, Federal Aviation Administration, 12 New England Executive Park, Burlington, Massachusetts 01803. Telephone number: 617–273–7060.

SUPPLEMENTARY INFORMATION: On March 16, 1992, FAA completed an Environmental Assessment (EA) of a proposed reconstruction and extension of the parallel taxiway serving Runway 02–20 (Taxiway B) and the construction of runway safety area improvements at the southerly end of Runway 02–20. (A runway safety area at the southerly end of Runway 02–20 is an area 1,000 feet long and 500 feet wide, prepared or suitable for reducing the risk of damage to airplanes in the event of an undershoot, overshoot, or excursion from the runway). The EA concluded that an EIS needed to be prepared because of the potential for significant adverse environmental effect, primarily to wetlands and floodplain areas.

Comments and suggestions are invited from Federal, State, and local agencies, and other interested parties, in order to ensure that a full range of issues related to the proposed projects are identified and addressed in the scope of work for the EIS. Copies of the EA may be obtained by contacting FAA at the above address or telephone number. Comments and suggestions may be mailed to the same address.

Public scoping meetings

In order to provide public input, a scoping meeting for Federal, State, and local agencies will be held on Thursday,

May 28, 1992, at 1:30 p.m., at Robinson Aviation, Tweed-New Haven Airport, 50 Thompson Avenue, East Haven, Connecticut. An additional meeting to receive public input will be held on Thursday, May 28, 1992, at 7:30 p.m., at City of New Haven, Hall of Records, 200 Orange Street, 4th Floor Caucus Room, New Haven, Connecticut. These meetings will be preceded by a field tour of the project area at 10 a.m. on the same day. The tour will commence from the entrance to the Tweed-New Haven terminal building, Burr Street, New Haven, Connecticut. The walking surface will be turf and crushed stone through a coastal marsh. Federal, State, and local agency representatives are encouraged to attend all three events. Additional information may be obtained by contacting FAA at the above address or telephone number.

Issued in Burlington, Massachusetts, on April 3, 1992.

Vincent A. Scarano,

Manager, Airports Division, FAA, New England Region.

[FR Doc. 92-8676 Filed 4-14-92; 8:45 am]

BILLING CODE 4910-13-M

Maritime Administration

Change of Name of Approved Trustee; Key Bank of Washington

Notice is hereby given that effective November 12, 1991, Key Bank of Puget Sound, Seattle, Washington, changed its name to Key Bank of Washington.

Dated: April 9, 1992.

By Order of the Maritime Administrator.

James E. Saari,

Secretary.

[FR Doc. 92-8627 Filed 4-14-92; 8:45 am]

BILLING CODE 4910-61-M

National Highway Traffic Safety Administration

[Docket No. 91-33, Notice No. 01]

Functional Capacity Index

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Notice and request for comment on proposed Functional Capacity Index.

SUMMARY: The National Highway Traffic Safety Administration (NHTSA) is developing a scale to measure the consequences of injuries received in motor vehicle crashes based on adjusted life-years. The factor used to adjust the injured person's remaining life-years is called the Functional Capacity Index. It combines decrements in each of ten dimensions of functioning into a whole body score. The development of the definitions of the functional attributes and their various capacity levels has been completed and a scaling approach has been chosen. This notice requests comments on the concept, on the attribute definitions, on the scaling approach, and on the adoption of the Functional Capacity Index for use in NHTSA's priority setting, regulatory analysis, and planning activities.

DATES: Comments are requested no later than June 1, 1992.

ADDRESSES: Written comments should refer to the docket and notice number of this document and should be submitted, (preferably in ten copies) to: Docket Section, National Highway Traffic Safety Administration, room 5109, Nassif Building, 400 Seventh Street SW., Washington, DC 20590. (Docket hours are 9:30 a.m. to 4 p.m.)

FOR FURTHER INFORMATION CONTACT: Stephen Luchter, Chief, Policy Development, National Highway Traffic Safety Administration, 400 7th St. SW., Washington, DC 20590. Telephone 202/366-1570.

SUPPLEMENTARY INFORMATION: In 1990, more than 44,000 people died and about 600,000 were injured seriously enough to be hospitalized as a result of motor vehicle crashes. NHTSA's mission is to reduce the number of these injuries, both fatal and non-fatal. To accomplish this mission effeciently, the agency needs accurate and reliable methods of measuring the consequences of injuries to those who are injured, as well as to their families and society in general.

NHTSA has developed sophisticated methods for measuring the economic consequences of deaths and injuries. These have been available for some time and widely applied. NHTSA uses these for, among other things, resource allocation, regulatory analysis, and in support of state and local programs.

Nothwithstanding their usefulness, the eonomic methods of evaluating injury consequences have certain inherent limitations. The most important of these is that economic consequences, especially those for injuries with long term effects, are related to a person's earnings from work. Young people, people in lower economic strata, and females in general are not counted the same as males in their peak earning years. This effect is particularly important for injuries received in motor vehicle crashes, where the injured population is highly skewed toward young people and there is some evidence that risk of motor vehicle injury is inversely proportional to income. Another limitation of the economic methods of measuring injuring consequences in that some consequences are difficult to monetize as they do not fit into the categories used in these analyses such as medical costs, or lost productivity. For example, how does one place a monetary value on being able to bend down to pick up a child who runs to greet you?

NHTSA has been interested in developing methods for measuring the consequences of injury that do not have the limitations of the economic methods. One approach is to measure changes in a injured person's functional capacity. This notice describes and requests comments on the current state of development of the Functional Capacity Index and the plan to complete the development.

The agency intends to use the functional capacity index as an additional analytical tool to those currently available in priority setting, regulatory analysis, and planning activities. When fully developed, this Index will be capable of being used as a measure of relative morbidity. A number of applications are now envisioned. Additional ones are likely to become apparent as experience is gained in the use of the index.

NHTSA expects that the index will be used as follows:

Resource Allocation

The Functional Capacity Index can be used when developing agency priorities. For example, if there are a number of alternative programs the agency believes would enhance safety, but resources are available to undertake only one or two of them, the Functional Capacity Index can be used to assist in making the choices among them. It would be used in additional to the estimated number of injuries and fatalities prevented and the societal cost saving resulting from successful completion of the program. The Functional Capacity Index will provide additional information that can be used to make a more refined decision. If two of the programs would provide about the same reduction in injury incidence and economic consequences, the Functional Capacity Index would provide an additional factor upon which to base a rational choice between them.

Regulatory Analysis

Executive Order 12291 requires agencies to consider the costs and benefits of a proposed action in making regulatory decisions, including non-monetary benefits. Most of NHTSA's regulatory actions are concerned with reducing injuries and fatalities, and a

change in functional capacity is one measure of the potential benefits that can accrue from a regulatior action.

Decisions Concerning Children

As noted earlier in this notice, the economic methods of estimating the consequences of injuries to children provides what could be a biased picture, especially for injuries with long term consequences. In our culture, children are valued quite highly, even though their economic contribution is if anything negative. This is because the discounted present value of the child's anticipated earnings is very low compared to that of older people. The Functional Capacity Index on the other hand does not have this limitation, as it is independent of the person's economic contribution. Thus, decisions concerning almost any action concerning children, such as school bus or child safety seat issues, can benefit from the use of the Functional Capacity Index as an indicator of potential benefits.

General Description

The basic assumption of the Functional Capacity Index is that life is its own best measure of value. If there are things a person cannot do as well following an injury as before, there is a reduction in their overall functional capacity. With the functional capacity approach, individuals of the same age and gender are counted equally. The injury consequences to young children are not discounted, and the longer average lifespan of females is accurately reflecetd.

The Functional Capacity Index (FCI) is a measure of the relative degree to which an injured person is unable to function at their pre-injury level on a scale of 0 to 100, where 0 represents no limitation of function and 100 represents maximum limitation of function. The overall consequences of an injury are found by multiplying the FCI by the injured person's remaining life expectancy. This results in the number of years of reduced functional capacity. The Functional Capacity Index can vary with time as the injured person's condition changes. Any effects of reduced life expectancy as a result of the injury also can be accounted for.

When the work described in this notice is complete, we will have determined the whole body functional capacity limitation for each of the injuries shown in the 1990 version of the AIS. For every injury in the agency's National Accident Sampling System data base, we will be able to find incidence of they injury and the age and sex distribution of the injured parties. From the Vital Statistics we can determine the life expectancy for each age and sex. Multiplying the number of life years affected by the whole body functional capacity factor will yield the number of life years affected by each particular injury. If the injury was fatal, all of the remaining life expectancy is counted.

The Functional Capacity Index has some similarities to the concept of Impariment as used by the American Medical Association, but 7 is fundamentally different. The AMA approach lists decrements in impairment for individual body regions, such as reduced range of motion of a joint, etc., and includes an approach to combining them into a whole body factor. The estimated decrements were developed independently for each body region. A level of impairment for one body region may not be equivalent to that same level of impairment in a different body region. The Functional Capacity Index, on the other hand, attempts to provide consistent measures of function for all parts and uses of the body.

The Functional Capacity Index also has some similarities to the Schedule for Rating Disabilities used by the Department of Veterans Affairs (38 CFR ch. 1, part 4). The Department of Veterans Affairs schedule represents reductions in earning capacity resulting from disease or injury. The Functional Capacity Index represents reduced functional ability in all aspects of a person's life (excluding psycho-social aspects).

Development of the Concept

The functional capacity concept has been under development since the early 1980's. The inital effort (Hirsch et al.) resulted in what was called an Impairment Scale. This was a listing of the levels of six attributes associated with each injury in the 1980 version of the Abbreviated Injury Scale (AIS): Mobility, congnitive, sensory, pain, cosmetic, and daily living. A physician, expert in a particular medical specialty, (neurology, orthopedics, plastic surgery, general surgery), judged which of four levels of reduced capacity (minor through maximum) would result for each injury, and the duration of that reduced capacity. Three time frames and four age categories were considered. Although this was a monumental undertaking, the results were difficult to use, and thus were not widely applied.

The Injury Priority Rating (Carsten and O'Day, Carsten) introduced the idea of callapsing Hirsch's matrix of attributes for injury into a "whole body impairment factor". This factor was used to adjust the cost of injury for a particular AIS level to more accurately represent the cost of specific injuries. Prior to that time, the cost to society of all injuries at a particualr AIS level were counted equally.

An in-house NHTSA study successfully tested the feasibility of using the whole body factor along with life expectancy as a direct measure of the consequences of injury (Luchter, 1987). This feasibility demonstration utilized the injury data for 1982 through 1984 found in the agency's National Accident Sampling System (NASS).

Before proceeding to invest additional resources to develop a new index, several existing functional status indices used in clinical or rehabilitation settings were studied to see if they were applicable to the motor vehicle injury situation (Luchter, 1989). Although a number of indices are available and widely used in a variety of settings, they either deal with current rather than long term status, related to the effects of disease rather than injury, are concerned with one aspect of a person's functioning rather than the whole person's functioning, or are focused on the person in a treatment environment rather than a normal enivronment. None was found that dealt with the long term effects of injury on the complete functioning of the person. Based on this, it was decided to complete the development of the index. A conceptual model was developed and a plan for further action prepared.

To implement the plan, NHTSA entered into a cooperative agreement with the John Hopkins University School of Hygiene and Public Health following a competitive procurement. The first product of this work was the refinement of the conceptual framework, based largely on the work of Nagi. Several terms were defined:

Active Pathology (resulting from injury): Anatomic or physiologic disruption resulting when energy is imparted from a blunt or penetrating force. Examples are a fractured femur and a laceration of the heart.

Impairment: Active pathology or residual losses or abnormalities to an organ or body system that remain after the active state of pathology has been controlled or eliminated. Examples are reduced length of one leg and reduced cardiopulmonary capacity.

Functional Limitation or Functional Capacity: Functional losses or deficits at the level of the organism as a whole. This term refers to the difficulties the individual has in his capacity to perform certain tasks that are considered important to everyday living. The same functional limitation may result from different impairments. For example, a

person might not be able to climb a set of stairs because of cardiopulmonary problems, or because one leg was shorter than the other. In either case the person would have difficulty walking.

Disability: Inability or limitation in performing socially defined roles and tasks expected of an individual within a socio-cultural and physical environment. For example, not being able to continue one's chosen occupation as a result of an injury is considered a disability. People with the same impairment or functional limitation may or may not be disabled.

These definitions (pathology, impairment, functional capacity and disability) do not follow those of the World Health Organization, but follow widespread, though not universal, practice in the United States. Once these definitions were developed, it became apparent to NHTSA that it was interested in functional capacity rather than impairment. Since that time, the work has proceeded under the rubric of Functional Capacity Index, or FCI.

Attribute and Severity Level Definitions

The work of selecting the attributes to be included in the index, and defining each attribute and each severity level has been completed. Ten attributes were chosen from a much larger number to describe the functions of a typical human. The choice was pragmatic, attempting to have as few as possible yet to have a sufficient number to fully describe the functioning of a complete human being. Some attributes were deleted from the long list because their significance can be measured by other attributes. (If you can't eat you can't digest.) Some are affected by only a very small number of injuries, and thus they would not have a significant effect on the societal totals.

Although the psycho-social functions of people are as real as the physical functions, a decision was made to not include them in this Index because they are of a different nature than the physical capacities used in this index. It also was recognized that normal functioning for young children may not be the same as for adults, and thus the current definitions are applicable only to people age 5 and older.

The number of levels within each attribute were chosen as needed to reflect observable variation in functional capacity for that attribute rather than arbitrarily deciding that some number of levels would be used for all attributes. Each attribute has levels of functioning ranging from no reduction in functional capacity to maximum reduction. Definitions were developed for each attribute and each severity level. The definitions were reviewed and refined based on suggestions made by a panel of 17 nationally recognized experts in trauma surgery as well as physicians and allied health professionals specializing in rehabilitation medicine. The panel's composition was established with the thought that the trauma surgeons would have first-hand experience in the short term effects of injury, and the practitioners in rehabilitation would have first-hand experience in the longer term effects of injuries.

The results are shown in Tables 1 through 10.

Eating (Table 1)

Difficulty eating is characterized by limitations in the ability to chew, swallow and digest foods. Defined in this manner, the ability to eat is independent of the ability to hold or use utensils.

Excretory Function (Table 2)

Excretory function is characterized by contol over urinary and fecal elimination. Levels of function are modified from the WHO classification.

Sexual Function (Table 3)

This function is determined by physical capabilities, dysfunction due to psychological reasons is not considered.

Ambulation (Table 4)

Ambulation is characterized by the ability to (1) stand, walk and run and (2) climb stairs. Limitations are described in terms of distance, speed, the need for a mechanical device or human assistance. Limitations may be due to motor impairments, contractures, pain, loss of equilibrium, reduced sensation or poor cardiopulmonary function. The ability to walk 150 feet was chosen as a key indicator of function since this is the distance generally thought to be required to get around in one's community. Twelve steps were chosen as representative of one flight of stairs.

Hand and Arm Function (Table 5)

Upper limb function is characterized by the ability to (1) grasp and manipulate objects, (2) move hand to mouth, and (3) move arms over head. Grasping and manipulating is described in terms of the size of the object. Hand to mouth movement is described in terms of number of repetitions and speed; a minimum of 20 times was chosen as this is generally thought to be needed for eating an average meal. Movement of the upper limbs may be limited by motor impairment, contracture, pain, or reduced sensation.

Bending and Lifting (Table 6)

Neuro-musculoskeletal function of the trunk is characterized by the ability to bend over from a sitting position and touch hand to foot, and by the ability to lift. Limitations in bending and lifting may be due to motor impairments, pain, or loss of equilibrium.

Visual Function (Table 7)

Visual function is characterized by visual acuity and presence or absence of functional diplopia. The levels of visual acuity parallel those delineated in the 9th revision of the International Classification of Diseases (ICD–9).

Auditory Function (Table 8)

Auditory function is described by degree of difficulty hearing under everyday listening conditions and by the average of hearing threshold levels at four standard frequencies. The levels of auditory function are in general agreement with classifications of the American Academy of Otolaryngology and the World Health Organization.

Speech (Table 9)

Limitations of speech include difficulties in voice production and articulation and not in the content or structure of language or communication. Function is characterized by (1) articulation and audibility and (2) functional efficiency or the ability to produce and sustain a serviceably fast rate of speech. The levels were modified from those defined by the American Medical Association.

Cognitive Function (Table 10)

Cognitive function is described by the capacity of the individual to manage his life independently. This capacity is based on the person's ability to make decisions for himself, to handle his own affairs, and make plans for the future.

Applying the Definitions to the AIS 90 Dictionary

The attribute and severity levels will be applied to each injury listed in the AIS 90 Dictionary. The expert panel will do this based upon their clinical judgment.

Developing a Numerical Scale

The final step in the development of the Functional Capacity Index is to translate the sets of qualitative statements applicable to each injury into numerical values. For NHTSA's purposes, this is intended to be a one time event, with the results being a listing of the Functional Capacity Index for each injury listed in the 1990 version of the AIS dictionary.

A number of methods are available to perform this scale development. One class of approaches, based on the application of multi-attribute utility theory, uses a variation of the classical economics concept of the standard gamble to obtain an individual's preference for the different possible states (see Torrance et. al 1982, Torrance 1987). Another uses people's opinions about the relative importance of different states (see Stewart et. al. 1988, Stewart et. al. 1989, Kaplan). The agency considered a number of these approaches. Based upon a balance between theoretical rigor and ease of application, it decided to use a variation of the Simple MultiAttribute Rating Technique or SMART (see von Winterfeldt and Edwards).

The SMART method will be applied in a three step process. The first step focuses on quantifying the severity levels within each of the attributes. Then the significance of the attributes relative to each other is determined. The final step is to combine the values into a overall "whole body" factor.

To implement the first step, values are assigned to each severity level within an attribute on a scale of 0 to 100. Each number on this scale represents a degree of severity such that 50 is ten degrees higher than 40, 90 is ten degrees higher than 80 and so forth. The number 0 reflects the lowest degree of severity (no limitation in functional capacity), and 100 reflects the highest degree of severity (maximum limitation in functional capacity). The numbers reflect the rater's judgment of the relative severity of the limitation in terms of its likely impact on overall function in everyday living. The major aspects of life are intended to include independent living, social interaction and major usual activity such as work, school or housekeeping. A separate chart is used for each of the attributes. An example of such a chart is shown in Table 11 for Ambulation. In these charts the end points are preprinted and the rater places the remaining intermediate levels of function on the scale such that the relative spacing between levels reflects their judgments of the expected degree of severity.

Once the within-attribute scaling has been completed, the second step is to rate the relative weights of the attributes with respect to each other. This step is more complex than the rating within attributes because it must consider the possibility that the attributes may not be completely independent. Also, some combined states are added to assist in the final step of combining into the whole body factor and to cover situations not included in the single state listing, for example, total blindness in one eye and both eyes, profound or total loss of auditory function in one or both ears, quadriplegia, deaf-blind, and simultaneously being at the most severe level on all 10 dimensions. Death is also scaled to provide an anchor point.

In this step, the rater first considers the most severe level for each of the attributes and identifies which has the greatest impact on everday living by placing a mark on a scale of 0 to 100 as shown in Table 12. The rater then places the remaining most severe states for the remaining nine attributes on the scale relative to the one judged to have the greatest impact. Death is scaled next. A scale value greater than 100 is acceptable. Next, the rater assigns a numerical value to the state representing the state of being at the most severe of all of the dimensions, and to some combined states not included in the list of attributes, such as quadriplegia and deaf-blind. These will be placed at scale values less than the value assigned to death.

Following these two steps, the values and weights will be normalized to a 0 to 100 scale with death as 100 and the remaining states relative to that. These values will then be combined using an appropriate model. Which model is most appropriate will be determined based on the ratings obtained from the expert panel, who will provide judgments based on their clinical experience. As noted below, it is also planned to determine if different population sub-groups apply similar values and weights.

Work on a thorough theoretical basis for the Functional Capacity Index began in the fall of 1991. As part of this work the judgments of groups other than the expert panel on the values for each attribute and severity level will be sought, for example, from injured persons and families of injured persons.

Future Plans

This notice presents the results to date of a program to develop a new index for measuring the consequences of injuries. The final product will be a table of values of the Functional Capacity Index for each injury listed in the 1990 version of the Abbreviated Injury Scale. The tasks remaining to accomplish this and their current status is as follows:

- The panel of experts will complete the development of the numerical scale.
- The panel of experts will apply the definitions to each entry in the AIS 90 dictionary of injuries and these will be translated into numerical values. The results of this effort will be a listing of the Functional Capacity Index for each entry in the 1990 version of the AIS dictionary.
- The final task will be the clinical evaluation of the long term consequences of injuries in order to establish validity and reliability. This task has progressed only as far as initial planning, and will be considered in detail following the completion of the basic development of the index. Revisions will be considered as needed following validation.

These future plans are subject to revision as the program progresses. The are included here to provide a broader context to facilitate the comment process.

Limitations

Although every attempt has been made to make the Functional Capacity Index as broadly applicable as possible, certain limitations are acknowledged. Some of these are topics that could be considered for further development.

1. With a few exceptions, the index in its present state of development is applicable to single injuries. (Certain multiple injuries are included for scale development purposes). For the intended applications with NHTSA, the maximum severity injury will be used when estimating the long term effects of injury. Methodologies to estimate the change in functional capacity resulting from any synergistc effects of more than one injury, particularly injuries to different body regions remain to be developed.

2. Changes in functional capacity from pre-existing conditions are not included, as this would require knowledge of differences in the consequences of injuries to different sub-populations. An average healthy person prior to injury is assumed in the current development.

3. The index is not applicable to young children. The present thought is that a separate index for pediatric injuries is needed, as the attributes of normal healthy children are not described by the present definitions.

4. The present effort to develop a Functional Capacity Index will be limited to the injury definitions in the 1990 version of the Abbreviated Injury Scale. Although the International Classification of Disease injury descriptions are widely used, they generally do not contain sufficient detail for the agency's countermeasure development purposes. Any efforts to develop a translation between these two scales would be applicable to the Functional Capacity Index.

5. The existence of "fates worse than death" is recognized. These are states where people say they would rather die

than continue living with the particular impairment. The agency position is that these are states of preference rather than states of function.

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Comments

NHTSA requests comments on the proposed Functional Capacity Index. General and detailed comments on this proposal are welcome to order to benefit from the opinions that interested parties and the public may wish to forward. All comments submitted in response to this notice will be considered by the agency.

Comments are specifically solicited on the following issues with respect to the material shown in Tables 1 through 10 of this Notice.

1. Do the ten attibutes reasonably cover the range of functions found in people age 5 and older?

2. Do the levels of functional capacity shown in Tables 1 through 10 reasonably cover the range for the individual functions?

3. Are the definitions of the functional capacity levels shown in Tables 1 through 10 unambiguous?

4. Are the definitions shown in Tables 1 through 10 comprehensible to a lay person? Comments are also solicited on the following issues.

5. The applicability of the rating technique as shown in Tables 11 and 12.

6. The use of the Functional Capacity Index for the possible applications mentioned in the body of the notice.

7. The focus of the agency's work on the injuries listed in the AIS 90 dictionary rather than other injury descriptors such as the International Classification of Diseases (ICD).

Written comments should be submitted to: NHTSA Docket Section, room 5109, Nassif Building, 400 Seventh Street, SW, Washington, DC 20590.

Comments should refer to Docket # 91–33, Notice 01.

It is requested, but not required, of interested persons that ten copies of each comment be submitted. All comments must not exceed fifteen pages in length. (49 CFR 553.21). Necessary attachments may be appended to these suggestions without regard to the fifteen page limit. This limitation is intended to encourage commentors to present their views in a concise fashion.

All comments received before the close of business on the comment closing date listed above will be considered and will be available for examination in the docket at the above address both before and after that date. To the extent possible, comments filed after the closing date will be considered. However, this action may proceed at any time after that date. The agency will continue to file relevant information as it becomes available. It is recommended that interested persons continue to examine the docket for new material. Those persons desiring to be notified upon receipt of their comments by the docket should include a self-addressed, stamped postcard in the envelope with their comments. Upon receiving the comments, the docket supervisor will return the postcard by mail.

Issued on April 9, 1992.

Donald C. Bischoff,

Associate Administrator, Plans and Policy.

TABLE 1—EATING

[Deglutition and Digestion]

Level A—No limitations	Level B—Dietary restrictions necessary	Level C—Tube feeding required
No restrictions in diet or preparation of foods because of difficulties chewing, swallowing or digesting.	Restrictions in diet, special preparation of foods or dietary supplement required because of difficulty chewing, swallowing or digesting.	Ingestion of foods requires tube feeding and/or gastrostomy.

TABLE 2—EXCRETORY FUNCTION

Level A—No limitations	Level B—Controllable excretory difficulty	Level C—Moderate incontinence	Level D—Severe incontinence
No significant difficulty controlling the elimination of urine or fecal matter.	Mitigation of consequences of excretory difficulties achievable by effecting degree of regulation, either by adaptive devices, electrical stimulators, special protective clothing or by some other means, (e.g., ileostomy or colostomy bag), so that effectively customary existence becomes possible.	Uncontrollable excretory difficulty—moderate incontinence (urinary and/or fecal); frequency greater than once every week by night and by day.	Uncontrollable excretory difficulty—severe incontinence (urinary and/or fecal); frequency every night and day.

TABLE 3—SEXUAL FUNCTION

Level A—No limitations	Level B—Some difficulty	Level C—No sexual function
Sexual function is possible without difficulty	Sexual Function is possible *but* only with varying degree of difficulty due to physical limitations.	Sexual function not possible.

TABLE 4—AMBULATION

	Level A	Level B	Level C	Level D	Level E	Level F
Function	No limitations	Independent without device but has minor limitations in amount of running or vigorous walking appropriate to age.	Independent, but requires device; takes more than reasonable amount of time to walk 150 ft. and climb 12 steps.	Minimally dependent; can walk a minimum of 150 ft. but only with assistance.	Moderately dependent; amount of walking limited to 50–150 ft. with or without assistance and/or device.	Completely dependent; severe limitation in amount of walking and stair climbing-including not being able to do it at all.
Standing/ Walking/ Running.	No limitations in the amount or endurance appropriate to age.	Some limitations with amount of running or vigorous walking appropriate to age; can walk a minimum of 150 ft. without assistance and at normal speed, but may have minimal gait deviation; does not require device.	Can walk a minimum of 150 ft. without assistance but takes more than reasonable amount of time; requires some device.	Can walk a minimum of 150 ft. but only with assistance; may or may not require device.	Walking limited 50–150 ft. with or without assistance/ or device.	Has difficulty standing for long periods and walking a minimum of 50 ft., including not being able to do it at all.
Climbing Stairs	No limitations in the amount or endurance appropriate to age.	No or some limitations with amount appropriate to age; can climb a minimum of 12 steps without assistance and at normal speed; does not require device.	Can climb a minimum of 12 steps without assistance but takes more than reasonable amount of time; requires device or handrail.	Can climb a minimum of 12 steps with or without assistance and/or device.	Stair climbing limited to less than 12 steps with or without assistance and/or device.	Cannot climb a minimum of 12 stairs.

TABLE 5—HAND AND ARM FUNCTION

	Level A	Level B	Level C	Level D	Level E	Level F
Function	No limitations	Minor limitation in hand function; no limitation in arm function.	Major limitation in hand function; no limitation in arm function.	No limitation in hand function; minor to moderate limitation in arm function.	Complete or near paralysis of one, but not both limbs.	Complete or near paralysis of both limbs.
Grasp and Manipulation with Fingers.	No difficulty with small or large objects.	No difficulty with large objects but has difficulty with small objects.	Difficulty with small and large objects (including not being able to do it at all).	No difficulty with small or large objects.	Difficulty with small and large objects.	Difficulty with small and large objects (including not being able to do it at all.
Hand Movement to Mouth.	No difficulty moving both hands to mouth at least 20 times.	No difficulty moving both hands to mouth at least 20 times.	No difficulty moving both hands to mouth at least 20 times.	No or little difficulty moving both hands to mouth at least 20 times.	Can move one but not both hands to mouth at least 20 times.	Cannot move either hand to mouth at least 20 times.
Arm Movement over Head.	No difficulty lifting both arms over head.	No difficulty lifting both arms over head.	No difficuly lifting both. arms over head.	Has difficulty lifting one or both arms over head (including not being able to do it all).	Has difficulty lifting one or both arms over head (including not being able to do it at alld.	Cannot lift either arm over head

TABLE 6—BENDING AND LIFTING

Function	Level A—No limitations	Level B—Minor limitations in lifting amounts appropriate to age	Level C—Major limitations in bending and lifting	Level D—Cannot bend or lift
Bending	No difficulty bending over from sitting position, touching hand to foot and returning to sitting position at least 20 times.	No or minor diffiulty bending over from sitting positions, touching hand to foot and returning to sitting position at least 20 times; *may* take more than reasonable amount of time.	Can bend over from sitting position, touch hand to foot and return to sitting position at least 5 times but less than 20 times.	Cannot with controlled motion bend over from sitting position, touch hand to foot and return to sitting position for a minimum of 5 times; includes not being able to sit up at all.
Lifting	No difficulty lifting amounts appropriate to age and body weight.	Some difficulty lifting amounts appropriate to age but can lift a minimum of 10 lbs with no or very little difficulty.	Has major difficulty lifting a minimum of 10 lbs. including not being able to do it at all.	Cannot lift a minimum of 10 lbs.

TABLE 7—VISUAL FUNCTION

[With best possible correction]

Level A—No limitations	Level B—No loss in VA but with diplopia	Level C—Near-normal vision	Level D—Moderate-low vision	Level E—Severe low vision (legal blindness in USA)	Level F—Profound low vision	Level G—Total blindness
Normal vision; no significant loss of VA; VA is 20/25 or better; no functional diplopia.	No significant lost of VA; VA is 20/25 or better but functional diplopia is present.	Near-normal vision; VA is 20/30–20/60.	Moderate low vision; VA is 20/70–20/160.	Severe low vision; legally blind in USA; VA is 20/200–5/200.	Profound low vision VA is 5/200 (count fingers at less than 3 mm) but with light perception.	Total visual impairment; black blind; no light perception.

TABLE 8—AUDITORY FUNCTION

Level A—No limitations	Level B—Minor loss	Level C—Moderate loss	Level D—Severe loss	Level E—Profound or total loss
No significant loss; able to hear under everyday listening conditions; average hearing level of 500, 1000, 2000 and 3000 Hz is $\leq$25 dB.	Minor difficulty hearing only when listening conditions are less than optimal (e.g., when significant background noise is present or voices are low); readily correctable with hearing aid; average hearing level at 500, 1000, 2000 and 3000 Hz is 26 dB–40 dB.	Moderate difficulty hearing under everyday listening conditions; usually correctable with hearing aid; average hearing level at 500, 1000, 2000, and 3000 Hz is 41 dB–70 dB.	Severe difficulty hearing even under optimal listening conditions; often but not always correctable with hearing aid; average hearing level at 500, 1000, 2000 and 3000 Hz is 71 dB–91 dB.	Profound to total loss of hearing; noncorrectable; average hearing level at 500, 1000, 2000 and 3000 Hz is $\geq$91 dB.

TABLE9—SPEECH

Function	Level A—No limitations	Level B—Minor difficulty	Level C—Serious difficulty	Level D—Severe difficulty
Articulation and Audibility	Can meet all demands* necessary for everyday speech and communications.	Can meet many to most demands* necessary for everyday speech; may occasionally be asked to repeat.	Can meet some of the demands* necessary for everyday speech; strangers may find it difficult to understand person; often asked to repeat.	Can meet few if any of the demands* necessary for everyday speech; may be able to produce some phonetic units; unintelligible out of context.
Functional Efficiency	Can meet all demands of articulation and phonation with adequate speed and ease.	Speech may sometimes be discontinued, interrupted, hesitant or slow.	Can often sustain consecutive speech for brief periods only; speech is labored; rate is often impractically slow.	Cannot speak with adequate speed or ease necessary for everyday speech.

* Demands for everyday speech include: articulation, phonation, audibility

TABLE 10—COGNITIVE FUNCTION

Level A—No limitations; complete independence	Level B—Hampered or adjusted independence	Level C—Aided independence	Level D—Unconfined dependence	Level E—Confined dependence	Level F—Complete dependence; limited orientation (incl. PVS)
No problems with judgment, memory, attention concentration, or behavior that would effect either the adequacy or efficiency with which a person functions. Does not require presence or advice of other in managing life.	Can function independently in managing life without assistance. However, due to mild congnitive deficits or mild inappropriate behavior, has reduced efficiency in handling own affairs (e.g., difficulty sustaining concentration, mild memory problems, reduced information processing). May also have to modity normal way of doing things to take care of their customery activities. (e.g., take more rest, study for longer periods of time).	Due to moderate difficulties with memory, organization and/or judgment, assistance from others is required for managing at least some affairs (e.g. financial affairs; planning for future). However, these individuals can live independently and constant presence or supervision of another individual is not required in order to function on day-to-day basis.	Major problems with memory, attention, concentration and problem solving, necessitate assistance in handling affairs and making decisions. Lack of judgement in determining what to eat, when to take medication and/or what activities are safe to paticipate in make an independent living situation impossible. However, 24 hours monitoring and supervision is not required and individual can be left alone for several hours at a time.	Due to lack of judgment, disorientation and/or memory problems 24 hours of supervision is required. These individuals may be able to participate in their daily care and interact in some fashion with others. However, they do not require others to take responsibility for them 24 hours of the day.	May be able to follow simple commands and interact with others in some minimal way (e.g., blinking, nodding head, etc.) but if so, does not usually have the capacity to initiate interaction, make requests or participate in own day-to-day function. The extreme severity of their cognitive limitations requires an environment which controls even the smallest details in the individual's life. Includes individuals in a persistent vegetative state.

Level A No Limitations

Standing/Walking/Running: No limitations with amount/endurance appropriate to age.

Climbing Stairs: No limitations with amount/endurance appropriate to age.

Level B Independent Without Device but has Minor Limitations in Amount of Running or Vigorous Walking Appropriate to Age

Standing/Walking/Running: Some limitations with amount of running or vigorous walking appropriate to age; can walk a minimum of 150 ft. without assistance and at normal speed; does not require device.

Climbing Stairs: No or some limitations with amount appropriate to age; can climb a minimum of 12 steps without assistance and at normal speed; does not require device.

Level C Independent but Requires Device; Takes More Than Reasonable Amount of Time to Walk 150 feet and Climb 12 Steps

Standing/Walking/Running: Can walk a minimum of 150 ft. without assistance but takes more than reasonable amount of time requires some device.

Climbing Stairs: Can climb a minimum of 12 steps without assistance but takes more than reasonable amount of time; may or may not require device.

Level D Can Walk a Minimum of 150 feet But Only With Assistance

Standing/Walking/Running: Can walk a minimum of 150 ft only with assistance; may or may not require device.

Climbing Stairs: Can climb a minimum of 12 steps with or without assistance and/or device.

Level E Amount of Walking Limited to Less Than 150 feet With or Without Assistance and/or Device

Standing/Walking/Running: Walking limited to 50–150 ft with or without Assistance and/or device.

Climbing Stairs: Stairs climbing limited to less than 12 steps with or without assistance and/or device.

Level F Severe Limitation in Amount of Walking and Stair Climbing—Including Not Being Able to Do It at All:

Standing/Walking/Running: Has difficulty standing for long periods and walking a minimum of 50 ft., including not being able to do it at all.

Climbing Stairs: Cannot climb a minimum of 12 stairs.

0: A ..... :0
10: A ..... :10
20: A ..... :20
30: A ..... :30
40: A ..... :40
50: A ..... :50
60: A ..... :60
70: A ..... :70
80: A ..... :80
90: A ..... :90
100: F ..... :100

Table 12—Scaling Across Attributes

The most severe level for each attributes is listed below along with some additional states representing bilateral reductions in functional capacity.

EX—Excretory Function: Severe Incontinence
EAT—Eating: Tube Feeding Required
SEX—Sexual Function: No Sexual Function
AMB—Ambulation: Severe Limitation in Amount of Walking and Stair Climbing, Including not Being Able to Do It At All
HAND—Hand and Arm Function: Complete or Near Paralysis of Both Limbs
BEND—Bending and Lifting: Cannot Bend or Lift
VIS1—Visual Function: Total Blindness in One Eye
VIS2—Visual Function: Total Blindness in Both Eyes
AUD1—Auditory Function: Profound or Total Loss in One Ear
AUD2—Auditory Function: Profound or Total Loss in Both Ears
SPCH—Speech: Severe Difficulty
COG—Cognitive Function: Complete Dependence; Limited Orientation, Including Persistent Vegative State

Consider the scale below ranging from 0 to 100, where 0 represents No Limitation of Function (healthy). Identify the state listed above which you believe represents the greatest impact on everyday living and write its abbreviation next to 100 on the scale. Consider the remaining states and place them on the scale between 0 and 100 according to your judgments of their relative importance.

01	10	No Limitation in Functional Capacity.
10	10	
20	20	
30	30	
40	40	
50	50	
60	60	
70	70	
80	80	
90	90	
100	00	Severe Limitation.

Next, consider the following additional states. Using the scale above, assign a numerical value to each of these states using the same criteria as you used in placing the twelve states noted above. First assign a numerical value to death relative to 100 on the scale above. Note that death is considered to be a complete loss of functional capacity. Death may be given a value greater than 100. For the remaining states, values may be greater than 100 but cannot be greater than the value assigned to death.

WORST—Worst on All Dimensions: Being Alive, but Simultaneously Being at the Most Severe Level on all 10 Dimensions
QUAD—Quadriplegia: The Most Severe Levels for Excretory, Ambulation, Hand/Arm, and Bending/Lifting Dimensions

DF/BLD—Deaf/Blind: The Most Severe Level of Auditory Loss in Both Ears and Visual Loss in Both Eyes

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DEPARTMENT OF THE TREASURY

Public Information Collection Requirements Submitted to OMB for Review

Date: April 9, 1992.

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 1980, Public Law 96–511. 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 3171 Treasury Annex, 1500 Pennsylvania Avenue, NW., Washington, DC 20220.

Bureau of the Public Debt

OMB Number: 1535–0095.
Form Number: None.
Type of Review: Extension.
Title: Regulations Governing United States Savings Bonds, Series E/EE and H/HH.
Description: The regulations mandate the payment of H/HH interest by direct deposit (ACH method). The affected public is H/HH bond-owners.
Respondents: Individuals or households, State or local governments, Businesses or other for-profit, Non-profit institutions, Small businesses or organizations.
Estimated Number of Respondents: 741,405.
Estimated Burden Hours Per Response: 5 minutes.
Frequency of Response: On occasion.
Estimated Total Reporting Burden: 61,537 hours.
Clearance Officer: Rita DeNagy, (202) 874–1148, Bureau of the Public Debt, Room 137, BEP Annex, 300 13th Street, SW., Washington, DC 20239–0001.
OMB Reviewer: Milo Sunderhauf, (202) 395–6880, Office of Management and Budget, Room 3001, New Executive Office Building, Washington, DC 20503.

Lois K. Holland

Departmental Reports, Management Officer.

[FR Doc. 92–8681 Filed 4–14–92; 8:45 am]
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Sunshine Act Meetings

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This section of the FEDERAL REGISTER contains notices of meetings published under the "Government in the Sunshine Act" (Pub. L. 94-409) 5 U.S.C. 552b(e)(3).

BOARD OF GOVERNORS OF THE FEDERAL RESERVE SYSTEM

TIME AND DATE: 11:00 a.m., Monday, April 20, 1992.

PLACE: Marriner S. Eccles Federal Reserve Board Building, C Street entrance between 20th and 21st Streets, N.W., Washington, D.C. 20551.

STATUS: Closed:

MATTERS TO BE CONSIDERED:

1. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.
2. Any items carried forward from a previously announced meeting.

CONTACT PERSON FOR MORE INFORMATION: Mr. Joseph R. Coyne, Assistant to the Board; (202) 452-3204. You may call (202) 452-3207, beginning at approximately 5 p.m. two business days before this meeting, for a recorded announcement of bank and bank holding company applications scheduled for the meeting.

Dated: April 10, 1992.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 92-8763 Filed 4-10-92; 4:26 pm]

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federal register

Wednesday
April 15, 1992

Part II

Environmental Protection Agency

40 CFR Part 79

Fuels and Fuel Additives Registration Regulations: Proposed Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 79

[FRL-4121-4]

Fuels and Fuel Additives Registration Regulations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This notice presents proposed regulations for the registration of motor vehicle fuels and fuel additives as authorized by sections 211(b)(2) and 211(e) of the Clean Air Act (CAA). Under the proposed regulations, producers of motor vehicle fuels and fuel additives would be required to conduct certain tests and submit information regarding the composition of emissions produced by such fuels and fuel additives and the effects of these emissions on the public health and welfare. Additional provisions for determining the effects of fuels and additives on the performance of vehicular emission control devices would be coordinated with existing and future rules under section 211(f). The proposal includes a grouping system and other mechanisms designed to avoid duplicative efforts and reduce the costs of testing by producers of fuels and fuel additives.

The proposed regulations would supplement existing registration requirements, and would potentially apply to both current and future fuels and additives. The proposed new requirements are designed to provide a body of information that would assist EPA in evaluating the potential adverse effects of various types of fuels and fuel additives and in determining whether futher risk assessment or regulatory action is needed under section 211(c).

DATES: Written comments on this Notice of Proposed Rulemaking (NPRM) will be accepted until June 30, 1992. A public hearing will be held May 28, 1992 at 9 a.m. It will be extended to May 29, if necessary, but prospective presenters should be prepared to testify on the first day.

ADDRESSES: Comments on the NPRM should be submitted in duplicate to: EPA Air Docket (LE–131); Attention: Docket No. A–90–07; U.S. Environmental Protection Agency, room M–1500, 401 M Street SW., Washington, DC 20460; phone (202) 382–7548. This docket is located at the above address on the first floor of Waterside Mall and is open for public inspection weekdays from 8:30 a.m. to 12 noon and from 1:30 p.m. to 3:30 p.m. As provided in 40 CFR part 2, a reasonable fee may be charged by EPA for copying services. The public hearing will be held in Ann Arbor, Michigan at the Ann Arbor Regent—Best Western Domino's Farms Hotel and Conference Center, 3600 Plymouth Road (U.S. 23 at Plymouth Road); phone (313) 769–9800.

FOR FURTHER INFORMATION CONTACT: Mrs. Carolyn Krueger, SDSB12, Regulation Development and Support Division, U.S. Environmental Protection Agency, 2565 Plymouth Road, Ann Arbor, MI 48105; phone (313) 668–4274. Persons who wish to receive a copy of the regulatory text for this proposed rule (including the proposed health testing guidelines) should leave a message, including their name, complete mailing address, and telephone number, at (313) 668–4361. The proposed regulatory text is also available in the public docket referenced above.

SUPPLEMENTARY INFORMATION:

I. Public Hearing

Any person interested in presenting testimony at the public hearing should notify the contact person listed above at least seven days prior to the day of the hearing. The notification should include the estimated time required for the presentation and identification of audio/visual equipment needs, if any. A sign-up sheet will be available at the registration table the morning of the hearing for scheduling the order of testimony. It is suggested that sufficient copies of the statement and other presentation materials be brought to the hearing for distribution to the audience. All materials submitted will be made part of the official record for this rulemaking.

Mr. Richard D. Wilson, Director of the Office of Mobile Sources, has been designated as presiding officer for the hearing. The hearing will be conducted informally, and technical rules of evidence will not apply. Written transcripts of the proceedings will be made by a court reporter. Copies will be available for examination in the public docket or for purchase by individual arrangement with the court reporter.

II. Background

A. Introduction

Over 2,200 fuels and 4,100 fuel additives are currently registered with EPA and, to some degree, each of them produces emissions which may contribute to potentially harmful air pollution in the United States. The primary purpose of this proposed rulemaking is to establish registration requirements which will provide information for identifying and evaluating the potential adverse air pollution effects of motor vehicle fuels and fuel additives and for guiding the direction of related regulatory actions in the future.

The remainder of this section reviews the statutory history of this proposed rulemaking, summarizes the public comments received in response to the Advanced Notice of Proposed Rulemaking, and defines certain key terms used in later discussion. The overall scope of the program is described in section III. Section IV outlines the objectives, rationale, and implementation of the proposed grouping system for fuels and additives. Issues germane to the generation of fuel/additive emissions for subsequent testing are discussed in section V, and proposed requirements for evaluating the effects of fuels and additives on the public health and welfare are described in section VI. Section VII outlines the proposed reporting requirements for the program. Subsequent sections discuss special program provisions, compliance considerations, confidentiality issues, public participation, and administrative topics.

B. Statutory History

Section 211(a) of the Clean Air Act (CAA), 42 U.S.C. 7545, authorizes EPA to designate any motor vehicle fuel or additive and prohibits producers of designated fuels or additives from selling such products unless they have been registered by EPA in accordance with section 211(b). The basic data elements which producers of fuels and additives must submit for purposes of registration, as stipulated by section 211(b)(1), include commercial identifying information, range of concentration, purpose-in-use, and chemical compostion. EPA issued regulations implementing this provision in 1975 (40 CFR part 79).

The 1970 CAA also provided EPA with discretionary authority to establish additional requirements for fuel and fuel additive registration. According to section 211(b)(2), EPA "may also require" producers "to conduct tests to determine potential public health effects of such fuel[s] or additive[s] (including, but not limited to, carcinogenic, teratogenic, or mutagenic effects)," and to furnish other "reasonable and necessary" information to identify fuel and fuel additive emissions and determine their effects on vehicular emission control performance and on the public health and welfare. The statute further stipulates that testing for health effects is to be conducted

according to procedures and protocols established by the Administrator, and that test results will not be considered confidential. When the producer has submitted the required information and has given assurances that the Agency will be notified of future changes in that information, section 211(b)(3) directs the Administrator to grant registration to the fuel or additive.

EPA did not exercise its discretionary authority to require fuel and additive testing under section 211(b)(2) when the general registration regulations under section 211(b)(1) were issued in 1975. However, in the CAA Amendments of 1977 (Pub. L. 95–95, August 7, 1977), Congress added section 211(e) to the statute, which made implementation of section 211(b)(2) mandatory and contained additional provisions concerning the implementation of the statute.

Section 211(e)(1) requires implementation of the section 211(b)(2) authority within one year of enactment of the 1977 amendments. In an effort to fulfill this requirement, EPA published an Advanced Notice of Proposed Rulemaking (ANPRM) in 1978 (see 43 FR 38607, August 29, 1978; Docket ORD–78–01); however, the rulemaking did not go forward during the next ten years. Nevertheless, this action has remained on the EPA regulatory agenda, and a development plan for the rulemaking was created in 1988.

C. Recent Events and Agency Actions

In 1989, a citizens group brought a lawsuit (*Thomas* v. *Reilly*, C.A. No. 89–6269 [D. Oreg. 1989]) challenging EPA's failure to promulgate fuel and fuel additive testing regulations within the one-year time limit permitted by CAA section 211(e). EPA entered into a consent decree in settlement of this lawsuit without adjudication of any issue of fact or law. The consent decree, which was signed by the Court, required that the EPA Administrator sign an advance notice of proposed rulemaking by August 1, 1990, a notice of proposed rulemaking by January 1, 1992, and a final rule by June 1, 1993. The decree did not address "the substance of the rulemaking," nor did it "limit or modify the discretion accorded * * * by section 211 * * * or general principles of administrative law in any fashion". By agreement with the plaintiff, the NPRM signature deadline was later extended to April 1, 1992.

The Agency published the required ANPRM on August 7, 1990 (55 FR 32218). A public hearing was held on September 26, 1990, followed by a 30-day period for written commentary. Public reponse included four oral presentations at the hearing and the subsequent submission of 24 written comments.

To gain further public involvement in the rulemaking, the Agency engaged the services of a private consultant group to assess the feasibility and appropriateness of applying regulatory negotiation procedures (under the provisions of section 583 of the Negotiated Rulemaking Act of 1990) to the development of the section 211 regulations. During the months of March and April, 1991, the consultants interviewed representatives of a variety of affected industry groups and environmental organizations to gauge their level of interest in the program and their willingness to participate in potential negotiations. These parties were also invited to a meeting in Washington, DC on May 2, 1991, to discuss the program issues further and to explore the potential advantages and disadvantages of a formal regulatory negotiation process. Susbsequently, the meeting attendees were polled again about their willingness to enter negotiations. The results indicated that there was insufficient support among a number of key parties, and EPA thus decided not to convene a regulatory negotiation for this proposed rulemaking.

D. Summary and Analysis of Comments

1. Program Focus and Jurisdictional Issues

The overall focus and scope of the potential new registration requirements were frequent topics of public comment received in response to the ANPRM. With respect to provisions in section 211 concerning the public health and welfare impacts of fuels and fuel additives, nearly all respondents recognized that information and testing requirements related to fuel and additive emissions were mandated by the statute. However, not all respondents agreed about the propriety, necessity, and desirability of requirements for the conduct of tests on the "raw" (i.e., uncombusted liquid) fuels and additives themselves. The majority maintained that the underlying objectives of the Clean Air Act and the specific language of section 211 would best be met by restricting the focus of the regulations to fuel and fuel additive emissions. According to these respondents, requirements addressing the potential adverse effects of "raw" fuels and additives would not help to elucidate the sources and effects of air pollution, and would thus fall outside the scope of the statute. A few commenters held the opposite point of view, arguing for broad and comprehensive health testing of fuels and additives in their original liquid formulations as well as in the combusted and vaporized states.

As discussed more fully in section III.B of this NPRM, EPA believes that the Agency has some discretion under section 211 to determine the focus of fuel and additive evaluation requirements. Consistent with the goals of the CAA, EPA has decided to focus this proposed rulemaking on the emissions-based effects of fuels and fuel additives. Thus, the proposed health effects testing provisions specifically address the effects of inhalation exposure to fuel and additive emissions, inculding both evaporative and combustion emissions. Tests to determine the direct toxicity of "raw" fuels and additives (e.g., by oral or dermal exposure) are not included except insofar as such information may be needed to determine the effects of their emissions. The Agency believes this focus to be compatible with the intent of Congress and the scope of authority granted by section 211.

Focusing today's proposed rulemaking on the emissions of fuels and fuel additives will also serve to relieve concerns about possible areas of overlap between section 211 and other Federal regulatory programs. Existing authority under the Toxic Substances Control Act (TSCA), 15 USC section 2601 *et seq.*, has often been cited in this regard. TSCA provides EPA authority to examine the potential environmental and health risks associated with chemical substances or mixtures, and several respondents felt that promulgation of the health effects testing provisions in section 211(b) would be duplicative of the regulatory mechanisms already in effect under TSCA. While rejecting the notion that TSCA might eliminate the need for implementation of section 211(b), EPA recognizes the need for coordination between the two programs.

To a large extent, the potential overlap between TSCA and section 211 is more legalistic than programmatic, and need not result in overlapping regulations. Because of the technical difficulties associated with testing complex mixtures, the TSCA program has traditionally focused on the toxicity of discrete chemcial substances rather than on complex mixtures such as fuels and additives. In fact, under the Premanufacturing Notification process implemented for new chemical review, TSCA excludes chemical mixtures except those which occur in nature. Moreover, under both CAA and TSCA programs, persons may submit existing data to fulfill regulatory requirements

and are not required to submit duplicative data. Nevertheless, some individual chemicals used in fuel and additive formulations have been subject to review and testing under TSCA. EPA's plan to limit the focus of section 211 regulations to emmissions-based effects will help to avoid the possibility that such activities under TSCA might overlap with testing requirements promulgated under section 211(b).

Concerns about potential regulatory overlap were also raised in conjunction with the mobile source-related air toxics provisions added by the 1990 CAA Amendments (CAA Section 202(l)). Section 202(l) requires that EPA complete a study of the need for and feasibility of controlling unregulated toxic air pollutants associated with motor vehicles and fuels. Based on this study, EPA must promulgate vehicle or fuel standards to control mobile source emissions of benzene and formaldehyde. At EPA's discretion, other toxic pollutants may also be controlled.

In the opinion of some respondents, EPA's informational objectives in regard to the air pollution effects of fuels and additives would be better served by the air toxics provisions of section 202(l) than by the health and environmental provisions of section 211(b). According to this view, section 202(l) mandates a more direct approach, focusing on specific mobile source air pollutants which represent the greatest risk to human health and requiring the identification of currently unregulated mobile source pollutants which should be subject to control.

While acknowledging that the two parts of the CAA share a general concern about the public's exposure to toxic chemicals produced by mobile sources, EPA believes that they can complement rather than duplicate or supplant one another. Section 202(l) addresses the toxic emissions themselves, while section 211(b) focuses on the components and effects of emissions generated by particular motor vehicle fuels and additives. The required study under section 202(l) may or may not identify any fuel-related causes of toxic air pollutants, while the testing required under section 211(b) will provide such information. This should prove useful in EPA decisionmaking regarding the need for feasibility of additional vehicle or fuel regulations to reduce toxic emissions. Furthermore, a different regulatory approach underlines each of the two statutes. Section 202(l) seeks to determine the extent to which existing toxicologic data on specific identified air pollutants warrants additional regulation, and requires certain EPA actions in this regard by mid-1995. The purpose of the current rulemaking is to establish testing requirements that will provide EPA with adequate information on the emissions effects of existing and future fuels and additives to determine whether the commercial distribution or use of any such fuels or additives should be controlled.

2. Emission Control System Testing

Several respondents representing segments of the vehicle and engine manufacturing industries favored rigorous requirements for testing the potential effects of fuels and fuel additives on vehicular emission control performance. These respondents maintain that emission control test requirements under this rulemaking should involve different driving cycles for urban vehicles, tractor trailers, and alternatively fueled vehicles, and should include such parameters as long-term durability, deterioration rate, wear, corrosion, deposition, and compatibility with a variety of lubricating oil formulations. Furthermore, they argued that test requirements for existing products should be just as stringent as those required for the market entry of new fuels and additives, and that the effects of each fuel or additive on emission control performance should be tested in a statistically significant sample of engines.

EPA recognizes the concerns of these respondents regarding the potential impact of fuel and/or additive formulations on emission control system integrity. On the other hand, it is not in the public interest to establish registration requirements so onerous that they would discourage the introduction of beneficial new additives and alternative fuels.

EPA believes that the existing prohibitions in section 211(f) have avoided these unfavorable results while preventing the introduction of fuels and additives which would significantly degrade the performance of emission control equipment. In effect, these mechanisms call for emission control testing of fuels and additives only when their composition departs significantly from the general range of fuel formulations which would ordinarily be anticipated by manufacturers of motor vehicle engines and emission control devices. This objective has been accomplished by the issuance of interpretive rules which lay out specific chemical and physical criteria for a category of fuels and additives considered "substantially similar" to certification gasoline fuels (46 FR 38582 and 56 FR 5352). Products which meet these "sub sim" criteria can be placed in commercial use without first undergoing testing to determine their potential emission control impact. Conversely, manufacturers of fuels and additives which do not conform to the "sub sim" criteria are required to apply for a waiver of section 211(f) restrictions. This process requires the waiver applicant to demonstrate, through testing if necessary, that such products do not decrease the ability of vehicular emission control systems to comply with emission standards.

Section 211(f) was passed by Congress in 1977, seven years after enactment of the section 211(b) provisions which are the primary subject of today's proposed rulemaking. In EPA's judgment, the mechanisms already implemented under section 211(f) are adequate to satisfy the section 211(b) requirement for testing to determine the effects of fuels and additives on emission control systems. Three factors must be considered in this regard: (1) The adequacy of test procedures conducted for the purpose of waiver applications under section 211(f), (2) the adequacy of existing "sub sim" criteria for determining which fuels and additives must apply for a section 211(f) waiver, and (3) the scope of section 211(f) prohibitions. These factors are discussed below.

(1) *Adequacy of testing.* While EPA believes that the level of emission control system testing conducted in support of section 211(f)(4) waiver requests has generally been appropriate and effective, the comments summarized at the beginning of this subsection indicate that some industry segments consider such testing inadequate for determining the potential impact of fuels and additives on emission control devices. To the extent that more comprehensive or standardized emission control test requirements might be needed, EPA believes they should be implemented as changes to the existing waiver application procedures under section 211(f) rather than as new, overlapping regulations under section 211(b). While such revisions are outside the scope of the proposed rulemaking, EPA would separately welcome suggestions regarding possible changes in conjunction with section 211(f).

(2) *Adequacy of "substantially similar" criteria.* In EPA's view, more than a decade of experience has demonstrated the practical value of the "substantially similar" concept for determining whether a fuel or additives needs to be tested for its effects on emission control equipment. Among gasoline fuels and their related bulk

additives (the only fuel/additive categories subject to section 211(f) prohibitions prior to the 1990 CAA Amendments), EPA is not aware of instances in which products excused from testing because they met "sub sim" criteria were later discovered to have adverse effects on vehicular emission control performance. Rather than tightening up the criteria, the Agency has been persuaded by practical experience in conjunction with the waiver application process to publish a revision of the "substantially similar" definition, which raised the limitation on the amount of oxygen permitted in formulations considered to be "sub sim".

(3) *Scope of section 211(f) prohibitions.* Until the 1990 CAA Amendments went into effect, the statutory language of section 211(f) was interpreted as applying only to unleaded gasoline fuels and related bulk additives. Interpretive rules establishing the criteria for fuels and additives considered to be "substantially similar" to certification fuels thus were published only for products in the unleaded gasoline category. With enactment of the 1990 CAA Amendments, all types of motor vehicle fuels and additives were placed under section 211(f) jurisdiction. Proposed criteria for fuels and additives considered "substantially similar" to diesel fuel have now been published (56 FR 24362–3, May 30, 1991). In addition, "sub sim" criteria appropriate to other fuel/additive categories are now under development or planned for all fuels (other than leaded gasoline) for which certification procedures and emission standards exist.

However, the expanded scope of section 211(f) applies only to products first introduced into commerce on or after November 15, 1990, the effective date of the CAA Amendments. Consequently, a large number of products introduced and/or registered prior to this date will still fall outside the regulatory domain of section 211(f). These "grandfathered" products include aftermarket additives sold for use in gasoline-powered vehicles, as well as all non-gasoline fuels and fuel additives, introduced prior to the 1990 CAA Amendments. If these products are to be subject to possible testing requirements and regulatory control on the basis of their potential emission control effects, the statutory authority has to derive from sections 211(b) and (c) rather than section 211(f).

The possibility that some grandfathered products may have deleterious effects on emission control performance is addressed in the proposed rulemaking as follows. In general, section 211(b) provisions relating to emission control system testing are integrated with the regulatory structure of section 211(f). Products not subject to section 211(f) because they were first introduced prior to the effective date of the applicable prohibition would not routinely be required to undergo emission control testing. However, the proposed rulemaking provides a mechanism by which EPA can choose to require testing for such grandfathered products, similar to the testing which a waiver applicant would have to conduct, if so petitioned by outside parties or if other information available to the Agency indicates that such review is appropriate. This topic is further discussed below in section III.D.

3. Grouping Provisions

The ANPRM discussed EPA's intent to develop a grouping system by which manufacturers of similar fuels and additives could voluntarily pool their efforts and resources to satisfy program requirements. According to this plan, fuels and additives would be grouped according to criteria specified by EPA. Representatives from each group would then be selected for testing, with the test results and attendant costs shared by the participating manufacturers. As a result, both costs and duplicative efforts would be reduced.

Public comment about the grouping concept was generally supportive. However, at least one respondent pointed out that participation in cooperative testing arrangements would not be a viable option for makers of proprietary specialty fuel additives, because valuable trade secrets about product formulations would have to be revealed to potential competitors. EPA acknowledges that the opportunity for group participation will be most attractive to manufacturers of generic or commodity-type products. On the other hand, there are a number of approaches under which group participation may not require detailed chemical formulations to be divulged. For example, persons could use an agent, such as an accouting firm or a trade association, to coordinate testing and represent the group to EPA while preserving the anonymity of the other members in the group. Manufacturers of specialty products will have to judge for themselves whether the amount of confidential business information that must be revealed in order to participate in group testing arrangements is acceptable to them.

In regard to the development of criteria for establishing the groups, a number of respondents suggested that fuels and fuel additives be grouped according to their emission components. EPA agrees that emissions-based grouping would be ideal, but until this rulemaking has gone into effect, the requisite information on emission will not be available. Recognizing this problem, some respondents suggested that EPA first collect emissions data from fuel and additive manufacturers and then develop the grouping criteria. However, to follow this suggestion would necessitate two separate regulatory proceedings: A preliminary rule requiring manufacturers to submit the results of emission speciation procedures and a second rule creating an emissions-based grouping system and promulgating regulations to implement all of the other program requirements. This is not a viable alternative for the Agency, given the time constraints of the statute and the provisions of the Consent Decree. Therefore, the grouping system proposed here is based on the composition of raw fuels and additives, with the underlying assumption that fuels and additives with similar raw constituents will generate similar emissions.

Some respondents submitted specific suggestions to EPA concerning the definition of fuel and additive groups. For example, one respondent proposed that fuels be subdivided for health testing on the basis of their octane number and/or PONA number (paraffins, olefins, naphthenes, and aromatics). EPA has not found these numerical indexes useful for distinguishing meaningful health effects testing groups. Moreover, the significance of the associated hydrocarbon proportions in the raw fuel state will be reduced in the case of the exhaust emission by the "homogenizing" effect of the combustion process. Nevertheless, recent evidence suggests that varying the relative olefin and/or aromatic content of a fuel may impact the concentration of some emission components. Thus, olefin and aromatic content are among the parameters under consideration by EPA for defining groups or selecting group representatives for testing.

Opinions differed among respondents about the usefulness of the section 211(f) "substantially similar" criteria in the context of a grouping system for fuel and additive health testing. As previously described, the "sub sim" criteria currently serve to designate which fuels and fuel additives must obtain a waiver of section 211(f) prohibitions. While some respondents endorsed the incorporation of existing "sub sim" criteria into the grouping

system for health effects testing, others felt that the resulting "sub sim" group would be too broad to allow the health test results obtained for selected representatives to be generalized to the group as a whole.

EPA believes that, in most respects, the "sub sim" criteria (56 FR 5352, February 11, 1991) are useful determinants of "baseline" conventional fuels and fuel additives (see section IV of this NPRM). The established criteria restrict the elemental composition of "sub sim" formulations to carbon, hydrogen, oxygen, nitrogen, and sulfur, with limits placed on the amount of methanol, oxygen, sulfur, and certain other substances. However, EPA is considering several variants of these criteria for distinguishing between "baseline" and "non-baseline" formulations. Extreme concentrations of aromatics and olefins are two possible distinguishing characteristics. A different restriction on the amount of oxygen permitted in baseline formulations is another possibility. The oxygen restriction for "sub sim" fuels is currently 2.7 percent by weight (and somewhat higher for certain waivered fuels and additives), and this may be appropriate for defining baseline formulations in this proposed program. However, EPA is also considering restricting baseline formulations to those with less than 1.5 weight percent of oxygen. In the latter case, "reformulated" fuels would be excluded from the "baseline" classification. This would result in the generation of more explicit information for various oxygenated gasoline fuels.

4. Health Effects Testing Provisions

A number or respondents argued that an overly stringent and expensive health effects testing program would be counter to the public interest. They pointed out that unreasonably high costs of program compliance would discourage the development of new fuels and additives and would reduce the availability of products potentially beneficial to the public health and welfare. While the testing program must provide adequate information for assessing the toxicity of fuels and additives, EPA is well aware of the importance of striking an appropriate balance between scientific demands and technical and financial constraints, taking into account both the need for adequate information and the need for continued innovation. The Agency believes that the program outlined in the proposed rulemaking is consistent with the statute and reflects a reasonable and cost-conscious approach to a very complex regulatory area.

In comments directed at the health assessment approaches described in the ANPRM, respondents urged EPA to include provisions for taking relevant existing information into account, to use a tiered testing approach as a means for identifying products which should undergo long-term study, and to take advantage of existing standardized test guidelines whenever possible. These suggestions are reflected in today's proposed rule.

Some respondents stated that successful implementation of a broadly-based health effects testing program was doubtful in view of the many technical problems which must first be overcome. They maintained that years of testing would be required to validate test protocols and establish baseline data, in view of the chemical complexity of fuel and additive formulations and the impact of vehicle choice, engine type, emission control technology, and operating conditions on the composition of emissions.

EPA is well aware of these technical difficulties, but does not agree that they are insurmountable. Today's proposed rule contains a number of proposals for bringing the sources of variability under reasonable control, including rules for the selection and operation of vehicles and equipment, base fuel specifications for each major fuel/additive family, standardized procedures for the generation, sampling, and storage of emissions, and guidelines for animal inhalation exposure testing. Together with experimental control requirements, these measures should reduce the testing program's inherent variability to acceptable limits. EPA invites comments from the public on the adequacy of these measures and on ways to improve them.

Many commenters urged EPA to "set priorities" for testing among the large universe of motor vehicle fuels and fuel additives potentially subject to the proposed rulemaking. However, there was little agreement about which specific formulations or product categories—fuels vs. additives, conventional vs. reformulated vs. alternative fuels—should be placed high and low on the priority list. Under section 211, Congress has mandated that EPA enact a scheme for testing that would generally and reasonably assess the health risks of all fuels and fuel additives. Therefore, EPA has proposed a grouping system which provides an efficient mechanism for obtaining information on all types of fuels and additives. A system of evaluation tiers has also been developed, enabling EPA to determine whether more definitive testing is needed for any particular fuels or additives (or types of fuels and additives) based upon toxicity and exposure data obtained from the literature, from modeling techniques, and from a battery of screening tests. Finally, EPA intends, under section 211(e)(3)(C), to recognize existing adequate data as compliance with the rule.

Related comments were submitted regarding the applicability of program requirements to fuel additives which are considered "substantially similar" to conventional fuels. Some respondents pointed out that when a "sub sim" additive is mixed with gasoline it is extremely difficult if not impossible to differentiate from the fuel itself, and that efforts to detect the negligible contribution of such an additive to the emissions produced by the gasoline/additive mixture would be futile. Thus, according to these respondents, "sub sim" fuel additives should be exempt from program requirements.

EPA agrees with some of the reasoning behind these arguments. The public health and welfare provisions in this rulemaking are concerned with the impact of emissions generated by fuels and fuel additives in normal use. Since additives are properly used only in conjunction with their associated fuels, program requirements pertaining to the potential effects of additives are focused specifically on the emissions of the respective fuel/additive mixtures. For additives with essentially the same chemical makeup as their parent fuels, currently available technology will generally not be capable of differentiating the emission products of the additive/fuel mixture from the emission products of the parent fuel itself.

EPA does not agree, however, that the manufacturer of an additive should be relieved of registration responsibilities just because of the additive's similarity to its parent fuel. Instead, provisions within the proposed grouping system should be able to account for these relationships. Such mechanisms are discussed further in section IV, below.

5. Small Business Provisions

Under section 211(e), EPA is authorized to create special program allowances and/or exemptions which would reduce the burdens of program compliance for small businesses. If EPA should choose to exercise this authority, the operative definition of a small business would be specified within the associated regulations. Respondents who commented on this matter felt that any small business definition would be arbitrary and unfair. In their view, small

business provisions could potentially place individual manufacturers who sold multiple low-volume products at a disadvantage relative to single-product manufacturers. They also believed that the rules governing small business allowances could be manipulated by large manufacturers, creating loopholes never intended by EPA.

While EPA does not necessarily share each of the respondents' concerns, this NPRM does not contain specific proposed provisions for small businesses. In general, the proposed grouping scheme, tiered testing structure, and other general provisions should assure that undue burdens are not placed upon small businesses. Nevertheless, EPA's analysis indicates that the costs of compliance with the proposed program may place a few small businesses in financial jeopardy. EPA is thus attempting to identify the characteristics which may make some small companies unusually vulnerable to the potential financial impact of the proposed requirements, and to specify fair and appropriate approaches for providing cost relief to such companies. These topics are discussed further in section VIII.C.

E. Key Terms

A *fuel* is defined to be any material which is capable of releasing energy or power by combustion or other chemical or physical reaction. Only fuels intended for use in motor vehicles are included under the proposed regulations. Currently, fuels intended for use exclusively in off-road vehicles are not designated for registration. Both domestic and foreign products are included in the designation.

A *fuel additive* is any substance that is intentionally added to a fuel and that is not intentionally removed prior to sale or use. *Bulk additives* are products which are added to fuel before the fuel is commercially available for introduction into the fuel tank of a motor vehicle, whether added at the refinery as part of the original blending stream or after the fuel is transported from the refinery. *Aftermarket additives* are products marketed for introduction directly into the fuel system of a motor vehicle.

A *base fuel* is a generic fuel formulated from a set of specifications to represent a given fuel family and used in conjunction with the testing of additives in that family.

Combustion emissions are the exhaust products of the combustion of fuel and/or additives in a motor vehicle engine. For the purposes of this rulemaking, this designation refers to controlled exhaust products (i.e., post-aftertreatment tailpipe emissions) unless otherwise specified.

Evaporative emissions are chemical compounds emitted into the atmosphere by vaporization of the components of a fuel or additive/fuel mixture. For purposes of this rulemaking, the term "evaporative emissions" refers both to emissions created by vaporization from the fuel system of a motor vehicle (hot soak, diurnal, and running losses) as well as those displaced from the fuel tank by incoming fuel during refueling operations.

Atmospheric transformation products are compounds formed in the atmosphere from the reactions of primary emissions such as volatile organic compounds (VOCs) in the presence of atmospheric gases such as nitrogen oxides. The formation of many such compounds also requires the presence of sunlight. Transformation products include ozone, formaldehyde, peroxylacetyl nitrate (PAN), and other nitrated and oxygenated low molecular weight organic compounds.

III. Program Scope

A. Overall Purpose and Applicability

Section 211 of the Clean Air Act establishes a framework for registering motor vehicle fuels and additives, for gathering information about them, and for possibly limiting or prohibiting their commercial distribution and sale when the available information warrants such action. Previous regulatory actions have implemented sections 211 (a) and (b)(1), which govern the general registration of fuels and additives, as well as section 211(f), which prohibits the commercial introduction of certain fuels and additives prior to a demonstration by the prospective registrants that these products do not adversely affect emission control system performance. Today's Notice proposes new registration requirements for motor vehicle fuels and fuel additives under sections 211 (b)(2) and (e). These sections grant EPA authority to require information on the potential health, welfare, and emission control system effects associated with motor vehicle fuels and additives, and to specify procedures and protocols to be used by fuel and additive producers in complying with these requirements.

The proposed new requirements would apply to any motor vehicle fuel or additive which is already registered or is subject to the general registration requirements in effect under sections 211(a) and 211(b)(1). At the present time, this designation encompasses both current and new gasoline and diesel fuels and additives produced and commercially distributed for use in motor vehicles. While alternative fuels and their additives are not yet designated for registration, EPA plans to designate them before this proposed rule becomes final. Currently, fuels and fuel additives intended only for off-road vehicular use (e.g., in farm and construction equipment, aircraft, boats, and railroad engines) do not need to be registered, and thus are not subject to the new registration requirements proposed in this rulemaking. However, if these fuels and additives are covered under future registration requirements, this program (modified as needed) would extend to them as well.

By this proposed rule, EPA intends to satisfy Congress' mandate under section 211(e) that EPA implement its authority under section 211(b). EPA interprets section 211(b) to give it the authority to require testing of fuels and fuel additives to identify their health and environmental effects. Section 211(b), however, must be read in conjunction with section 211(c), which in part gives EPA authority to control or prohibit the manufacture, introduction into commerce, offering for sale, or sale of any fuel or fuel additive if the Administrator finds that the emission products of such fuel or fuel additive "causes, or contributes, to air pollution which may reasonably be anticipated to endanger the public health or welfare." Further, the Administrator must find that such prohibitions "will not cause the use of any other fuel or fuel additive which will produce emissions which will endanger the public health or welfare to the same or greater degree than the use of the fuel or fuel additive proposed to be prohibited." Therefore, the purpose of section 211 is not to require submission of data and information for its own sake, but to assist EPA in the regulation of fuels and fuel additives.

EPA faces practical constraints in accomplishing its task. Currently, 2,200 fuels and 4,100 fuel additives are registered for use. Emissions speciation and emissions toxicity testing are complex, requiring the operation of vehicles or engines in a laboratory and, in the case of toxicity testing, the inhalation exposure of animals to emissions under very controlled conditions. EPA knows of only a few commercial laboratories which currently offer the full range of emission generation and speciation procedures proposed in this rule, and is not aware of any commercial biological testing facilities which, at the present time, offer toxicity testing services involving the constant inhalation exposure of live animals to fuel and fuel additive

emissions. Also, while screening batteries can be conducted in only a few weeks or months, more extensive testing may require long term exposures or the exposure of more than one generation of animals.

Accordingly, the proposal attempts to address these practical constraints while providing EPA with sufficient information to exercise its authority under section 211(c). First, EPA proposes to recognize adequate existing data. By adequate, EPA would recognize studies conducted reasonably in accord with the guidelines specified in this rule. Second, EPA has proposed a voluntary grouping scheme by which manufacturers of fuels and fuel additives with similar chemical composition may test one substance as a representative of all substances within the group. (Because manufacturers may not wish to share data on the composition of their products with others, the grouping scheme would be voluntary; however, each fuel or fuel additive would be required to be tested either separately or as part of a group.) EPA would use the information from the test substance to evaluate the risk of all substances within the group, unless adequate data on a particular member of the group becomes available. Manufacturers would benefit by sharing the cost of testing. Through this voluntary grouping system, EPA estimates that, among currently registered unleaded gasoline, leaded gasoline, and diesel products, about 115 groups could be formed, which is a much more reasonable number of testing subjects given the practical constraints on testing. Test data obtained as a result of the proposed rule would thus give EPA a general picture of how different types of fuels and fuel additives compare to one another, which is consistent with section 211(b) in light of EPA's authority under section 211(c).

Fuels and additives registered as relabeled products (i.e., simply repackaged versions of formulations which are also registered by the original manufacturers) would be specifically exempted from the new information gathering and testing requirements proposed in today's rulemaking. Because separate assessment of relabeled products would clearly duplicate the efforts of the original manufacturer, EPA has chosen to exercise the authority in section 211(e)(3)(C), which allows EPA to exempt fuels and additives from the provisions of section 211(b)(2) under duplicative circumstances. However, if the original manufacturer should fail to fulfill the proposed registration requirements, then the relabeler would be at risk for losing his supply of the relabeled product. Furthermore, EPA expects that the original manufacturers would pass the costs of testing along to their customers, including repackagers.

In another matter pursuant to section 211(e)(3)(C), EPA requests comment from the public in regard to the adequacy of existing information on "baseline" conventional fuels and fuel additives, including baseline diesel, unleaded gasoline, and leaded gasoline formulations (as defined in Section IV, below). A multitude of studies, conducted by many researchers over several decades, have addressed the emissions-based effects of these products on the public health and welfare and on emission control system performance. The published results and conclusions from these tests have provided the foundation for many legislative initiatives and regulatory actions in the area of mobile-source air pollution. EPA invites detailed comment on the extent to which the available information on these conventional fuels and additives is adequate for ongoing regulatory decision-making and, with respect to the testing requirements proposed in this rulemaking, the extent to which significant gaps may still remain in the available data base.

B. Emissions Focus

While the requirements proposed in this NPRM are primarily concerned with information collection, the underlying purpose of the rule is to guide the direction of related regulatory activities which might be undertaken in the future. The statute instructs EPA to promulgate requirements for "reasonable and necessary" information about the effects of fuels and additives and, as described above, provides mechanisms under section 211(c) for taking action based upon this information. Therefore, it would appear most reasonable in this instance for EPA to focus its information requirements to subject areas which serve the regulatory objectives of section 211(c).

Accordingly, EPA interprets section 211 to give it authority to focus testing on the emissions effects of fuels and fuel additives. By emissions effects, EPA means both the effects from combustion and evaporation of fuels and fuel additives resulting from their use in motor vehicles. The purpose of obtaining data on fuels and fuel additives is to provide a basis for further risk characterization and possible regulation under section 211(c). CAA section 211(c)(1) states:

> The Administrator may, from time to time on the basis of information obtained under subsection (b) of this section or other information available to him, by regulation, control or prohibit the manufacture, introduction into commerce, offering for sale, or sale of any fuel or fuel additive for use in a motor vehicle * * * (A) if in the judgment of the Administrator any emissions product of such fuel or fuel additive causes or contributes to air pollution which may reasonably be anticipated to endanger the public health or welfare * * * or (B) if emission products * * * will impair * * * the performance of any emission control device or system in general use * * *

Similarly, CAA section 211(c)(2)(C) states:

> No fuel or fuel additive may be prohibited by the Administrator under paragraph (1) unless he finds, and publishes such finding, that in his judgment such prohibition will not cause the use of any other fuel or fuel additive which will produce emissions which will endanger the public health or welfare to the same or greater degree than the use of the fuel or fuel additive proposed to be prohibited.

Thus, the plain language of CAA section 211(c) states that EPA is authorized to regulate fuels or fuel additives based on the impact of their emissions on health or welfare. This is consistent with the legislative history of the provision as well. The House and Senate Reports on the CAA Amendments of 1970 link the information to be obtained under CAA section 211(b) to EPA's authority to regulate under CAA section 211(c).[1] The Senate explicitly stated:

> In matters related to public health and welfare, the Committee's concern is with the effect of the actual emissions from the tailpipe, not with the composition of the fuel. The combustion of the fuel in its intended environment—inside an engine with emission control would be the proper criterion for the Secretary to use in judging the health and welfare effects of that fuel. (Leg. Hist. at 434)

The legislative history of the 1977 CAA Amendments also indicates that CAA section 211 is focused on emissions effects. For example, in characterizing section 211(b), the House report states that it allows testing "to determine the health effects of the emission products of fuels or fuel additives."[2] Thus, based on the plain language of the statute and its legislative history, EPA believes it is reasonable to interpret section 211 of the Clean Air Act to allow EPA to focus testing on the emissions effects of fuels and fuel additives.

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[1] H. Rep. No. 1146, 91 Cong. 2d Sess. (1980) at 13, reprinted in Environment and Natural Resources Division of the Library of Congress, 93d Cong., 2d Sess.; A Legislative History of the Clean Air Act Amendments of 1970 (Comm. Print 1974) ("Leg. Hist.") at 433–434.

[2] N. Rep. No. 294, 95th Cong., 1st Sess. (1977) at 25, reprinted in 1977 U.S. Code Cong. & Ad. News 1103.

The proposed emissions focus will help to avoid overlap with regulatory initiatives which may be taken in conjunction with the Toxic Substances Control Act (TSCA), the Resource Conservation and Recovery Act (RCRA), and the Occupational Safety and Health Act (OSHA). Under certain circumstances, the health and/or welfare effects associated with the production, handling, and use of fuels and additives may fall within the domain of these other regulatory programs. Restricting the general focus of today's proposed rulemaking to the effects of fuel and additive emissions will help to minimize the potential for programmatic overlap.

C. Applicability of Types of Emissions

Both combustion emissions (exhaust) and evaporative emissions are major contributors to potentially harmful air pollution, and both are included within the general focus of today's proposed rule. Concerns about the public health impacts of emissions from both of these sources are documented in the legislative proceedings associated with the enactment of section 211. Since that time, however, a number of existing and planned regulatory initiatives and industry innovations have decreased the potential risk of exposure to fuel and additive evaporative emissions, including the vapors which arise from fueled vehicles and those which are released during refueling operations. Thus, EPA invites comments in regard to the continuing need for assessing the health and environmental effects of evaporative emissions.

Exhaust emissions are inevitable products of the engine combustion process, and requirements to assess the potential adverse effects of engine exhaust are generally applicable to all motor vehicle fuels and fuel additives. This is not always true for evaporative emissions. In the case of fuels which are supplied to motor vehicle engines by way of sealed containment and delivery systems (e.g., liquified petroleum gas and compressed natural gas), the need for evaporative emission testing is less important, since human and ecosystem exposures will be extremely low or nonexistent. For ordinary liquid fuels and additives, the significance of vaporization varies widely, depending on the inherent volatility of the fuel or additive.

In this regard, a readily available volatility measurement which correlates with fuel tank evaporative losses is the Reid Vapor Pressure (RVP). Based on empirical analysis, EPA proposes that an RVP of 2.0 pounds per square inch (psi) be designated as the threshold for determining the applicability of evaporative emission testing requirements for fuels. That is, fuels with RVP of 2.0 psi or greater would be subject to information and testing requirements established for evaporative emissions, while those with RVP less than 2.0 psi would be excused. Among motor vehicle fuels available in today's marketplace, only diesel fuel, with its extremely low volatility reflected in an RVP of approximatley 0.1 psi, falls below the proposed threshold. Gasoline, alcohol fuels, and gasoline/oxygenate blends have RVPs well above the 2.0 psi cutoff point, and would thus be subject to any requirements which might be established for evaporative emission testing. Arguments can be made that other RVP cutoff points in the range of 2.0–5.0 psi might also be appropriate, and EPA requests comments on the best alternative.

With respect to additives, EPA proposes to require evaporative emission testing when the applicable additive/base fuel mixture meets either of two criteria. First, evaporative emission testing would be required if the RVP of the additive/base fuel mixture is increased by 0.1 psi or more in comparison with the RVP of the base fuel alone. Second, evaporative emission testing would be required if the partial pressure of the additive in the vapor phase, at 100 degrees Fahrenheit and atmospheric pressure, is 0.1 psi or greater. The partial pressure of the vaporized products of the additive/fuel mixture in ambient air could be determined through testing or by using thermodynamic models that account for the vapor pressures and interactions of the substances involved. While the specified criteria reflect a conservative approach, they would not require testing when an additive has a negligible volatility effect.

EPA asks for comment in regard to the suitability of using Reid Vapor Pressure and partial pressure measurements to determine the applicability of evaporative emission testing requirements for fuels and additives. Comments are also invited regarding the proposed threshold RVP and partial pressure values.

In addition to requirements for testing the effects of combustion and evaporative emissions, EPA has considered incorporating the atmospheric transformation products of such emissions within the proposed testing program. Transformation products arise in the atmosphere from a series of extremely complex chemical reactions involving atmospheric gases and volatile emissions, usually in the presence of ultraviolet sunlight. One of the results of the transformation process is known as photochemical smog. Its characteristics include reduced visibility, high levels of oxidants such as ozone, formaldehyde, acrolein, peroxyacetyl nitrates, and other oxygenated and nitrated organic substances. These secondary air pollutants from motor vehicle emissions are prevalent in the air of all urban areas in the United States, posing threats to public health, vegetation, and materials which may surpass those associated with the parent compounds themselves. By causing crop losses and accelerating the deterioration of natural and man-made materials such as rubber, paint, building stone, and fabric, urban smog also causes substantial economic losses. Thus, atmospheric transformation products are a major factor to be considered in characterizing the overall risks associated with fuel and additive emissions, and a great deal of study on their formation and effects is needed.

At the present time, however, rather than requiring laboratory testing of transformation products, EPA is proposing a theoretical approach to the issue. The conduct of valid sampling and testing procedures on the primary emissions of fuels and additives requires many technical problems to be overcome and many sources of variability to be addressed. These complexities are compounded further when attempting to create secondary transformation products of the emissions under controlled conditions and trying to carry out a meaningful testing program on the resulting chemical mixture.

While the scientific community has begun to develop experimental methods for modeling emission transformation processes in the laboratory, experience in this area is relatively limited and the necessary facilities are available in only a very few academic settings. Furthermore, the current knowledge base in this field of investigation does not permit the unequivocal identification of cause and effect relationships between discrete fuel or additive formulations and specific products of photochemical transformation. Thus, even if a broad-based testing program could be implemented, the results would probably not be useful in discriminating the specific contributions of different fuels and additives to the formation and effects of transformation products.

These scientific, technical, and practical considerations have persuaded EPA to exclude laboratory testing requirements for atmospheric

transformation products from today's proposed rule. However, these considerations do not preclude theoretical approaches for providing information about the photochemical reactivity of the emission products of fuels and fuel additives. Possible approaches include the use of mechanistic kinetic models, which can in many instances predict the degradation products arising from atmospheric photochemical reactions, or theoretical projections by qualified atmospheric chemists. Such requirements are included in the proposed program and are discussed further in Section VI.B of this NPRM. Furthermore, requirements for direct laboratory testing of atmospheric transformation processes may be added in future amendments to the rule if advances in the field make this feasible.

D. Scope of Emission Control System Testing

As previously discussed (see section II.D.2), EPA proposes to satisfy the provisions in section 211(b)(2) regarding emission control system testing by reference to the existing fuel and additive waiver application program implemented under section 211(f). Under the existing program, fuel and additive formulations which are not "substantially similar" to designated certification fuels (as defined in 56 FR 5352, February 19, 1991) cannot be introduced into commerce unless a waiver is issued by EPA. To obtain such a waiver, the producer of the fuel or additive must show that the "dissimilar" product does not adversely affect the ability of a motor vehicle's emission control system to achieve compliance with certification standards during the useful life of the vehicle.

A waiver request must address the impact of the product on tailpipe emissions, evaporative emissions, materials compatibility, and driveability. This has typically involved emission testing in accordance with the Federal Test Procedure (FTP) (40 CFR part 86) and, in certain cases, substantial durability testing to assess potential long-term effects.

Rigorous protocols are necessary to ensure fully that emission control performance will not be compromised, and are warranted for fuels or fuel additives which depart from conventional formulations. As routine requirements for the registration of fuels and additives, however, such rigorous and costly protocols may not be reasonable. The section 211(f) waiver program functions on an exception basis, an approach which has proven both practical and effective as applied to unleaded gasoline fuels and additives. Revisions currently under development will extend the applicability of the waiver program to other fuel and additive categories for which emission certification standards are established. These changes will enhance the capacity of the waiver program to adequately fulfill the aims of the emission control testing provisions of section 211(b).

Therefore, the emission control system testing provisions in today's proposed rulemaking are fully integrated with the existing section 211(f) program. With respect to new fuels and additives, manufacturers' responsibilities in this area would be unchanged. Products which conform to applicable "sub sim" definitions would not be required to undergo emission control system testing before they can be registered. On the other hand, new fuels and additives which do not meet "sub sim" criteria would be subject to the regular section 211(f) waiver application process prior to registration.

The only proposed new application of EPA's authority under section 211(b) to require emission control testing pertains to fuels and additives which were registered in the past even though they were not "sub sim" and did not undergo waiver application procedures. As discussed previously in section II.D.2 of this NPRM, such registrations have occurred because fuel and additive products other than unleaded gasoline and related bulk additives did not become subject to section 211(f) prohibitions until the enactment of the CAA Amendments on November 15, 1990. As a result, some "non-sub-sim" products introduced prior to that date were allowed to be registered without first undergoing the emission control system testing which the waiver application process ordinarily entails. Nevertheless, in the absence of evidence linking "grandfathered" products to emission control system problems, EPA believes it may not be reasonable or necessary to force all such products to undergo emission control system testing years after their initial registration and commercial distribution.

Such evidence of adverse emission control effects may come to light as a result of emission characterization requirements included within the health effects testing provisions of today's proposed rulemaking. The proposed emission characterization requirements include Federal testing procedures to determine the levels of regulated emissions generated by the fuel/additive of interest. Should any of the regulated emission products exceed established certification standards, a need for examination of the product's effects on emission control may be indicated.

EPA also proposes to set up a mechanism which would permit vehicle manufacturers or other outside parties to submit petitions to EPA, citing evidence that certain brands, formulations, or specific components of fuels or additives are harmful to vehicular emission control. If EPA judges that emission control system testing is warranted after reviewing the petition arguments, emission characterization results, and/or other available information, the authority provided by section 211(b) will be exercised to bring specified fuels and additives into the waiver application program when they would otherwise be excused by the "grandfathering" provisions of section 211(f).

EPA requests comments on the adequacy of this proposed approach. As an alternative, the authority of section 211(b) could be exercised to require all "grandfathered" products to undergo waiver request procedures under section 211(f) if they do not conform to applicable "sub sim" criteria. Comments are solicited in regard to the specific necessity and the likely costs and benefits of this more comprehensive approach in comparison to the mechanism described above.

E. Scope of Health Effects Evaluation

1. Background

Registration requirements concerning the health effects of fuels and fuel additives could potentially encompass a vast range of endpoints, exposure scenarios, mechanisms of action, and experimental protocols. Taking into account the number of fuels and additives in question, a comprehensive toxicologic program could easily overwhelm the capacity of existing laboratory facilities and support systems, and the total costs of such a program would be very likely to exceed its expected benefits. Over 6,000 fuels and additives are currently registered, and this population is expected to undergo further growth in the near future as reformulated and alternative fuels and their additives gain a wider role in the marketplace.

Other than stipulating three endpoints which must, at a minimum, be included in the regulations, section 211(b) gives EPA discretion to apply its expertise in determining the scope of the health effects evaluation program. In exercising this discretionary authority, EPA has recognized that some areas of inquiry

which are of legitimate scientific interest may not be reasonable or necessary to include in the context of a regulatory program. Rather than mandating comprehensive health effects testing as a routine registration requirement for every fuel and fuel additive, the program is designed to address testing needs on a tiered basis, with allowance for more rigorous, resource-intensive requirements as indicated by existing data and lower tier screening tests.

As previously discussed, EPA's plan to focus the rulemaking on the primary emissions of fuels and additives represents a major reduction in the potential scope of the health effects evaluation program. Consistent with this focus, the proposed health testing requirements are concerned with the effects of inhalation exposure to the evaporation and combustion products of fuels and additives. They do not specifically address the possible adverse effects of exposure to fuels and additives in the liquid state, nor do they include studies of atmospheric transformation products except at the level of data analysis and modeling. Significant reductions in program costs and overall impact on the fuel and additive industry are also expected as a result of proposed grouping mechanisms and provisions for exempting relabeled products from program requirements.

2. Health Effects Endpoints

According to section 211(b)(2)(A), the endpoints to be addressed by the program must include, but need not be limited to, "carcinogenicity, mutagenicity, and teratogenicity". Carcinogencity refers to the potential of a substance to initiate or contribute to the transformation of normal cells into neoplastic cells and the further development of neoplastic cells into tumors. Mutagenicity is the ability of an agent to produce mutations, i.e., changes in the genetic information stored in the DNA of living cells. When such genetic changes occur in germinal tissue, they may represent heritable events. Teratogenicity, in the strictest sense, refers to the potential of a substance to cause adverse effects to a fetus in-utero, resulting in fetal mortality or birth defects. In today's proposed rule, EPA has chosen to expand this category to encompass general reproductive toxicity, including adult fertility effects.

In addition to these mandatory areas of inquiry, many other health effect endpoints are germane to the assessment of the public health impacts of fuel and additive emissions. As discussed further below, the proposed program incorporates a literature search which covers all such endpoints and, on a case-by-case basis, also provides for possible testing to follow up on any significant concerns highlighted by the available literature. However, testing will routinely be required for only two health effect endpoints in addition to the mandatory endpoints described above. First, consistent with the program's focus on inhalation exposure, testing of pulmonary toxicity is proposed. Second, in view of particular scientific concerns about the potential effects of fuel and additive emissions on the nervous system, testing for neurotoxicity is included. Neurotoxicity also serves as a good general indicator of potentially harmful chemical activity.

3. Health Effects Evaluation Tiers

As depicted in Figure 1, the proposed requirements for evaluating the health effects of fuels and additives are organized within a three-tier structure, with more rigorous requirements contained in each successive tier. In part, each tier is intended to function as a screen for determining the need for and applicability of requirements in subsequent tiers. The tiered approach also permits fuel and additive producers to make full use of test results and other information which may already be available about their products. This is consistent with the objectives of section 211(e)(3), which authorizes EPA to take existing information into account to avoid duplicative testing requirements.

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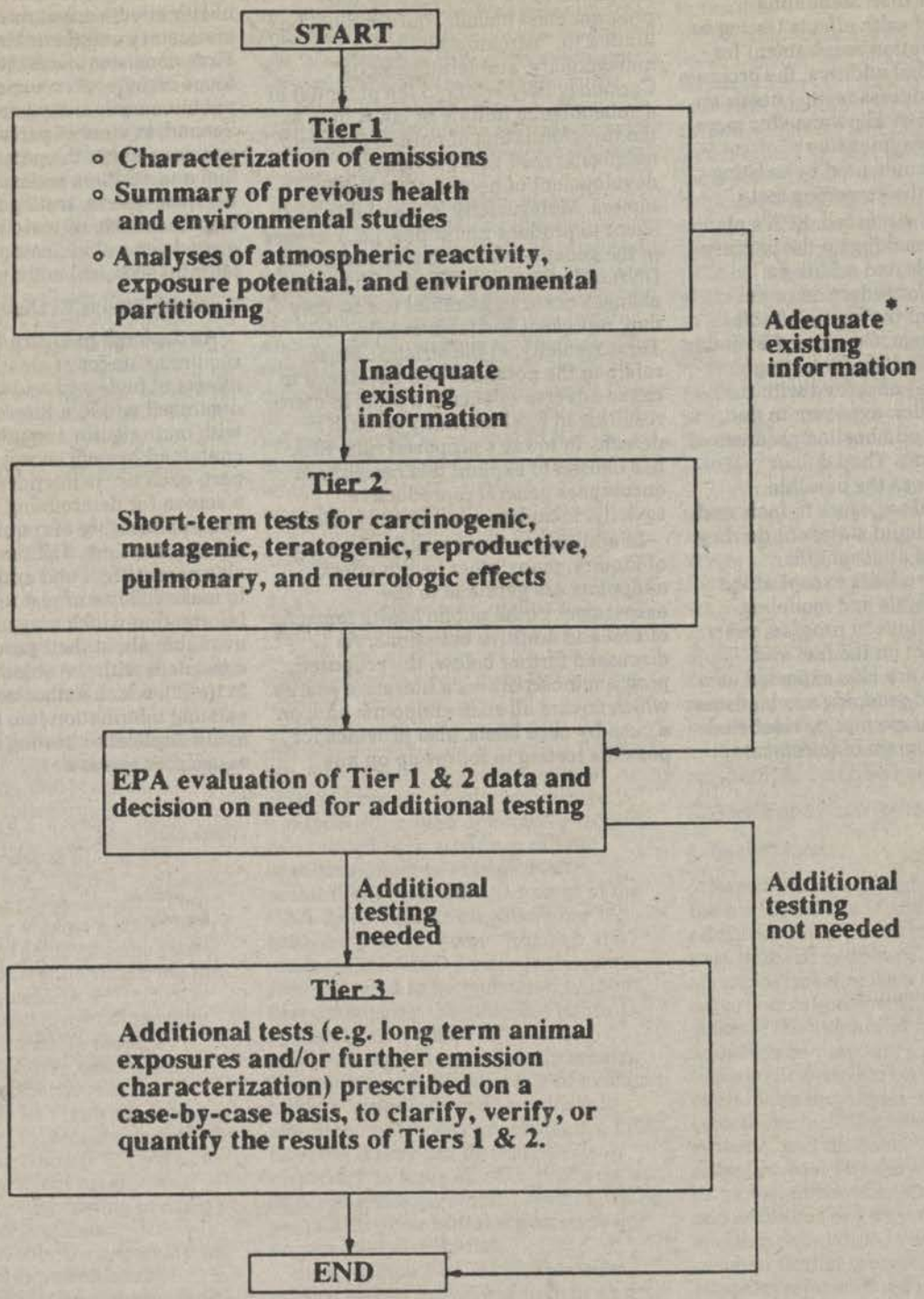
Figure 1 : Overview of Evaluation Tiers



* "Adequate" implies that the existing information includes the results of properly performed and well-documented studies comparable to the tests required in Tier 2.

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In brief, the proposed relationship between the three evaluation tiers would function as follows. Each manufacturer of a fuel or additive would be responsible for satisfying the requirements of Tiers 1 and 2. The results of both of these tiers would be reported to EPA simultaneously, according to the report format described in section VII of this NPRM. To the extent that previously conducted studies were available for the fuel or additive which satisfied the specified guidelines for the chemical and/or biological tests required in Tiers 1 and 2, the manufacturer could submit such existing studies in lieu of performing new duplicative tests. The requirements of Tiers 1 and 2 could be satisfied by manufacturers either on an individual basis or by way of a group submission consistent with the provisions of the grouping system discussed in section IV.

Within eighteen months after receipt of a report for Tiers 1 and 2, EPA would determine whether the submitted information and testing were, in fact, in compliance with the specified guidelines. Manufacturers of existing products who failed to submit data or submitted data from tests that did not comply with the specified guidelines would be in violation of this rule and would be subject to the penalties specified in CAA section 211(d). Such persons would also have to submit the data originally required. Furthermore, if EPA determined that the data requirements of the rule were not met, EPA could revoke the registration of the subject fuel or additive. Manufacturers of fuels and additives not previously registered would be prohibited from registering and selling such products until EPA determined that the requirements of Tiers 1 and 2 were met satisfactorily.

On the basis of the submitted Tier 1 and Tier 2 data and any other available information, EPA would also determine, within five years of its receipt of a given Tier 1 and 2 submittal, whether further testing of the subject fuel or additive were required under the provisions of Tier 3. As discussed further below, this determination would depend on the extent to which Tiers 1 and 2 provide sufficient toxicity and exposure information to permit regulatory decisions to be made based on the severity and extent of adverse health risks. If Tier 3 testing were deemed necessary, EPA would notify the responsible manufacturer (or group) by certified letter of the specific Tier 3 requirement(s) along with a schedule for compliance and a deadline for submittal of the final report to EPA. EPA would provide the responsible manufacturer (or group) a 30-day comment period on the Tier 3 requirements, compliance schedule, and submission deadline. EPA would extend the comment period if it appeared from the nature of the issues raised that further time for comment were warranted. In the event that EPA received no comment within the given period, the manufacturer would be considered to have consented in full to the requirements.

To keep the general public informed about the status of the testing program and to provide an opportunity for public input to the Tier 3 decision process, EPA intends to implement additional notification procedures. Beginning three years after promulgation of the final rule, and updated at least every two years thereafter while program activity remains high, EPA proposes to publish a notice in the **Federal Register** containing the following three lists: (1) Products (or groups) for which EPA has prescribed Tier 3 testing, (2) products (or groups) for which EPA intends not to prescribe Tier 3 tests based on current information, and (3) products (or groups) for which an adequate Tier 1 and 2 submittal has been received by EPA but for which a decision on the necessity of Tier 3 testing is still pending. A product would not be included in the notice until EPA has received the respective Tier 1 and 2 submittal and has reviewed it for adequate compliance with Tier 1 and 2 requirements.

For six months following each **Federal Register** notice, EPA would accept petitions from the public requesting that particular products be required to undergo Tier 3 testing when EPA has indicated that such testing would not be prescribed or when the Tier 3 decision is still pending. To be considered by EPA, such petitions would be expected to include substantive reasons for the specific testing requested. The petitions would not be binding on EPA; however, each such petition and EPA's formal response would be placed in the docket for public inspection.

The following sections discuss the general scope of the requirements in each health effects evaluation tier and the criteria to be used in making the compliance determinations mentioned above. More detailed discussion of the individual tier requirements is provided in sections V–VII of this NPRM.

Tier 1. The scope of Tier 1 encompasses chemical analysis, literature search, and modeling or analytic methods. These components of the evaluation are designed to provide basic data on fuel and additive emission products and to permit a review and assessment of the adequacy of existing information on related health effects.

Proposed requirements for the chemical analysis of fuel and additive emissions would satisfy the provision in section 211(b)(2) "to determine the emissions resulting from the use of the fuel or additive contained in such fuel", and would also provide a useful inventory of potentially harmful fuel and additive emission products. To this end, manufacturers would be responsible for the generation, collection, and sampling of the combustion emissions of their fuels and additives, and for the conduct of tests to determine the identity and concentration of individual emission products. The analyses would include (1) EPA procedures for the measurement of regulated emissions, (2) chromatographic procedures for the speciation of volatile hydrocarbon compounds, aldehydes, ketones, alcohols, ethers, and polycyclic aromatic hydrocarbons (PAHs and NPAHs), and (3) special procedures for the determination of the chemical fate of metals, halogens, and other elements of special concern when such elements are known to be present in the raw fuel or additive formulation. When applicable, evaporative emissions would also need to be generated, collected, and characterized. In the case of additives, the emissions from the respective additive/base fuel mixture would need to be compared with the emissions from the base fuel alone, in order to distinguish the additive's contribution to the emission products.

The second proposed Tier 1 requirement is a comprehensive survey of the relevant scientific literature. Both public and in-house (e.g., manufacturer or industry) sources would be included in the survey, providing a compilation of all available information from previous emission characterization and health effects testing done on the whole emissions and emission products of the fuel or additive in question or on the emissions of similar fuels and additives. For this purpose, "similar" fuels and additives would be those which meet the criteria for enrollment in the same fuel/additive group as the subject fuel or additive, pursuant to the grouping system proposed in section IV of this notice.

One of the functions of the literature search would be to determine the availability of adequate existing testing which could be submitted by manufacturers in compliance with the requirements of the registration program. If the results of the required emission characterization procedures mentioned above were already

available in the existing literature, then those procedures would not need to be repeated. Similarly, manufacturers could use the outcome of the literature search to determine the applicability of Tier 2 biological testing requirements. To the extent that the literature contained adequately conducted previous studies that conformed to the guidelines specified for any tests included in Tier 2, then such Tier 2 tests would not need to be done.

In determining whether such previous studies were adequate substitutes for conducting the Tier 2 tests, the manufacturer would need to consider a number of factors. First, the previous testing in regard to any given endpoint would have to address the effects of inhalation exposure to the whole combustion or evaporative emissions of the respective fuel or additive. Tests performed on the emissions of fuels and additives which could be classified in the same group as the subject fuel or additive would be considered relevant, but tests on products not conforming to the relevant group definition would not apply. Raw product testing, using fuels or additives in the liquid state or as whole aerosolized preparations, would not suffice. In general, inhalation studies on the individual emission products of the fuel or additive would not adequately substitute for whole emissions, unless emission characterization studies showed that an additive has only one emission product that differentiates its emissions from the base fuel. Documentation would need to be sufficient to determine that the studies were conducted in a manner consistent with generally accepted scientific principles, good laboratory practices, and the specific testing guideline in question. Important parameters would include the type and number of test subjects, the number and adequacy of dosages, the methodology and duration of inhalation exposure, and the technical methods used for monitoring the progress of the test and for analyzing the results. In general, the exposure duration would need to be at least as long as that stipulated in the specified Tier 2 guideline; however, shorter exposures would be acceptable if the test results were positive, including a demonstrable dose-response relationship. Finally, the age of the data would be a consideration. In view of technological advances and changing technical standards, older studies would be less likely to be acceptable than more recent studies. Nevertheless, the quality of the study would be the deciding factor, not the age per se. These same considerations would later be used by EPA in judging whether the submitted tests were in compliance with the program requirements.

The third proposed Tier 1 requirement would involve data analysis and modeling approaches. Appropriate methods would need to be selected and used for projecting ambient concentrations of the various emission products and for evaluating the chemical reactivity and fate of the emitted compounds in the atmosphere.

Tier 2. The second evaluation tier is composed of a series of short-term laboratory tests which comprise a minimum screening battery for the previously designated health endpoints. Most of the proposed tests involve exposure of laboratory animals to the whole emissions of fuels or additive/fuel mixtures. One exception is the Ames reverse mutation assay, which is comprised of a series of in-vitro studies utilizing bacterial substrates.

Because mutation is one of the major mechanisms involved in the transformation of normal cells to neoplastic cells, there is some overlap in the screening tests required for determining the potential carcinogenicity and mutagenicity of fuel and fuel additive emissions. Proposed Tier 2 requirements related to one or both of these two endpoints include (1) the Ames reverse mutation assay, (2) *in vivo* micronucleus assay, and (3) *in vivo* sister chromatid exchange assay. As mentioned above, the Ames assay involves *in-vitro* procedures. The other tests in this series require inhalation exposures of test animals to the emissions of the fuel or fuel/additive mixture, followed by harvesting, culture, and analysis of designated cell types.

The proposed screening tests for the other specified endpoints would generally involve the controlled exposure of test animals by inhalation to fuel or additive emissions at three different dilutions for six weeks. Following the period of exposure, relevant structures would be examined for morphologic, histologic, and functional changes related to the given endpoint. Developmental (teratogenic) effects would be studied by exposing pregnant females to emissions during the most sensitive period of pregnancy, followed by examination of the uterus and its contents just prior to the normal time of parturition. Testing for adult reproductive effects would require the exposure of rodents before and after mating and throughout pregnancy, with subsequent evaluation of the offspring as well as analysis of the reproductive organs and tissues of the adult animals.

Together with the information from Tier 1 on the composition of emissions and on the estimated chemical reactivity and potential risk of exposure to these substances, the proposed Tier 2 tests will provide a substantial body of data on the potential public health and welfare effects of the emissions produced by a fuel, additive, or group of formulations. If significant adverse effects appear very unlikely, the evaluation process would be complete at the end of Tier 2. However, if the associated risks are still uncertain, additional testing might be required under Tier 3.

Tier 3. After the results of the first two tiers have been submitted and reviewed, EPA will determine whether sufficient data are available on the health effects and exposure characteristics of the fuel/additive emissions to permit potential regulatory decisions to be made. If the information is adequate to allow EPA reasonably to conclude that the fuel or additive is quite likely to have either very low health risks or unacceptably high health risks, additional testing would probably not be required. However, if the health risk potential is still uncertain, additional studies might be required at the Tier 3 level to resolve the uncertainties. The specific Tier 3 tests required would be determined on a case-by-case basis at EPA's discretion.

While EPA will not ordinarily perform a formal risk characterization when determining whether to exercise the Tier 3 authority, both health effects data and exposure information will be considered. For example, if the potential health effects of exposure were very severe, then a need for Tier 3 would be suggested even if the exposed population were relatively small. If the potential adverse effects were more moderate or equivocal, a larger population would generally need to be at risk before Tier 3 testing would be required. Additional testing might also be required when the results of Tier 2 tests are negative (i.e., apparently non-toxic), if EPA judged that inadequate laboratory procedures or techniques interfered with the test results.

While the specific objectives and scope of Tier 3 testing would vary depending on the concerns identified in the earlier tiers, chronic (2–3 year) inhalation studies would sometimes be included. Chemical disposition studies, exposure studies, and dosimetry analyses as well as additional emission characterization requirements might also be imposed. These requirements would most often be intended as follow-up to studies included in Tier 2. However, EPA reserves the general

authority to require the evaluation of other endpoints if available information indicates that this is necessary for regulatory decision-making. For example, if the literature search suggests that the emissions of a fuel or additive are toxic to the liver or kidneys, then EPA would not be precluded from imposing hepatotoxicity or renotoxicity testing requirements under Tier 3 simply because screening studies for these endpoints were not included under Tier 2.

Section VI of this NPRM presents further discussion on the circumstances which would lead EPA to conclude that Tiers 1 and 2 provide sufficient information without invoking Tier 3, the potential criteria for imposing Tier 3 testing requirements, and the likely nature of such requirements.

4. Timing Considerations

The organization of the program's health effects evaluation requirements into hierarchical tiers ensures that the proposed rule accommodates the goals of both section 211(e) and section 211(b). Section 211(e) requires that, for existing fuels and fuel additives, the "requisite information" be furnished to EPA within three years of the implementation of the final rule. For fuels and additives not yet registered when the final rule is promulgated, submission of the required information will be a prerequisite for registration. However, section 211(e) also requires EPA to implement the authority under section 211(b), which gives the Administrator discretion to require testing to determine the potential public health or welfare effects and to "receive changes in the information required." Thus, while section 211(e) contains a time frame of three years for submission of data, it also mandates that EPA implement its broad discretionary authority to require the testing it considers necessary to assess the public health and welfare effects of fuels and fuel additives.

In 1977, Congress believed that short term testing methods would often be adequate to determine long term health effects. (See H. Rep. No. 95–294, at 309, Legis. Hist. at 2776, "However, the paramount interest in protection of public health requires that test protocols be reasonably comprehensive * * *. Relatively inexpensive but reliable test methods are increasingly becoming available for these purposes and these test methods should be utilized insofar as possible.") The proposed short term tests included in Tier 2 reflect this approach and, indeed, may often eliminate the need for further evaluation of a fuel's or additive's effects on certain endpoints.

However, these "relatively inexpensive" methods have generally not advanced to the point where they can always serve as acceptable substitutes for traditional studies entailing long term *in vivo* exposures. In some instances, the short term tests may reveal potential hazards without providing sufficient information to determine the longer term consequences of the observed effects or the extent to which they represent significant public health or welfare risks. To obtain more definitive information, tests of longer duration may sometimes be needed. For example, a higher order reproductive/developmental study would take close to a year, chronic toxicity tests might require one to two years, and carcinogenesis might not be observable until the late stages of a two- to three-year experimental exposure. The additional time required for test vehicle mileage accumulation, Tier 1 and 2 assessments, protocol development, study set-up, and results evaluation would effectively preclude submission within the prescribed three years.

Therefore, EPA has accommodated the time frame set forth in section 211(e) with the objectives of section 211(b) by using a tiered approach to testing. Data prescribed under Tiers 1 and 2 would be required to be submitted within three years of the effective date of the rule for existing products, and prior to receiving registration for new products. On the basis of such information, EPA would determine if further testing were needed under Tier 3 to assess the attendant risks. If Tier 3 testing were required, for either new or existing products (or groups), registration would be granted, but would be conditioned upon satisfactory compliance with the Tier 3 data requirements according to a timetable determined by EPA to be appropriate to these requirements. If additional testing were needed only to make up for deficiencies in information content or testing technique related to Tiers 1 and 2, then the original three-year time frame would still be in force. Notwithstanding the granting of a registration, if EPA determined that a fuel or additive was likely to present a substantial risk to the public health or welfare, then EPA could invoke available regulatory authority under other Federal law, including CAA section 211(c) or applicable sections of TSCA.

F. Scope of Welfare Effects Evaluation

Section 211(b)(2)(B) states that the Administrator may require manufacturers to furnish "reasonable and necessary" information for determining "the extent to which (fuel and fuel additive) emissions affect the public health or welfare". The term "welfare effects" refers generally to the impact which air pollution produced by motor vehicle fuels and fuel additives may have on the environment, and encompasses a broad range of effects on aquatic and terrestrial ecosystems, cultivated crops and other vegetation, natural and man-made materials, wildlife, and stratospheric ozone. Air pollution effects on the public welfare also include important environmental concerns such as noxious orders or visibility impairment, which may detract from human well-being while not representing specific dangers to human health.

A full assessment of the welfare effects of mobile-source air pollution would need to take into consideration a large number of complex and interrelated factors: the residence time of fuel and additive emissions in the air, the chemical reactions of the emissions with other air pollutants, the dispersion and deposition of the emissions and their atmospheric by products, the ability of animals and plants to bioconcentrate these substances, and the specific consequences to various ecosystems and to the public's well-being. Such avenues of investigation are extremely important to our general understanding of the causation and effects of air pollution. Future scientific study in these areas will be critical in guiding the development of general policies and effective regulatory approaches for reducing the environmental risks of air pollution.

However, at the present time, EPA proposes not to include laboratory testing for welfare effects in the requirements of the fuel and additive registration program. Except for stipulating that welfare effects requirements should be "reasonable and necessary", section 211(b) gives EPA the discretion to determine the scope of the assessment. In contrast to the provisions regarding health effects, the statue does not specifically require testing to be done to evaluate the effects of fuels and additives on the public welfare, and does not mandate specific endpoints for welfare effects assessment. At the present time, scientific experience and laboratory screening methods in this complex area are more limited than in the area of health effects. Furthermore, other EPA programs are actively involved in researching and controlling mobile and stationary source contributions to major air pollution problems such as tropospheric/stratospheric ozone, global warming, and acid rain.

For these reasons, EPA plans to address the area of welfare effects using approaches other than biological testing. Under this proposal, welfare effects requirements would include emission characterization, literature research, and modeling/analytic methods. As previously discussed, Tier 1 requires responsible producers to conduct chemical speciation procedures to identify the emission products generated by fuels and additives. These procedures will yield an inventory of potential harmful air pollutants which may have significant impacts on the general environment and public welfare as well as on the public health. Secondly, Tier 1 includes a thorough literature search for existing health-related information about the emissions of fuels and additives. This requirement will be widened to encompass available scientific literature on welfare effects, including, but not necessarily limited to, the exposure and response of plants and animals to emissions, the potential for bioaccumulation, and the concentration and persistence of the emission products in the air, soil, and water. A search of databases on environmental toxicity (aquatic and terrestrial) will be included in this requirement. Finally, the modeling requirements of Tier 1 will include analysis of the environmental partitioning and fate of fuel and additive emission products and the potential for aquatic and terrestrial ecosystem exposure. As a result of these expanded Tier 1 activites, EPA would expect to obtain useful summaries and analyses of existing data on the welfare effects of fuel and additive emissions.

While, at this time, EPA is not proposing to require biological testing for welfare effects, comments are requested on the need for and feasibility of including such tests in the program requirements. To be most useful, such comments should include specific issues to be addressed in possible welfare effects testing and practical apporoaches for examining these issues within the context of the registration program. One alternative is to retain the option of imposing welfare effects testing requirements at the Tier 3 level when the outcome of Tier 1 demonstrates both significant environmental toxicity and exposure potential. The criteria for such decisions would be similar to those used for making health-related Tier 3 decisions. Thus, Tier 3 testing for welfare effects might be required if the environmental partitioning and exposure analysis reveals the potential for broad exposure at concentrations that are likely to pose a threat to sensitive plants and animals.

If this alternative were adopted, Tier 3 welfare effects testing would be determined by EPA on a case-by-case basis. Numerous protocols are available. Endpoints of concern for aquatic, mammalian, and avian toxicology might include, but are not necessarily limited to, lethal concentrations, effects on growth and reproduction, and bioaccumulation. Plant toxicological endpoints might include growth, yield, reproduction, fruit quality, and tissue damage or loss. The exposure treatments for such tests would be administered at expected environmental concentrations.

Specific Tier 3 test requirements would be tailored to evaluate the potential environmental problems identified in Tier 1. For example, if the Tier 1 modeling results indicated that toxic emissions partitioned to air or soil and posed a risk to vegetation, Tier 3 tests on seedling vigor, life cycle, growth and reproduction, and bioaccumulation could be required to quantify the risk. Similarly, if the pollutants partitioned to water, tests relating to fathead minnow growth, reproduction, bioaccumulation, mortality, or other appropriate concerns would be required. Comment on this possible approach and other alternatives is requested.

IV. Grouping System for Fuels and Fuel Additives

A. Background and Objectives

Section 211(e) provides a number of mechanisms by which EPA can reduce the costs and burdens of compliance with the registration requirements set forth in section 211(b). In particular, section 211(e)(3)(B) permits the Administrator to "provide for cost-sharing with respect to the testing of any fuel or fuel additive which is manufactured or processed by two or more persons, or otherwise provide for shared responsibility" so that the program requirements can be met without duplication of effort. In accordance with this provision, EPA intends to establish a grouping system which would permit manufacturers of similar fuels and fuel additives, on a voluntary basis, to pool their resources and efforts in satisfying the registration requirements described in this NPRM. The groups defined by EPA in the final rule (unless modified by subsequent rulemakings) would be the only groups permitted for satisfying the requirements of the program.

To this end, proposed criteria have been developed for sorting individual fuels and additives into groups of related formulations based on similarities in their chemical/physical composition. The fuels and additives within each group are expected to have similar emission characteristics and thus essentially the same general activity with respect to their potential effects on the public health and welfare. Therefore, chemical or toxicologic information associated with individual members of a given group can reasonably be generalized to all fuels and additives in the group, and tests perfomed on selected representatives can be considered valid for the group as a whole.

While each producer of a fuel or additive would still be held individually accountable for compliance with the registration program, the grouping system would provide an opportunity for meeting the health/welfare evaluation requirements in association with manufacturers of similar products. Participation in the fuel and fuel-additive groups would be strictly voluntary, and any manufacturer could choose to fulfill the requirements on an independent basis. Those who chose to take advantage of the grouping opportunity would be able to share their planning efforts, research capabilities, and financial resources in satisfying the information-gathering and testing requirements of the program. To satisfy requirements for chemical and biological testing, the required tests would be done on one or more formulations selected to represent the group, rather than being repeated for each of the fuels and additives in the group. The results of the tests on the group representative(s) would be submitted jointly for all members of the group, with applicable costs to be shared by the respective manufacturers. Manufacturers who questioned whether the results obtained for their group's representative(s) were valid for their own products could conduct confirmatory tests on their products on an independent basis and at their own cost. However, until such independent test results were made available to EPA, the original results submitted on behalf of the group would be considered valid for all member products, and could be applied by EPA in risk assessment and risk management under CAA section 211(c).

The grouping system for fuels and additives is expected to provide a number of benefits to the producers and blenders who are responsible for registration, as well as increasing the efficiency and functionality of the registration program itself. The primary objective of the grouping system is to maximize the efficiency of the program to the public, the manufacturers, and

EPA. First, the grouping system will reduce the overall costs of the registration program by avoiding the unnecessary generation and submission of essentially redundant information by individual manufacturers with similar products. In addition, by reducing the number of individual formulations that will be subject to testing, the grouping system is expected to ease the pressure and demands on scarce laboratory capacity. Group submissions of test results and other registration information will also decrease the volume of materials which EPA must review and process.

The following sections explain the logical approach and functional rationale for the proposed grouping system and individual group definitions. Rules regarding the appointment of group representatives for health effects testing are also presented. Following these sections, issues relating to the practical implementation of the grouping system are discussed.

B. Grouping System Rationale

1. Emissions vs. Raw Product Basis

Because the information and testing provisions of the registration program are focused on air pollution effects, the fuel/additive groups would ideally be defined according to the emission products of the fuels and additives rather than the chemical composition of the raw (uncombusted) fuel and additive formulations. Unfortunately, the emissions data needed to define and carry out an emissions-based grouping system will not be available until the final rule related to this NPRM has been implemented and the new registration requirements have been completed by fuel and additive producers. Thus, the groupings presented in this proposal have been defined according to characteristics of the raw fuels and additives. EPA believes this to be a reasonable approach, based on the principle that similar raw formulations are expected to generate similar emission products and, furthermore, that the variability which may exist between similar fuels and additives will be reduced by the process of combustion. Comments are requested on the validity of using raw product characteristics as the fuel/additive grouping criteria for this emissions-based testing program and the adequacy of this grouping approach for evaporative as well as combustion emissions. If subsequent information indicates that the original groupings are inadequate, EPA reserves the authority to modify them to better reflect similarities in emission characteristics. In addition, the grouping system will be updated as necessary to accommodate unanticipated fuel and/or additive formulations which may be introduced in the future. Such changes would be implemented by appropriate rulemaking procedures.

2. Fuel/Additive Relationships

Because all fuel producers or blenders and all additive producers are individually responsible for registering their products, the possibility of duplicative testing for related fuels and additives is a problem inherent to the registration program. Registered fuel formulations nearly always contain a complement of "bulk" additives, including performance boosters, detergents, rust inhibitors, and other agents. In fact, the basic registration information submitted for most existing fuels has typically included a list of many alternative "substantially similar" additives within each purpose-in-use category, any of which may be contained in various formulations of the commercially distributed fuel. At the same time, these bulk additives must also be separately registered by their original producers, and are subject to the same health/welfare effects evaluation procedures that the related fuels must undergo. In meeting the requirements of this NPRM, each bulk additive must be mixed with an associated fuel prior to generating emissions for testing. To the extent that the resulting additive/fuel mixture is similar to existing formulations of fuels (with their bulk additive components), the health effects tests conducted on the emissions of the additive/fuel mixture would be duplicative of existing or new tests conducted on the related fuels themselves.

Similar overlap exists for aftermarket additives which are "substantially similar" to their respective fuels. As in the case of bulk additives, aftermarket additives must be mixed with the appropriate fuel prior to generating the emissions which will be subject to testing under this program. If the composition of the additive/fuel mixture closely resembles that of the fuel alone, testing efforts for the additive and the related fuel formulation will be redundant. The likelihood of redundant efforts is increased by the fact that it is the fuel/additive emissions rather than the raw fuels and additives which are subject to the proposed testing requirements.

To avoid these potential duplication problems, the proposed grouping system does not require closely-related fuels and additives to be segregated into separate groups. When the combination of an additive and its respective fuel results in a mixture that is essentially the same as typical commercial formulations of that fuel, then the additive and associated fuels are grouped together. Thus, the producers of the fuels and the related additives can fulfill their individual registration responsibilities through jointly-supported testing of one or more formulations representative of their group rather than through duplicative independent efforts. That is, the requirements for additives which are registered as part of a fuel formulation can be met in conjunction with the fuel producers. Furthermore, other bulk or aftermarket additives which have essentially the same chemical makeup as additive components of fuel formulations can also meet their requirements in conjunction with these fuel products.

By grouping similar fuels and additives together, the proposed grouping scheme also avoids the need to define each generic product or product component arbitrarily as either a "fuel" or an "additive". This problem would otherwise arise when a given substance (or mixture) can serve as either a fuel or an additive.

A good case in point is methanol. Methanol can function as a "substantially similar" additive to unleaded gasoline or, at higher concentrations, as the oxygenating additive agent in "reformulated" gasoline or diesel fuels. On the other hand, there are dedicated methanol-fueled vehicles as well as variably- and flexibly-fueled vehicles which can make use of methanol as their basic propellant, in such form as 100 percent methanol fuel (M100) or fuel composed of 85 percent methanol and 15 percent gasoline (M85).

The approach taken in the development of the proposed grouping system recognizes that fuel and additive formulations are complex mixtures of varying proportions rather than pure chemical substances. The proposed grouping system seeks to categorize fuel and additive products according to their expected in-use combinations. To the extent possible, it does not make grouping decisions based upon sometimes artificial distinctions between fuels and additives. This categorization process is further explained in the next section.

3. Grouping Approach

The basic conceptual framework for the proposed grouping system is illustrated in Figure 2. In essence, EPA has specified seven broad "fuel families" and three general "formulation

classes. The criteria which define the formulation classes" are used to subdivide the fuel families into a series of "fuel/additive categories." Another way to view this relationship is in the form of a cross-tabulation, as shown in Figure 3. Here, the fuel families serve as column headings and the formulation classes describe the rows. The resulting combinations of fuel families and formulation classes (i.e., the boxes in Figure 3) are the fuel/additive categories.

Within each category, EPA has developed criteria for further subdividing the products into "fuel/additive groups". These groups are the working units of the grouping system: it is among the members of the fuel/additive groups that cooperative evaluation and testing efforts can be pursued using designated group representatives.

This conceptual framework provides some important practical benefits. First, it avoids the need to anticipate and attempt to define all of the possible fuel and additive groups which might be required. Instead, generic rules for categorization and grouping are proposed, and specific fuel/additive groups are created in response to the product components encountered. The proposed framework should also facilitate the manufacturer's task of assigning a given fuel or additive to the appropriate group. The first step would entail the selection of the applicable fuel family and formulation class for the product according to criteria discussed below. These selections would define the proper fuel/additive category for the product. Criteria within each category would then be used to determine the appropriate group assignment. After the group had formed and arrangements made for cooperative testing efforts, applicable criteria would be applied to select a representative of the group to be used in group-sponsored testing.

BILLING CODE 6560-50-M

Figure 2: Fuel / Additive Classification Hierarchy

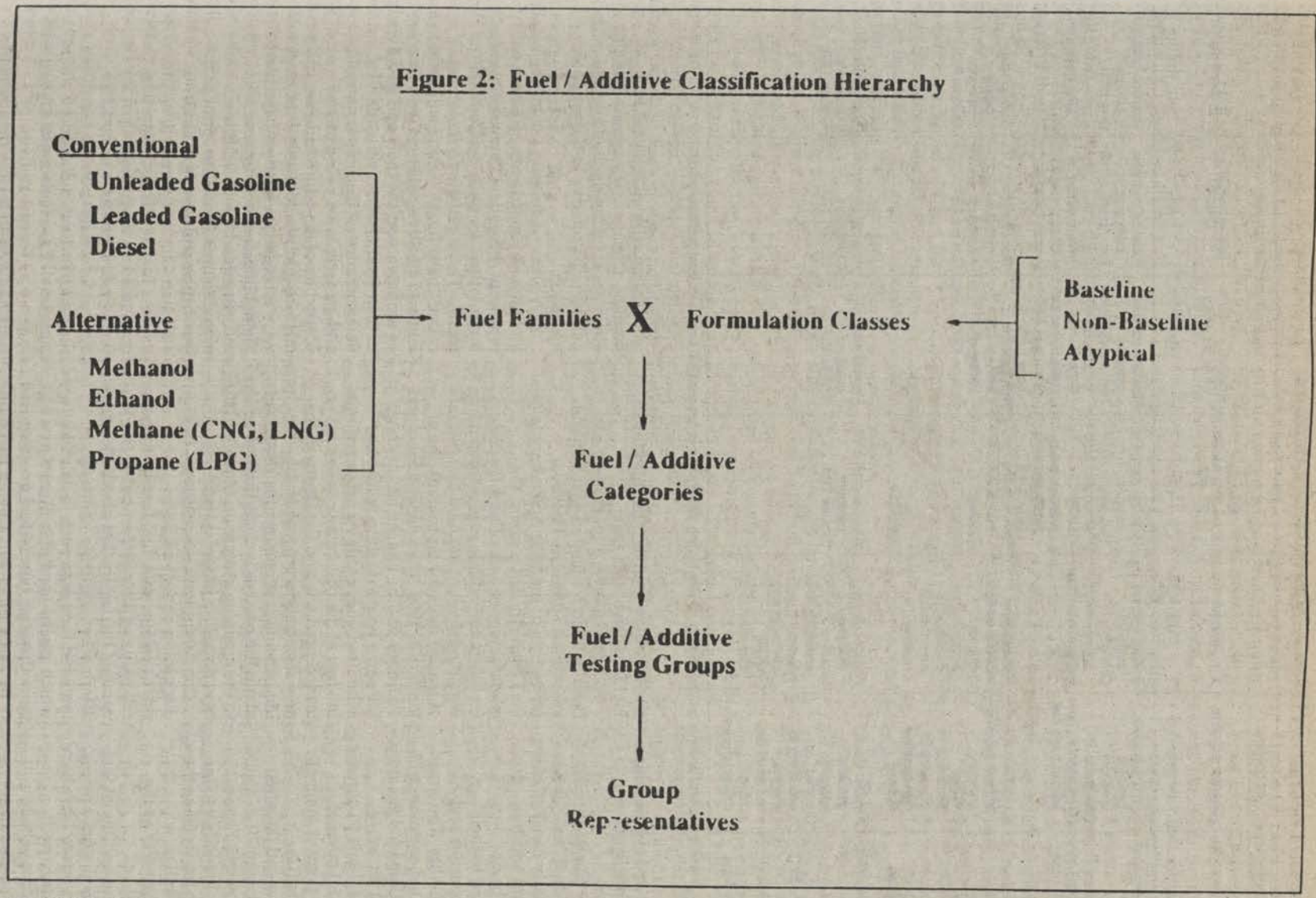

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FIGURE 3.—FUEL/ADDITIVE CATEGORIES

	"Conventional" fuel families			"Alternative" fuel families			
Formulation classes	Unleaded gasoline	Leaded gasoline	Diesel	Methanol (>=50% MeOH BY VOL)	Ethanol(>=50% EtOH BY VOL)	Methane (CNG, LNG)	Propane (LPG)
	(A)	(B)	(C)	(D)	(E)	(F)	(G)
(1) Baseline formulations.	Baseline unleaded gasoline category. One group represented by unleaded base fuel.	Baseline leaded gasoline category. One group represented by leaded base fuel.	Baseline diesel category. One group represented by diesel base fuel.	Baseline methanol category. Two groups (M96–M100 and M50–M95) represented by M100 and M85 base fuels.	Baseline ethanol category. Two groups (E96–E100 and E50–E95) represented by E100 and E85 base fuels.	Baseline methane category. Two groups (CNG and LNG) represented by CNG and LNG base fuels.	Baseline propane category. One group represented by LPG base fuel.
(2) Non-baseline formulations.	Non-baseline unleaded gasoline category. Grouped according to presence of non-baseline factors.	Non-baseline leaded gasoline category. Grouped according to presence of non-baseline factors.	Non-baseline diesel category. Grouped according to presence of non-baseline factors.	Non-baseline methanol category. Groups TBA.....	Non-baseline ethanol category. Groups TBA.....	Non-baseline methane category. Groups TBA.....	Non-baseline propane category. Groups TBA.
(3) Atypical formulations.	Atypical unleaded gasoline category. Grouped according to atypical elements and other characteristics.	Atypical leaded gasoline category. Grouped according to atypical elements and other characteristics.	Atypical diesel category. Grouped according to atypical elements and other characteristics.	Atypical methanol category. Groups TBA.....	Atypical ethanol category. Groups TBA.....	Atypical methane category. Groups TBA.....	Atypical propane category. Groups TBA.

*Each category contains one or more fuel/additive groups. Health effects testing information is required for each such fuel/additive group.

The key parameters and relationships within this grouping framework are further explained below.

Fuel families. Three "conventional" and four "alternative" fuel families have been defined. Each family consists of a constellation of fuel and additive products which share basic characteristics in regard to their chemical/physical properties and engine/vehicle applicability. The seven fuel families, represented as columns A–G in Figure 3, are: (a) Unleaded gasoline, (b) leaded gasoline, (c) diesel, (d) methanol (containing at least 50 percent methanol by volume), (e) ethanol (containing at least 50 percent ethanol by volume), (f) methane (i.e., compressed natural gas and liquefied natural gas), and (g) propane (i.e., liquid petroleum gas). As shown in Figure 3, the unleaded gasoline, leaded gasoline, and diesel families are regarded as the "conventional" fuel families, while the remaining four are referred to as the "alternative" fuel families.

EPA expects to define additional fuel families in the future as the need arises. For example, hydrogen-based fuels have not been included in the current framework because motor vehicle hydrogen fuels and corresponding hydrogen-fueled engines are not expected to be commercially available for several years. However, EPA requests comments about the possible need for hydrogen or other additional fuel families at this time.

As noted above, a fuel family has been defined for leaded gasoline and associated additives. However, provisions in the 1990 Amendments to the Clean Air Act prohibit the manufacture or sale of new leaded-fueled motor vehicle engines beginning with model year 1993, and ban the sale of leaded fuels for on-road use as of January 1, 1996. Thus, leaded fuels and additives will be phased out at about the same time that data would be submitted under today's proposed rule. In view of the upcoming constraints on leaded products and the timing of the new registration program's implementation, comment is requested about the need to include these products in the grouping system or, indeed, in the new ristration program itself.

Consistent with the previous discussion on fuel-additive relationships, each fuel family includes not only the fuels referenced in the name of the family, but also bulk and aftermarket additives which are intended for use in such fuels. Additives which can be used in conjunction with more than one type of fuel are proposed to be assigned to the relevant fuel family of which the most gallons of fuel are sold relative to the other applicable fuel families. An alternative approach would require such additives to be tested in association with all relevant fuel families. Comment is requested on this alternative, including the expected costs and benefits relative to the proposed approach.

EPA plans to develop sets of chemical and physical specifications which will represent theoretical "industry average" formulations for each defined fuel family. These generic formulations, called "base fuels" (which will include a minimal additive package), will function as archetypes of the fuels and additives in their families. For fuel additives, determination of the proper category and group is to be based on the properties of the additive/base fuel mixture that would result if the additive were mixed in its family's base fuel at the maximum concentration recommended by the additive manufacturer. Moreover, prior to the generation and testing of additive emissions, the additive is to be mixed in its base fuel at this concentration. Tests conducted on the emissions of the base fuel would then serve as controls against which tests on the emissions of the additive/base fuel mixture would be compared. Base fuels are also proposed to serve as representatives in compliance with testing requirements for some fuel/additive groups. Further discussion on the definition and use of base fuels is presented in section V.E of this NPRM.

Formulation classes. The formulation classes serve to subdivide the fuels and additives in each family into categories according to their similarity to the base fuel(s) specified for the family. Displayed as rows 1–3 in Figure 3, three formulation classes have been defined: "baseline", "non-baseline" and "atypical".

(1) The baseline formulation class (row 1 of Figure 3) consists of fuels and associated fuel additives which resemble the respective base fuels in terms of their elemental composition and their conformity with certain quantitative limits for particular elements, compounds, or characteristics. Baseline formulations in the unleaded gasoline and diesel families, for example, would contain no elements other than carbon, hydrogen, nitrogen, oxygen, and sulfur, with limitations on the allowable content of oxygen, sulfur, and other specified components.

(2) Fuels and fuel additives in the non-baseline class (row 2 of Figure 3) would contain no elements other than those allowed in the baseline class; however, they would exceed the concentration limits for certain components (or the limits on other physical/chemical characteristics) which were established for the baseline class. For fuel additives, this determination would be based on the characteristics of the mixture which would result if the additive were mixed in the appropriate base fuel at the maximum concentration recommended by the additive manufacturer.

(3) The "atypical" formulation class (row 3 of Figure 3) consists of fuels and fuel additives which depart further from their respective base fuels in that they contain elements other than those present in the base fuel or exceed specified limits on the amount of sulfur allowed. Thus, in the unleaded gasoline family, "atypical" formulations would be those containing elements other than carbon, hydrogen, oxygen, nitrogen, and sulfur and those which exceed the maximum sulfur content specified for baseline formulations. Examples of fuels and additives which would potentially fall into the "atypical" formulation class include those containing compounds such as methylcyclopentadienyl-manganese-tricarbonyl (MMT), organocerium alkanediols, hexafluoro-ethylene diamines, cobalt chloride and other halogenated metal oxides, zinc or magnesium sulfonates, ferrous or copper sulfates, boron succinamide, and many others.

For the most part, the characteristics which define the "atypical" formulation class are relatively distinct. In contrast, the separation between the baseline and non-baseline classes is less obvious. The distinction between these two classes depends on relative amounts of certain components, not the absolute presence or absence of such components. Since these components may be present along a continuum of concentrations, it is necessary to establish cut-off points which would define the amounts considered appropriate to the baseline and non-baseline formulation classes.

In regard to the "conventional" fuel families (gasoline and diesel), EPA is considering two basic alternatives for distinguishing the baseline and non-baseline formulation classes. Comments are requested from the public on the advantages and disadvantages of each. For ease of reference, these two alternative approaches are termed Option A and Option B in the discussion which follows.

Under Option A, baseline and non-baseline formulations would be differentiated on the basis of their oxygen and methanol content. In regard to oxygen, the baseline class would be restricted to formulations having less than 1.5 weight percent of oxygen, while formulations with 1.5 percent oxygen or more would fall into the non-baseline class. Because the cut-off point of 1.5 percent is consistent with the proposed minimum oxygen requirement for reformulated gasolines, all reformulated gasolines would be assigned to the non-baseline formulation class under this option.

The baseline constraint on methanol content under Option A would correspond to the methanol limitations for "substantially similar" fuels (56 FR 5352, February 11, 1991): 0.3 percent methanol by volume or, if accompanied by an equal volume of butanol or higher molecular weight alcohol, up to 2.75 percent methanol. Formulations which exceed these methanol limitations would fall into the non-baseline class.

Option B would also take oxygen and methanol content into account in distinguishing baseline from non-baseline formulations, but would establish different cut-off points for these factors. The preliminary baseline limitations on both oxygen and methanol content under Option B would correspond to the limitations on these substances in the "sub sim" rule: oxygen would be limited to 2.7 weight percent and methanol would be subject to the limits cited above for Option A. However, fuels and additives which exceed these "sub-sim" oxygen or methanol limits, but have been waivered from associated section 211(f) restrictions, would also be included in the baseline formulation class. Reformulated fuels would thus be considered baseline formulations under Option B. The non-baseline formulation class under Option B would contain fuels and additives which are not "sub sim" and have not been waivered under section 211(f). (It is important to recognize that any fuel or additive containing an "atypical" element would be assigned to the "atypical" formulation class, whether or not it has received a section 211(f) waiver.)

Under both Options A and B, distinctions between baseline and non-baseline formulations are also under consideration for other fuel and additive characteristics, including limits on the permissible levels of compounds such as aromatics, olefins, and PAHs, as well as physical characteristics such as T90 (the temperature at which 90 percent by volume of a liquid is evaporated). EPA asks for comment on whether formulations with relatively high levels of these substances or characteristics should be assigned to the non-baseline class and, if so, what specific cut-offs should be established for making the baseline/non-baseline determinations. EPA also asks for comment on whether the baseline oxygen limitation is appropriate under Option B, or whether tighter restrictions should apply, as under Option A. To be able to assess these options and alternatives, however, their potential implications for the fuel/additive categories and groups must first be understood. These relationships are described in the following sections.

Categories. As mentioned previously, the fuel/additive categories are equivalent to the "boxes" in a cross-tabulation defined by the intersection of the seven fuel families and the three formulation classes. For example, as displayed in the first column of Figure 3, the unleaded gasoline fuel family is subdivided into baseline, non-baseline, and "atypical" fuel/additive categories by the three formulation classes. Some of the categories shown on Figure 3 have been defined in anticipation of future product introductions and registration designations under section 211(a), and may not have immediate applicability to the proposed new registration program.

The precise specifications of the three categories in the unleaded gasoline fuel family will depend on whether the baseline and non-baseline formulation classes are defined by Option A or Option B. Under either option, the definition of the baseline unleaded gasoline category would incorporate some of the criteria which define "substantially similar" products. Fuels and additives in the baseline unleaded gasoline category would (1) contain no elements other than carbon, hydrogen,

nitrogen, oxygen, and/or sulfur, in the form of hydrocarbons, aliphatic ethers, and/or aliphatic alcohols, (2) contain no more than 0.3 percent methanol by volume or, if accompanied by an equal volume of butanol or higher molecular weight alcohol, up to 2.75 percent methanol, (3) contain no more than 1,000 ppm sulfur, and (4) meet applicable volatility class standards published by the American Society for Testing and Materials (ASTM D4814).

If Option A were adopted, one additional restriction would apply to fuels and additives in the baseline unleaded gasoline category: Their oxygen content would be limited to an amount less than 1.5 weight percent. If Option B were adopted instead, two other specifications would apply. First, oxygen content would be limited to 2.7 weight percent or less. Second, fuels and additives which exceeded the limitations on oxygen or methanol content, but received a waiver under section 211(f) for these "non-sub-sim" characteristics, would be included in the baseline category, as long as all other baseline criteria were met. Additional specifications would need to be established for the baseline unleaded gasoline category if restrictions were set on the aromatic, olefin, or PAH content, or on the basis of T90.

Unlike the "sub sim" interpretive rule, the specifications proposed for the baseline unleaded gasoline category do not include separate criteria for fuel additives. In this program, classification decisions for additives are to be based on the properties of the respective additive/base fuel mixture. Thus, the criteria used for sorting fuels into categories and groups can also be used for additives.

The non-baseline unleaded gasoline category is comprised of fuels (and additive/base fuel mixtures) which fail to conform to the baseline designation because their oxygen and/or methanol exceeds the baseline constraints. Under Option A, this category would include formulations of at least 50 percent unleaded gasoline blended with methanol, ethanol, methyl-tertiary-butyl ether (MTBE), ethly-tertiary-butyl ether (ETBE), and/or other alcohols and ethers, when the total oxygen content is at least 1.5 percent. Thus, the non-baseline category would include reformulated gasolines as well as a number of formulations which have previously been granted waivers of section 211(f) restrictions. In contrast, under Option B, these reformulated and waivered gasolines would fall into the baseline category. The non-baseline category under Option B would, for the most part, include gasoline formulations with oxygen or methanol in excess of waivered amounts. Under either option, the non-baseline category could contain additional fuels and additives if the other parameters previously discussed were also included in the definition of the non-baseline formulation class.

The third or "atypical" category in the unleaded gasoline fuel family includes fuels and additives which contain elements other than those in the baseline category. Thus, the "atypical" elements are those other than carbon, hydrogen, nitrogen, oxygen, and sulfur. Sulfur at concentrations greater than 1,000 ppm is also considered to be an atypical element. In many instances, products containing these elements are "grandfathered" aftermarket additives which were allowed to be registered, without consideration of their possible emission control or other effects, prior to the enactment of the 1990 CAA Amendments. To generate the emissions from such additives for subsequent emission characterization and health effects testing, the additives will be required to be mixed with the base fuel designated for the fuel family. The results obtained for the emissions of the additive/base fuel mixture will then be required to be compared to control studies conducted on the emissions of the base fuel alone.

The fuel/additive categories in the leaded gasoline fuel family are conceptually similar to the unleaded gasoline categories. The definition of the baseline leaded gasoline category would be the same as that for unleaded gasoline, except that the criteria would include allowable lead content and typical halogenated lead-scavenger compounds. The non-baseline leaded gasoline category would include products which exceed the baseline limits on oxygen or methanol.

Criteria for the baseline diesel category would also parallel those specified for unleaded gasoline, except that the limit on sulfur content would be 0.05 weight percent instead of 1,000 ppm and the applicable ASTM standard would be ASTM D975. However, the definition adopted for the final rule will depend on the suitablility for this purpose of the new "sub sim" criteria now under development for diesel products (see advanced notice of proposed rulemaking, 56 FR 24362, May 30, 1991). The non-baseline diesel category would contain products which exceed the applicable baseline restrictions. Potentially, these would be the same as "non-sub-sim" diesel fuels and additives. The "atypical" categories of leaded gasoline and diesel products would include products with elements other than those allowed in the respective family's baseline category or with sulfur in excess of the baseline limitations.

Categories within the "alternative" fuel families are shown in columns D–G on Figure 3. The baseline categories would contain typical M100 and M85 formulations within the methanol fuel family, E85 and E100 formulations within the ethanol fuel family, compressed and liquified natural gas formulations within the methane fuel family, and liquid petroleum gas within the propane fuel family. There is little prospective information regarding "non-baseline" or "atypical" products which may be introduced in these fuel families and it is possible that these categories will initially be empty.

Nevertheless, the boundaries between the baseline and the other potential categories within these four fuel families must be established. EPA is considering various sets of existing and proposed criteria for this purpose, including draft ASTM standards for alternative fuels and commercial specifications for alternative fuels proposed by the California Air Resources Board (CARB).[3] Some of these proposed specifications are summarized in the following paragraphs. However, the baseline category definitions which EPA adopts for the final rule may vary from these proposals, depending on the final standards and specifications promulgated by these and other organizations and the relative applicability of any "sub sim" criteria for alternative fuels which EPA may promulgate in the interim.

Within the baseline methanol category, M100 fuels are proposed to contain a minimum of 96 volume percent methanol. Up to 2 percent by mass may be composed of other oxygenate compounds (e.g., other alcohols and ethers) and up to 2 percent may be composed of hydrocarbons. The sulfur content of M100 fuel, according to a pending ASTM proposal, would be limited to 100 parts per million by weight (ppmw). M85 fuels would contain a minimum of 85 percent methanol by volume. The remaining volume would be composed of commercial unleaded gasoline under the CARB proposal, or of unspecified hydrocarbons according to the draft ASTM standards. CARB proposes a maximum sulfur content for

[3] Francis, Stephen R. Staff Report: Initial Statement of Reasons for Rulemaking. Public Hearing to Consider Adoption of Specifications for Alternative Fuels for Motor Vehicles. State of California Air Resources Board (CARB), Stationary Source Division, October 28, 1991.

M85 of 150 ppmw because of the unleaded gasoline component of the fuel, while a 50 ppmw limit is proposed by the Motor Vehicle Manufacturers Association for certification M85 fuel. All baseline methanol fuels would be required to contain a flame luminosity additive for safety reasons, due to the virtual invisibility of a methanol flame. The allowable composition of this additive would need to be determined for the final definition of the baseline methanol category.

Specifications for the baseline ethanol category would closely parallel the criteria for baseline methanol fuels, except that the ethanol must be denatured with commercial unleaded gasoline before being used in motor vehicle fuels. E100 would be required to have a minimum of 92 volume percent ethanol (98 volume percent denatured ethanol), with a maximum sulfur content of 100 ppmw. E85 would consist of a minimum of 81 volume percent ethanol (85 volume percent denatured ethanol), with sulfur content limited to 150 ppmw.

In the baseline methane category, compressed natural gas (CNG) and liquified natural gas (LNG) differ only in the manner in which they are transported and stored. Otherwise, both CNG and LNG fuels would be required to contain at least 88 mole percent methane, with 6 mole percent ethane allowed. Inert gases, principally CO_2 and N_2, could comprise up to 5 mole percent of the fuel and "other hydrocarbons" could make up a further 3.5 mole percent.

Liquified petroleum gas (LPG), or propane gas, would be required to contain, at a minimum, 80 percent propane by volume. CARB proposes that it also contain a maximum of 10 volume percent propene, while ASTM supports a maximum of 5 volume percent. The limit for butane and other hydrocarbons is proposed to be 2.5 volume percent and the sulfur content is restricted to 123 ppmw.

Comments and suggestions are requested regarding the most appropriate criteria for distinguishing the baseline, non-baseline, and atypical categories within the alternative fuel families. As EPA acquires additional data on alternative fuel and additive formulations, this information will be placed in the docket and made available for public inspection.

Groups. The fuel/additive groups are subdivisions of the fuel/additive categories, and represent the final level of product classification within the grouping system. These groups are the actual operating units of the grouping system. Within each group, one or more formulations will be chosen to represent all of the member products in compliance with the registration program's testing requirements. Related costs will be shared by participating blenders and manufacturers.

The number of groups defined in a particular category of fuels and additives depends on the variability among the potential products in that category and the likelihood that this degree of variability would cause important differences in their emission products. The magnitude of expected variability in the emissions of different fuels and additives must also be viewed in relation to the variations that will inevitably be introduced by the emission generation system itself. A single fuel/additive formulation will yield somewhat different emission products depending on the vehicle and engine used to generate them, and may even differ when the same vehicle is used under different operating conditions. Thus, absolute precision is not a logical goal. Instead, the objective underlying the group definitions is to sort fuels and additives together when it is reasonable to assume that their emission products would be essentially the same on a qualitative basis.

Given these considerations, the proposed groups and group representatives within each of the fuel/additive categories are described in the following sections.

(a) *Groups within the baseline "conventional" categories.* EPA is initially proposing that the baseline categories in the unleaded gasoline, leaded gasoline, and diesel fuel families (row 1, columns A–C on Figure 3) each be regarded as equivalent to a single fuel/additive group. EPA further proposes that each of these groups be represented in required emission characterization and health effects tests by the base fuel designated for the respective fuel family. Under this proposal, the baseline conventional fuel/additive groups would be very large, and each of the respective base fuels would potentially be used to represent hundreds of products. Thus, two alternative approaches are under consideration.

The first alternative would retain the concept of a single group for each baseline fuel/additive category, but would increase the number of representatives for each such group. For example, the baseline unleaded gasoline group might be represented by three base fuels, corresponding to regular, mid-grade, and premium formulations. Likewise, the diesel group might be represented by both D–1 and D–2 base fuel formulations. In addition, appropriate commercial formulations could be selected as representatives reflecting extremes in aromatic, olefin, or PAH content. If the baseline categories and groups were defined under Option B, consideration might also be given to the designation of selected oxygenated fuels as additional group representatives.

In practice, however, the designation of more than one representative per group would run counter to the general approach in the program that adequate existing information for any product in a given group can be used to satisfy the associated testing requirement for all products in the group. If adequate testing had previously been done, say, on one of the representatives of a group, these test results could be applied to all products in the group, including the other representatives. Therefore, full testing would not be required for each representative.

The second alternative would avoid this result by splitting the baseline fuel/additive categories into more than one group. Under this approach, the baseline unleaded gasoline category could be divided, say, into three groups (regular, mid-grade, and premium) and the diesel category into two groups (D–1 and D–2). Other groups, based on the factors previously discussed, would also be possible. A corresponding base fuel or selected member product would be designated to serve as the representative for each group. This approach would require the submittal of a complete set of test information, either existing or new, for each of these classifications. However, most of the previous testing on products in the baseline categories has made use of regular gaoline and D–2 diesel fuels. As a result, the other potential groups in these categories would largely be precluded from using existing test data for compliance with program requirements. EPA asks for comment on these various options for defining the baseline conventional fuel/additive groups and their representatives.

(b) *Groups within the non-baseline "Conventional" categories.* EPA proposes to subdivide the non-baseline categories of unleaded gasoline, leaded gasoline, and diesel products (row 2, columns A–C on Figure 3) into different working groups based on the specific compound(s) present in the formulation. In the non-baseline unleaded gasoline category, for example, separate groups are proposed for gasoline formulated with methanol alone, ethanol alone, MTBE alone, ETBE alone, and other individual alcohols and ethers. Products containing combinations of oxygenate compounds would be assigned to

additional groups, with separate groups defined for each combination present in one or more product formulations. Among currently registered fuels and fuel additives, EPA estimates that this proposal would produce 17 groups in the non-baseline unleaded gasoline category and one group in the non-baseline diesel category, assuming Option A were used to define the formulation classes.

Within each of these groups, the member fuel or additive/base fuel mixture containing the highest total weight percent of oxygen would serve as the group representative. In case of "ties" within a given group, the proposed regulations contain decision criteria for selecting the representative product based on the proportion of the total oxygen content which is contributed by particular oxygenate compounds. The proposed criteria give precedence to oxygenate compounds in the following order:

(1) Methanol,
(2) Ethanol,
(3) Tert-butyl alcohol (TBA or GTBA),
(4) MTBE,
(5) Tert-amyl-methyl-ether (TAME),
(6) ETBE,
(7) Isopropanol,
(8) Isopropyl ether,
(9) Other alcohols,
(10) Other ethers.

Some would argue that the groups proposed within the non-baseline categories are so narrowly defined that, in some cases, the exhaust emissions from products in different groups will probably be indistinguishable. At the current time, EPA is unaware of detailed emission speciation tests on various oxygenated formulations which would support this theory. However, it might be possible to establish programmatic mechanisms which would allow some groups to be collapsed for purposes of studies on the health effects of combustion emissions, if the results of speciation tests indicated that the emissions from the representative products in different groups were the same. Such mechanisms would need to include speciation results on the emissions from a sufficient number of vehicles that objective statistical conclusions could be reached regarding the emissions variability. Comments and suggestions on these issues are welcome.

Depending on the final definitions adopted for the baseline and non-baseline formulation classes, the non-baseline categories may contain fuels and additives with distinguishing characteristics other than oxygenate components. As mentioned previously, three such factors under consideration are aromatic, olefin, and PAH content. In these instances, the definition of groups and group representatives would follow principles similar to those applied above. To use aromatic content as an example, and applying the principles presented in the supporting regulatory text, individual compounds of concern would be grouped separately; however, if two compounds of concern were present, the representative would be that with the greater proportion of the heavier weight aromatics (e.g., greater weight given to nine-carbon than seven-carbon compounds).

(c) *Groups within the "Atypical" gasoline and diesel categories.* For fuels and additives in the "atypical" gasoline and diesel categories (row 3, columns A–C on Figure 3), EPA proposes to define a relatively large number of distinct groups according to the element(s) which caused these products to be categorized as atypical. First, separate groupings would be established for any single atypical element and any unique combination of atypical elements which occurred among the products in each category. These groupings would then be further subdivided according to the presence or absence of polymers and the presence or absence of oxygen in an amount greater than the baseline amount.

For currently registered fuels and additives, EPA estimates that this approach would result in 48 "atypical" unleaded gasoline groups and 47 "atypical" diesel groups. Comments are requested concerning this proposed grouping scheme and possible alternative approaches. For example, comment is requested on the necessity of establishing separate groups for each unique combination of "atypical" elements and conditions, as is proposed. Alternatively, it might be possible to define some reasonable rules of precedence which would allow products containing certain combinations of "aytpical" characteristics to be grouped with products containing only one of these characteristics. Such an approach would decrease the total number of groupings and would increase the number of potential products in each group. Suggestions are also welcome in regard to additional variables (e.g., aromatic content or the presence of specific oxygenate compounds) which should be taken into account in defining groups of atypical products, recognizing that each new factor could increase the number and decrease the size of the resulting groups.

For each group, the representative to be used in satisfying the group's testing requirements is proposed to be the member product with the highest concentration of atypical elements. In case of ties, a process for selecting the representative is proposed which would give precedence to the relevant characteristics in the following priority order:

(1) Total metals,
(2) Total halogens,
(3) Total of other atypical elements,
(4) Total oxygen content,
(5) Polymer content.

EPA has proposed that the representative be selected to reflect the highest concentration of atypical elements so that, if subsequent tests are negative, these results can safely be generalized to all group members. If, instead, the representative were chosen to reflect the average or median concentration of atypical elements among products in the group, the significance of negative test results would be unclear for group members with higher concentrations of atypical characteristics. In case a particular group contains products which generally reflect a distinct clustering of concentrations plus one or more products with much higher concentrations, the associated manufacturers may choose to divide the group on this basis to prevent a distant "outlier" from serving as the representative for all.

(d) *Groups within the baseline "Alternative" Categories.* Within the baseline methanol category, EPA proposes to establish two fuel/additive groups. One group would include M100 formulations (containing at least 96% methanol) and would be represented by a designated M100 base fuel formulation. The second group would consist of methanol/gasoline blends containing 50–96% methanol. The latter group would be represented by a designated M85 base fuel, reflecting the expected preponderance of end-use formulations in this group.

Because EPA has little experience with formulations in the ethanol, methane, and propane fuel families, suggestions from the affected industry organizations are requested in regard to appropriate numbers of groups and representatives for the baseline category in each of these families. At this time, EPA proposes to define two groups within the baseline ethanol category, defined in parallel to the two methanol groups described above. The baseline methane category is also proposed to contain two groups (CNG and LNG), while the baseline propane category would constitute a single group. Depending on the rapidity with which products in these categories are introduced into the marketplace, and the timetable for implementation of

expected regulations requiring the registration of these products, it may be possible to define baseline ethanol (E85 and E100), CNG, LNG, and LPG formulations to serve as the respective group representatives in time for the final rule related to this proposal. Alternatively, if products in these groups are not registered until after publication of the final rule, it may be necessary to designate the first commercial fuel to seek registration in each group as the prospective representative for similar products seeking registration at a later time. In that instance, technical amendments could be published defining the specific product formulation criteria which would be used to determine when producers of later products could rely on the testing information submitted for the first product in satisfaction of their own registration requirements. A time limit for the initial registrant's right to reimbursement would also need to be established. Comment is solicited on these topics.

(e) *Groups within the "Non-Baseline" and "Atypical" "Alternative" categories.* With respect to products which may fall into the "non-baseline" and "atypical" methanol, ethanol, methane, and propane categories (rows 2 and 3, columns D–G on Figure 3), EPA must defer the devlopment of applicable groups until information on the nature of these future products becomes available. As a practical matter, such groups are likely to be defined in response to proposed new product introductions rather than in advance of their introduction. As described above in regard to the baseline alternative fuels, the first manufacturers of atypical products in these categories to satisfy the testing and other registration requirements would have the right to seek reimbursement from manufacturers of other products who wished to rely on the first manufacturer's data for registering subsequent similar products. EPA would welcome comments on these proposals and on alternative mechanisms for defining and establishing groups within these new fuel/additive categories.

4. Alternatives for Group Responsibilities

In the approach described above, a designated representative would represent the members of a fuel/additive group in compliance with all health effects testing requirements, including both the Tier 1 requirements for chemical speciation of emissions and the biological testing requirements of Tiers 2 and 3. An alternative approach would require all unique fuel and additive formulations to undergo emission characterization independently, applying the group representative principle only in regard to biological testing requirements. This approach would provide more definitive information on the emission products of each fuel and additive, but would increase program costs to individual manufacturers and would increase demands on scarce commercial laboratory capacity. EPA requests input from the public on the likely benefits and costs of imposing separate emission speciation requirements for each fuel and additive as compared to requiring the emissions data only for the designated group representative.

C. Grouping System Implementation Issues

The practical implementation of the grouping system involves two major tasks: the organization and administration of group functions, and the development of equitable arrangements for cost sharing. Backed by its experience with respect to the TSCA testing program, EPA believes that the fuel/additive industry, under the aegis of its various trade associations or other third parties, is capable of accomplishing these tasks with little or no Agency assistance and interference. However, effective operations will be critical to the overall success of the grouping provisions of the registration program, and suggestions from the industry are invited as to practical ways in which EPA may be able to facilitate the implementation of the rule.

1. Organizational Tasks

The primary organizational task is the formation of consortiums of refiners and manufacturers whose products are potential members of the same EPA-defined fuel/additive groups. This task will entail the development of procedures which will allow manufacturers who wish to participate in group functions to locate and form working associations with other manufacturers of products which fit the same grouping criteria. While willing to provide a limited amount of support, information, and guidance when necessary, EPA does not intend to determine the proper group for each fuel and additive, nor to inform the manufacturer of that group assignment. Rather, manufacturers will be expected to determine the appropriate groups for their products independently, according to grouping criteria published in the final rule, and to enroll their products into those groups under industry-sponsored brokering mechanisms. EPA expects manufacturers to comment on the grouping scheme in this proposal and does not intend to address special requests for exceptions to the grouping scheme after the final rule is promulgated.

Once the group members have been identified, administrative agreements will need to be reached concerning the division of responsibilities among the respective manufacturers for meeting the specific requirements of the registration program and for preparing the joint submittal of test results and other information to EPA. To meet the program's literature search requirements and to document the extent to which existing test results are adequate to mitigate new testing requirements, arrangements may be needed for sharing in-house health effects test data and compiling additional information from published sources. For new testing, administrative arrangements will need to be reached with respect to the selection and/or formulation of the designated representative product(s) to be tested, the acquisition of vehicles required for emission generation, the identification of qualified personnel and laboratories to conduct the tests, and the establishment of quality assurance mechanisms which will ensure that procedures and protocols are performed according to acceptable standards. Some groups, especially those in the baseline conventional fuel/additive categories, will potentially be very large, and considerable coordination effort may be required.

The task of organizing the fuel/additive groups will be complicated by the fact that the respective producers will sometimes be competitors in the same specific market segment, and that even the identification of a product as a potential member of a given group may reveal information that a producer would prefer to keep confidential. Industry trade associations may be able to establish "third-party" mechanisms whereby individual manufacturers can enroll their products in appropriate groups while minimizing the extent to which confidential data must be revealed. Each producer will need to determine whether the cost-sharing advantages provided by group participation outweigh the possible competitive risks involved. However, whether a manufacturer chooses to participate in group functions or to satisfy the registration requirements through independent testing, section 211(b)(2) stipulates that "the results of such tests shall not be considered confidential".

2. Cost-Sharing Provisions

The main purpose of the proposed grouping system is to apply section 211(e)(3)(B), which permits producers who manufacture or process the same fuel or fuel additive to share the responsibilities of the program so that requirements can be met without duplication of cost and effort. EPA has had extensive experience with cost-shared testing conducted by manufacturers in compliance with regulations under TSCA Section 4. To date, EPA has found the persons conducting tests under Section 4 have chosen in each instance to work out their own arrangements for cost-sharing or reimbursement without any need for EPA involvement. While formal data reimbursement regulations were issued for this purpose in 40 CFR part 791, no one has yet invoked the procedures therein.

EPA believes that a similar result would be likely if cost-sharing rules were promulgated within the fuels and fuel additives registration program. At this time, therefore, EPA proposes to leave the development of specific cost-sharing agreements up to the participating manufacturers. However, comments are solicited concerning the potential need for EPA involvement in these arrangements. If such involvement is deemed necessary, opinions are requested on the adequacy of existing TSCA regulations for this purpose or an alternative cost-sharing guidelines or procedures.

One possibility under consideration would require manufacturers of existing fuels and fuel additives to notify EPA within one year after publication of the final rule if they intended to comply with the rule as part of a group and, if so, to identify the person or entity which was organizing the testing. For new fuels and fuel additives, manufacturers would be required to conduct the testing individually unless they first certified to EPA that they intended to rely on data previously submitted by a manufacturer of a similar product. The certification would need to include assurances that the first manufacturer had been notified of this intent and that the first manufacturer has the right to reimbursement under procedures such as those specified at 40 CFR part 791. Comments on these possible mechanisms are requested.

Arrangements for cost-sharing will need to account for two general situations. In one case, groups of producers would organize prospectively to complete the same program requirements for their similar products. In this instance, cost-sharing arrangements could be reached in advance of testing. Such arrangements might divide the program costs on a per-product basis or in proportion to applicable market share, sales revenue, production volume, and/or other relevant parameters which participating manufacturers agree would be equitable.

The second situation involves the case where adequate information already exists for the registration of a product because the required tests have been completed by another manufacturer (or group of manufacturers) on similar products (i.e., products meeting the criteria for membership in the same group as the new product). In this instance, the costs of program compliance would already have been incurred, and a manufacturer with a similar product wishes to reply on this existing testing in satisfaction of the registration requirements for his similar product. EPA proposes that, to use the existing test results, the new manufacturer would be required to notify the existing manufacturer that he has used the data and apprise him of his right to be reimbursed. EPA invites comments on whether these arrangements should be left to the producers to work out among themselves. Alternatively, EPA rules could be promulgated specifying the computation of reimbursement fees and the number of years that reimbursement rights would remain in effect. In that instance, EPA proposes that the "ownership" period for registration information should last for five years after data submission. To be reimbursed when new producers seek to rely on their existing data for fuel/additive registration, the original producers (or groups of producers) would be required to document the costs already incurred in conjunction with the registration program's information gathering and testing requirements. The level of reimbursement would be determined according to the applicable costs and the number of producers relying on the information for registration purposes. Comments are requested about the suitability of these or other alternative reimbursement arrangements.

V. Emission Generation

As discussed in section III.E, the proposed requirements for evaluating the potential emissions-based health and welfare effects of fuels and fuel additives include analytic procedures in Tier 1 for characterizing the chemical composition of fuel/additive emission products, as well as biological studies in Tiers 2 and 3 involving the exposure of laboratory animals to fuel/additive emissions. This section presents the methods proposed for generating, storing, and sampling the emissions to be used in these chemical and biological tests. With a few noted exceptions, emissions will be generated according to the Federal Test Procedures (FTP) for light-duty vehicles (40 CFR part 86).

A. Vehicle Requirements

1. Vehicle Selection

Because the composition of emissions produced by a given fuel or additive is likely to vary somewhat depending on the vehicle involved, a fully comprehensive testing program would need to encompass the emissions from many vehicles representing a complete cross section of the in-use fleet. In the context of the proposed Reformulated Gasoline Rulemaking, EPA suggested that to obtain a statistically significant set of emission characterization results encompassing the variety of emission control systems available, emissions would need to be generated from at least 20 vehicles for each fuel under evaluation (see Supplemental Notice of Proposed Rulemaking, available in Docket # A 91 02). For purposes of the routine registration of motor vehicle fuels and fuel additives, however, EPA believes that such an extensive emission sampling and testing scheme may not be reasonable or necessary. EPA is initially proposing that only one vehicle be required to generate the emissions to be used for the chemical and biological testing included in Tiers 1 and 2, while potential Tier 3 requirements might call for the use of additional vehicles. Alternatives to this basic proposal are discussed later in this section.

Similar to the reformulated gasoline proposal, the parameters to be considered in specifying the vehicles to be used for emission generation include vehicle class, emission control equipment, and vehicle sales volume. First, for each fuel family, the vehicle class and subclass to be used for emission generation will be that which reflects the highest yearly amount of consumption of fuels in that family. Normally, vehicle classes include light-duty vehicles (LDV), light-duty trucks (LDT), and heavy-duty vehicles/engines. For purposes of this program, however, EPA proposes that LDV and LDT be combined into one vehicle class. LDT represent a large fraction of the gasoline fuel consumed in the U.S., but less than the fraction attributable to LDV. Thus, if LDV and LDT are maintained in separate classes, LDT would probably not be selected for generating emissions from gasoline fuels and fuel additives. Although LDV and LDT are expected to

produce similar emissions, reflecting the fact that their engines, emission control systems, and emission standards are similar, the absence of LDT in the program might still reduce the representativeness of the test emissions for gasoline fuels and fuel additives. Comment on whether or not LDV and LDT should be combined into one vehicle class would be appreciated.

In view of the overwhelming proportion of total diesel vehicle miles which are traveled by heavy-duty diesel vehicles, heavy-duty engines are expected to be used to generate test emissions for diesel fuels and fuel additives. Because of the lack of heavy-duty vehicle testing facilities, however, emission generation using light-duty vehicles of the same fuel class may be preferable from the standpoint of practicality. Comments are requested on this issue.

The next step is to determine the selection criteria for specific vehicle models. The vehicles to be used for emission characterization must be new vehicles of the model year in which testing begins. However, vehicle selection criteria are to be based on technology characteristics of the previous model year. The group or company seeking registration would first determine the most common fuel system and emission control system combination in the applicable vehicle class. The criteria to be considered for light-duty gasoline powered vehicles, for example, might be fuel metering approach (carburetted, fuel injected (port, throttle body) and emission control approach (catalyst type, air injection, exhaust gas recirculation (EGR), feedback control, etc.). The company could then select for testing any one of the top five selling models with these characteristics, based on the previous model year's sales. If any of the five selected models were not available in the model year when the new vehicle was to be purchased for testing, the selection would be limited to the models remaining.

In general, the vehicle selection criteria described above would be used to determine the representative vehicles for all fuel families. However, fewer than five vehicle models may be available for "alternative" fuel families. In such instances, any available model could be used for testing. The proposed vehicle selection procedure is more thoroughly described and illustrated in a memorandum entitled, "Vehicle Selection Procedures for the Proposed Fuels and Fuel Additives Rulemaking," available in the public docket.

Comment is requested on how to determine the types of vehicles that should be used to test fuels and additives which are not commonly used or intended to be used in the vehicle type which the standard vehicle selection procedure would prescribe. This situation might arise, for example, in the selection of vehicles for testing lead substitute aftermarket additives (which may damage vehicle catalysts) and for testing number 1 diesel fuel (most commonly used in urban buses).

2. Mileage Accumulation Requirements

Mileage accumulation is important for this program for two primary reasons: It "breaks in" a new vehicle so that the emissions stabilize (an effect which is independent of the fuel used in the vehicle) and it allows potential long-term effects of the fuel or additive on emissions to be assessed. Suggestions for the amount of mileage accumulation appropriate for this program have varied. Some have suggested that the minimum mileage needed to "break in" a new vehicle (approximately 4,000 miles for light-duty vehicles) would be sufficient for this program, claiming that the fuels used in the vehicle do not drastically affect the emissions of a vehicle. Others have suggested that emission characterization be continued throughout the useful life mileage of the vehicle (50,000 miles for light-duty vehicles, changing to 100,000 miles in 1994) in order to determine the full effects of the fuel or additive being tested. Another advantage gained by requiring a significant amount of mileage accumulation is that it reduces the chance of "gaming" the test results by discouraging the testing of a number of vehicles and selection of the best results. Therefore, EPA proposes 25,000 miles as the minimum mileage which must be accumulated using the subject fuel or additive/base fuel mixture before testing is conducted. This value reflects a point between the two positions that provides a reasonable opportunity for long-term effects of the fuel or additive to be revealed, while at the same time avoids undue burden. As will be discussed further below in sections V.D and VI.A.2.f, additional mileage may be necessary for fuels and additives containing atypical elements. Comment with supporting data is requested regarding the appropriate mileage accumulation requirements for vehicles used in the testing of baseline/non-baseline and atypical formulations.

The proposed mileage accumulation would be required to begin when the vehicle was new, using only the fuel or additive/base fuel mixture of interest. Mileage could be accumulated by any appropriate means. For example, the vehicle could be placed in the company's fleet, held for controlled fleet use, or driven on the street, test track, or dynamometer solely for the purpose of mileage accumulation. Vehicles would be required to be unmodified and maintained as instructed in the vehicle owner's manual.

3. Alternative Approaches

As stated earlier, a comprehensive determination of the emissions from a fuel or additive could require testing the emissions from at least 20 vehicles, and EPA request comment on whether testing emissions generated by only one vehicle is sufficient to screen for representative emission compounds and their related biological effects in this program. EPA is considering a compromise between testing one vehicle and testing 20 vehicles, in which perhaps three to six vehicles, representing differing emission control technologies, would be used to generate emissions for emission characterization purposes. One of these vehicles, or perhaps a combination thereof, would be chosen to generate emissions for biological testing.

Another possible variation in the proposal would allow in-use vehicles which have already accumulated sufficient mileage to be employed for generating emissions instead of requiring mileage accumulation on new vehicles. While this alternative would reduce compliance costs, it has some possible drawbacks. Long-term emission effects caused by the fuels and additives previously used in these vehicles could alter the generated emissions and therefore the emission characterization and biological test results. It would then be difficult to assess the extent to which the test fuel was responsible for the test results. Another drawback is the absence of information on the long-term effects of the test fuel or additive. Finally, gaming could occur such that emmission characterization could be performed on many vehicles and only the best results submitted. Comment is requested on whether in-use vehicles would be acceptable for this program.

EPA has also identified an alternative emission generation scenario which incorporates a number of the possible program modifications described above. Because this scenario would require the use of more vehicles in the testing program in order to increase the confidence that can be placed in the results, methods of reducing other associated costs have also been identified.

First, with regard to fuels and additives that do not contain an atypical element (i.e., those in the baseline and

non-baseline formulation classes), the required number of vehicles would be increased from one to six. The vehicle selection criteria would include the same emission control system characteristics as described previously, except that six technology groups would be determined from the emission control system combinations, and the top seller from each group would be included in the program.

To reduce costs, mileage accumulation requirements per vehicle would be reduced, perhaps to the 4,000–10,000 mile range. The use of new vehicles would be encouraged, but in-use vehicles would be permitted after specified intermediate preconditioning, assuming that the fuel or additive producer was willing to accept the program outcome risk of using vehicles which had been operated on other fuels and additives.

A prime tenet of this approach is that emissions carryover from the use of one fuel or additive to another in the same vehicle can be eliminated by an intermediate preconditioning process. This would permit one vehicle to be used to generate emissions for more than one product. One potentially applicable intermediate preconditioning method has been used in the Joint Auto/Oil Air Quality Improvement Program. Additional discussion on preconditioning methods is available in a memorandum in the public docket. EPA asks for comment on the validity of the assumption that fuel emission carryover effects can be eliminated with a reasonable amount of intermediate preconditioning.

A valid preconditioning process would not only permit previously used vehicles to be employed in the testing program, but would also allow the same vehicles to be used for testing more than one product. For example, the proposed testing of fuel additives requires the emissions of an additive/base fuel mixture to be compared with the emissions of the base fuel alone. This could be accomplished by performing one set of emission characterization control tests on the base fuel in each of the six vehicles. Then, with intermediate preconditioning, the same set of six test vehicles could be used to perform emission characterization for any number of fuel additives in the same fuel family, excluding those with "atypical" elements. In this way, only one set of base fuel emission characterization results would suffice for all products that underwent testing using the same set of vehicles.

Specific fuel formulations subject to testing would also be required to undergo emission characterization using six vehicles. Comment is requested as to whether producers testing these specific formulations should, for comparison purposes, also be required to test the applicable base fuel using the same six test vehicles (assuming that the fuel being tested is not itself a base fuel). Under this scenario the incremental expense would be expected to be small. As was mentioned above, a specified intermediate preconditioning cycle would have to be performed at the time the vehicle is switched between different fuels, additive/base fuel mixtures, or the base fuel.

Once the emission characterization was complete, one of the same six test vehicles would be selected and used to generate emissions for biological testing. The selection of this vehicle would be based on analysis of the emission characterization data. A number of alternative selection criteria are possible. For example, the vehicle could be chosen to represent either the average or highest emission rate of volatile organic compounds, total toxicants, particulate matter, and/or PAH. EPA would appreciate comment on the parameters that should be used to select the vehicle to be used for emission generation for biological testing. Another possibility would be to use all six vehicles, with each vehicle generating emissions for one-sixth of the testing time period.

For fuels and additives in the atypical formulation class, the atypical elements potentially have a much greater chance of affecting the vehicles' emission control components, making long-term emission effects much more likely. Thus longer mileage accumulation to steady state may be necessary. Furthermore, multiple use of vehicles may not be possible because the intermediate preconditioning process may not be effective at eliminating potential carryover effects of the atypical elements. To increase confidence in the results of the testing, six vehicles selected as described above would be required to accumulate mileage. In order to isolate long-term effects, EPA proposes to require the use of new vehicles, but asks for comment on whether low mileage used vehicles would be an acceptable alternative. Emissions from all of the test vehicles would be characterized, and these results would be compared with the baseline group representative of that fuel class (see section V.E.2).

Finally, two alternatives have been identified for conducting biological testing on group representatives in the atypical formulation class. Under the first alternative, only one of the vehicles would be chosen to undergo further mileage accumulation to reach steady state (e.g., the vehicle with the highest atypical element emission rate of the six vehicles). Then, speciation of the emissions containing atypical elements and the required biological tests would be performed. Under the second alternative, all of the vehicles would need to reach steady state. Speciation of the atypical emissions would then be done for all six vehicles. Biological testing could be done either on one selected vehicle, or each vehicle share in the emission generation for biological testing (as was discussed above for the baseline and non-baseline formulation classes). EPA solicits comments on these scenarios designed to cost-effectively generate the data required by the statute.

B. Combustion Emission Generation

The FTP through the exhaust emissions test is the method proposed for generating the combustion emissions needed to meet the emission characterization requirements of Tier 1. These procedures are specified in 40 CFR part 86 for the certification of new motor vehicles, and may vary depending on the fuel family and vehicle class.

Consistent with the current FTP requirements, canister loading during the FTP preconditioning phase must be done by methods that use actual evaporative emissions rather than bench methods, which use a surrogate compound for canister loading. This will help to ensure that emissions are generated exclusively from the fuel or additive being tested. Modifications to the standard FTP will be needed to collect particulate and semi-violatile emissions, which are required both for emission characterization and in vitro biological testing. The particulate fraction is to be collected on filters and the semi-volatile emissions collected immediately downstream from these filters, using porous polymer beds or other equipment designed for their capture.

After collection, the organic fraction of the particulate and semi-volatile emissions would be extracted separately from each other using appropriate laboratory procedures. Because the extracted materials would be much more stable than gaseous combustion emissions, they could be stored for longer periods of time before use. For this reason, the particulate and semi-volatile emissions could be generated and used in different locations, as long as proper handling techniques were observed.

For in vitro biological testing purposes, the particulate emissions may

be collected on a single filter instead of on multiple filters as prescribed in the FTP. Similarly, semi-volatile phase emissions may be collected on one apparatus for the entire driving cycle. If an insufficient amount of particulate or semi-volatile material is obtained during a single driving cycle, the FTP may be repeated as required and the extracted organic fractions combined.

Many of the in vivo biological tests proposed in today's notice would require six weeks exposures of laboratory animals to whole combustion emissions for a minimum of six to eight hours per day. The continuous generation of emissions throughout the required exposure periods requires light-duty vehicles to be driven through repeated Urban Dynamometer Driving Schedule (UDDS) driving cycles and heavy-duty engines to be operated over repeated Engine Dynamometer Schedule (EDS) cycles (40 CFR part 86, appendix I), with emissions diluted and routed directly from the vehicle to the biological testing chamber. Provisions in the proposed regulations allow for a limited amount of emission generation disruption without voiding the biological test.

The use of automated systems may provide a means to reduce the difficulties associated with continuous emission generation. Automated systems would involve computerized mechanisms used to drive the vehicle on a chassis dynamometer or an engine on an engine dynamometer. These systems could be used in place of human operators to perform the monotonous task of performing repeated driving cycles. Throttle actuators linked to a computer system along with electric chassis dynamometers could be programmed to drive vehicles over driving cycles. Such systems have been used in the past for mileage accumulation purposes and for assembly line vehicle testing. However, their application is limited to vehicles equipped with automatic transmissions.

Robotic drivers are fairly recent options for automated vehicle operation, and are expected to provide high repeatability and versatility. The technology for these systems has been developed for related applications, but has not been widely used thus far.

A third possibility for automation would involve the use of an isolated engine (in conjunction, perhaps, with the vehicle's fuel and emission control systems) attached to an engine dynamometer. Since the input parameters required for controlling engine dynamometers are different from the wheel speed driving trace of the chassis dynamometer, the light-duty Urban Dynamometer Driving Cycle would need to be translated to an equivalent load-speed pattern, or else an alternate driving cycle would be required.

EPA is initially proposing to require the use of engine dynamometers to generate emissions for the heavy-duty class and chassis dynamometers to generate emissions from light-duty vehicles. In the heavy-duty case, use of an engine dynamometer for emission generation is consistent with all existing heavy duty emission testing programs and also provides considerable cost advantages. In contrast, in the light-duty case, existing emission testing programs require the use of a vehicle operated on a chassis dynamometer for emission generation. To use an engine dynamometer for this purpose, extensive testing would have to be done to demonstrate that the exhaust emissions were the same as those generated from the corresponding light-duty vehicle operated on a chassis dynamometer. Many technical problems would have to be confronted in attempting to isolate the engine and emission control equipment from the vehicle while assuring that the representativeness of the emissions would be maintained. These would include decisions on which vehicle systems must remain attached to the engine and what methods to use to terminate unnecessary systems; the addition of a flywheel, harmonic balancer, and bell housing to balance the system for vehicles equipped with automatic transmissions; determination of the effect of detaching transmission sensors such as gear sensors, clutch lock/unlock sensors, and torque coverter speed sensors; and the translation of the LA–4 chassis dynamometer driving cycle to an operating cycle appropriate for use with an engine dynamometer.

EPA believes that the putative cost savings associated with the use of a light-duty engine dynamometer rather than a light-duty vehicle and chassis dynamometer would be overridden by the costs associated with resolving these problems and performing tests to prove that the solutions were valid. However, EPA is open to comment on the relative costs and benefits of the light-duty chassis dynamometer vs. engine dynamometer, and would consider making the use of the engine dynamometer optional in this program if the comments provide persuasive evidence that this option would be advantageous.

C. Evaporative Emission Generation

As discussed above the section III.C, the evaporative emissions of some fuels and additives will be required to undergo emission characterization and biological testing. The composition of evaporative emissions does not, in general, resemble fully-evaporated whole samples of raw fuels or fuel additives due to differences in vapor pressure of the fuel or additive components and the effects of evaporative emission control equipment. The largest sources of evaporative emissions from vehicles are diurnal, hot soak, and running loss emissions. For the purpose of this rulemaking, refueling emissions are also regarded as evaporative emissions due to their generally similar composition. While the most technically accurate method of testing these emissions would be to characterize and perform biological tests on each evaporative source separately, such a plan would multiply the costs involved. The proposed evaporative emission characterization requires call for the speciation of emissions from all types of evaporative emissions measured in the FTP effective at the time the testing is done. EPA asks for comments on which types of evaporative emissions should be speciated and if the program should be expanded to include running losses and refueling emissions.

EPA is also proposing that evaporative emissions be generated without using key components of evaporative emission control systems, such as the carbon adsorption canister. An intact control system would represent normal system design, and removal of the canister would change the relative concentrations of the evaporative emission products. On the other hand, disconnecting the evaporative emission control system would provide the opportunity to examine emissions simulating uncontrolled emission sources such as refueling operations and leaky evaporative emission control systems. Furthermore, as discussed below, use of emission control may not be practical for evaporative emission generation for biological testing purposes. If the emission characterization procedures are to be performed on emissions that closely resemble those used for biological testing, it may thus be necessary to disconnect the emission control system when generating emissions for speciation purposes, as well.

Three simplified procedures are being considered for continuously generating evaporative emissions for in vivo biological testing. The first would require that evaporative emission generation be performed by using a

sealed housing for evaporative determination (SHED). The diurnal heat build section of the FTP would be performed, and samples of the vapors in the SHED would be withdrawn into Tedlar bags and used for testing. Chemical artifacts caused by storage of evaporative emissions are expected to be much less of a problem than for combustion emissions. For this purpose, the SHED would need to be equipped with a sampling port and sampling pump. To avoid modification of the sample, a pump with low hydrocarbon absorption and emission characteristics (e.g., a teflon diaphragm pump) would be required. Generating evaporative emissions without any of the key emission control system components in place would help increase the concentration of evaporative emissions in the SHED in order to produce a sample useful for biological testing. However, the concentration of evaporative emissions in the SHED might still be too low to be useful for biological testing purposes, even if the evaporative emission canister were disconnected.

Another alternative would use evaporative emission speciation data to make a surrogate mixture of adequate concentration for biological testing. While this method might seem to have some practical advantages, it would rely heavily on the speciation data as a complete and accurate representation of in-use evaporative emissions.

The third method for generating evaporative emissions would be an evaporative emission generation chamber instead of a vehicle. The chamber would be temperature and pressure controlled so that its characteristics were similar to the head space of the fuel tank of a vehicle where in-use diurnal and refueling emissions are generated. The chamber would be 40 percent filled with the fuel or additive/base fuel mixture, and the remainder filled with air. The system would be heated to a prescribed level and the fuel or additive mixture allowed to evaporate. When equilibrium was reached between the fuel in the liquid and vapor states, the vapor and air mixture would be withdrawn for dilution and testing. The fuel or additive/base fuel mixture would need to be renewed periodically to keep the emissions of constant character.

An extension of this concept would involve the construction of a bench apparatus using a duplicate of the fuel tank of the vehicle involved together with heating elements. Vapors could then be drawn directly from the head space of the fuel tank. However, this method might create safety concerns concerning the heating of the sample to cause evaporation. One option would be to reduce the air pressure over the fuel or additive/base fuel mixture to induce evaporation.

In comparison with the SHED-based system, the bench method has the advantage of requiring much smaller, less expensive, and simpler equipment. Emissions could be generated close to the biological testing chambers, and largely automated systems could be used. Another advantage is that the concentration of emissions which occurs in the biological test chamber could be controlled to a much greater extent with bench methods than with the SHED method, in which air dilution is fixed by the size of the SHED and the specific vehicle generating the emissions. The surrogate emission generation method has the drawback of relying too heavily on the speciation data for its accuracy. For these reasons EPA proposes to require the use of a bench method (i.e., evaporation chambers) for generating emissions for in vivo biological testing. Comments are requested on this issue.

EPA proposes that evaporative emission control equipment not be used on the emissions generated by the evaporation chamber. As stated above, this would enable the testing of emissions which represent uncontrolled emission sources such as refueling operations. In addition, removal of the emission control canister would allow the generation of more concentrated emissions, which are required for the biological tests specified under Tier 2 of this program. A third reason is the complexity of the procedures which would be required for canister loading and purging cycles if the emissions from the evaporation chamber were to resemble in-use vehicle evaporative emissions. EPA requests comment on this question of the proper use of evaporative emission control systems for biological testing purposes.

EPA is aware that the methods proposed are different for combustion and evaporative emissions with respect to the role of emission control equipment. This inconsistency arises from practical considerations. First, in the case of combustion emission control, many different vehicle components are involved. While some of these components could possibly be removed or disabled to simulate emission control malfunction, others are integral to proper running of the engine and their removal would cause the vehicle to be inoperable. Therefore, generating totally uncontrolled combustion emissions would not be a reasonable option. Secondly, the types of combustion emission control equipment and each component's individual effects on emissions varies greatly from vehicle to vehicle, making it extremely difficult to devise a reasonable basis for determining which components could selectively be disabled. Thus, all combustion emissions control components are proposed to be maintained in the proper functioning condition during combustion emission generation for this program.

Conversely, at the present time, the primary (vehicle-based) source of evaporative emission control is the evaporative emission canister. This device does not affect a vehicle's operability. In order to obtain evaporative emission samples of sufficient concentration for biological tests, and to represent uncontrolled emissions sources, EPA has proposed that evaporative emission control equipment be disconnected for evaporative emission generation.

Comments are requested on whether a consistent use of emission control equipment for combustion and evaporative emissions is important for this program, and if so, how the program should be restructured to accomplish this end. If the program were restructured, EPA specifically asks for comment on the desirability of using a controlled evaporative system for emission characterization purposes and an uncontrolled system for biological testing.

D. Additional Emission Generation Topics

1. Emissions for Atypical Elements

The "atypical" elements described in section IV (generally, those other than carbon, hydrogen, oxygen, nitrogen, and a limited amount of sulfur) may form particulate combustion products which can deposit on the inside of the vehicle's engine or emission control system. Deposition of the atypical elements inside the vehicle may be particularly significant when the fuel or fuel additive is first introduced, thus interfering with identification and accurate measurement of the atypical species. As the internal deposits increase, it is expected that a greater fraction will be emitted into the atmosphere until the net deposition inside the vehicle/engine is small.

As is discussed further in section VI.A.2.f below, additional requirements are thus proposed for "atypical" fuels and additives to ensure that the atypical elements are fully represented in the sampled emissions. After the minimum

25,000 miles have been accumulated, emissions will be collected from the vehicle and subjected to preliminary analysis, including the standard characterization required for all fuel and additive formulations and those which measure the presence of atypical elements in exhaust and, if applicable, evaporative emissions. Then, measurements will be made to determine whether a steady state has been reached between the rate of entry and emission of the atypical elements. If not, additional mileage accumulation will be performed until the emissions of the atypical elements reach steady state. Steady state will be defined as the point at which the mass of the atypical elements emitted during the performance of one or more Urban Dynamometer Driving Schedules/Engine Dynamometer Schedules is within 10 percent of the mass of the atypical elements that entered the combustion chamber during the driving cycles.

In determining whether steady state has been reached, some less obvious pathways for the loss or introduction of the atypical elements may need to be taken into account. For example, if the atypical compounds could be lost through evaporation, then the evaporative emissions would be speciated for these compounds. If the atypical element enters the motor oil via the combustion chamber, the concentration of the atypical element in the motor oil may be measured and entered into the mass balance. If there is reason to suspect that the air used during combustion or dilution may contain significant quantities of the atypical element under evaluation, this air must also be tested and the problem rectified.

EPA is initially proposing that mileage accumulation be continued either until steady state of the atypical elements has been reached or until the vehicle or engine has been operated on the atypical fuel or additive for the equivalent of 80 percent of its estimated useful life (e.g., 80,000 miles for light-duty vehicles). The purpose of this rigorous requirement is to ensure that the emission products of the elements of concern are known and that their concentrations are stable when the emissions are used in subsequent testing. In actual use, however, few vehicles are likely to be driven continuously on "atypical" fuels and additives. The use of such products by consumers is more likely to be intermittent and/or limited to particular owners along the chain of individuals who may own a given vehicle. Thus, the proposed requirement for accumulating mileage up to 80 percent of a vehicle's or engine's useful life (unless steady state is reached at an earlier point) may far exceed the amount of mileage and the concentration of atypical emission products which would generally be encountered in actual use. If so, a lower mileage requirement, perhaps in the range of 25–50 percent of the vehicle's useful life, may be more appropriate in pursuit of the steady state condition. Comments are requested on these issues and on appropriate mileage accumulation requirements. Data on typical consumer usage patterns for atypical products would be particularly helpful to this decision. If the comments are supportive of a change in the proposed requirements, EPA would expect to reduce the mileage accumulation required in the Final Rule for atypical fuels and additives to a mileage figure in the lower range mentioned above.

2. Verification Testing

A number of mechanisms can cause emissions to be captured in the dilution and sampling system before they can be characterized or used for animal exposures. The ratio of emissions that exit the sampling system to those that enter is called the "recovery factor" of the system. The recovery factor must be high in order for subsequent emission testing to be meaningful. Determination of the recovery factor is called verification testing.

Verification testing is required in the FTP using propane or carbon monoxide for gasoline and diesel fuels and using methanol for methanol-containing fuels. It is accomplished by injecting a known sample into the dilution system at the end of the exhaust pipe and measuring the amount that exits the sample probe. While the performance of this standard verification testing will determine if the system is leaking, recovery of these compounds does not necessarily imply the recovery of all of the different compounds subject to the speciation procedures of this program or all biologically significant emission products. EPA asks for comment on whether further verification testing should be required for this program using additional compounds.

In order for the system to be acceptable, a minimum recovery rate would be required for each compound in an injected sample composed of known chemicals of the type under analysis. Such verification procedures would be relatively easy to perform when emissions are being generated for characterization purposes, since calibration compounds and speciation equipment would be readily available. However, when emissions are being generated for purposes of biological testing, simplified verification testing may be in order, since biological testing laboratories may not always have sophisticated speciation apparatus available. In this case, an injected hydrocarbon sample could be detected with a gas chromatograph and flame ionization detector to estimate the recovery factor. EPA asks for comment on these proposed requirements for verification testing.

3. Emission Storage and Transport

As mentioned previously, emissions can be stored for only a limited period of time before chemical changes may occur. The critical time period is a function of the composition of the emissions, the temperature and pressure under which they are contained, the vessel in which they are stored, the amount of sunlight to which they are exposed, and the amount of deterioration that is considered acceptable. The maximum allowable storage times for emissions which are to be subjected to chemical analysis will vary depending on the speciation protocol, and are identified in relevant parts of the proposed regulatory text.

Storage time is not an issue in regard to biological tests using whole combustion or evaporative emissions, since these emissions are to be generated continuously. Particulate phase emissions can be stored up to six months, either on the collection filter or after extraction. The stored material must be sealed in a container that is opaque to ultraviolet light and maintained at −200 C or less. Semi-volatile phase emissions must be extracted immediately after collection, stored at −200 C, and used within six months. Special emission handling specifications for biological testing purposes are considered in section VI.C. Comments on these storage and handling specifications would be welcome.

4. Emission Generation Facilities for Biological Testing

While the continuous generation of combustion emissions appears to be an essential component of the proposed *in vivo* biological test requirements, EPA is unaware of any commercial biological laboratories which offer such services at the current time. Installation of the necessary vehicle-related equipment by biological laboratories would require significant capital expenditure and considerable time for start-up and training. Similar problems would arise if vehicle testing labs were to install

biological exposure chambers adequate for the proposed program. EPA asks for comment on the ways in which adequate facilities for the biological testing required by this program can be made available to the fuel/additive producers seeking registration, either through increased facility availability or simplified testing requirements. EPA also asks for comments and suggestions on what remedies are available under the Act if adequate facilities have not become available when testing is to be conducted.

E. Special Requirements for Additives

1. Base Fuel Specifications

As discussed in Section III, fuel additives subject to testing are to be mixed with the designated base fuel formulation for their respective fuel family prior to the generation of emissions. The base fuel formulations are also proposed to serve as the representatives for groups in the baseline fuel/additive categories. To define appropriate base fuel formulations for the gasoline, diesel, and methanol fuel families, EPA proposes to establish specifications based on the national annual average of fuel sales. For this purpose, EPA plans to adopt the method proposed in the reformulated gasoline rulemaking (56 FR 31176), which uses sales-weighted averages of fuel survey data to determine national average parameters for wintertime unleaded gasoline. The averaging procedure will be based at least in part on Motor Vehicle Manufacturers Association (MVMA) fuel survey data.

In the near future, "alternative" fuels are expected to generate demand for a variety of new bulk and aftermarket fuel additives. At the present time, however, base formulations for these alternative fuel families will not be defined. When the time comes that a fuel additive to an alternative fuel requires a base fuel for testing purposes, an industry average of important parameters in existing fuels will be determined and the base fuel specification defined.

Fuel additives will need to be added to the "average" fuels determined by the survey in order for these fuels to be used in motor vehicles. Examples of necessary fuel additives may be stabilizers, deposit control additives, and corrosion inhibitors. Only additives determined to be necessary for proper fuel and vehicle functioning will be components of the base fuels. These additives, along with their in-use concentrations, will be determined by EPA with input from interested industries and groups.

A memorandum entitled, "Base Fuel Determination Procedures for the Proposed Fuels and Fuel Additives Rulemaking," is available in the public docket. This memorandum illustrates the proposed approach for specifying base fuel formulations and presents sample values for base gasoline and diesel fuels. It also discusses such issues as base fuel blending tolerances and the need for a standard set of base fuel additives.

2. Additive and Base Fuel Emissions Comparison

Emissions from fuel additives may, in some cases, be difficult to distinguish from the emissions of the base fuel itself. Ideally, the emissions contributed by an additive would be determined by performing tests on two identical vehicles, one fueled with the base fuel alone and the other fueled with the additive/base fuel mixture. Test results on the emissions from the two vehicles would be compared and the difference attributed to the fuel additive. However, significant variability can exist between vehicles even of the same year and model. Furthermore, the additional expenditure for conducting tests on two vehicles, one with and one without the fuel additive, would be considerable. Nonetheless, from a scientific perspective, side-by-side testing would be the preferred approach.

An alternative to this method is proposed, in which only one vehicle model would generate and test the base fuel emissions for each fuel family, with the results made available for use as control data for all additives in the fuel family. Standardization of the vehicle make, model, and year would be an important requirement. Under this approach, base fuel testing would be done as part of the program automatically, since the group representative for each baseline group is also a base fuel for the respective fuel family. Thus, no additional effort would be required on the part of the additive producers in order to perform the comparison analysis. This method could provide a reasonable set of control data for comparison against the test results for fuel additives (both emission characterization and biological studies), at a fraction of the cost of the more rigorous approach. However, the requirement that the same vehicle make, model, and model year be used for testing the base fuel and the additive/base fuel mixture would become problematic for fuel additives tested some years after the base fuel was tested, since acquiring a new (unused) vehicle of a previous model year would be difficult. EPA asks for suggestions as to how this requirement can be effectively implemented. Of course, any additive producer could conduct independent base fuel testing in lieu of relying on the results of the group responsible for base fuel testing.

In case the baseline group(s) in some fuel families are able to satisfy the Tier 1 and Tier 2 requirements based on existing testing, EPA asks for comment on how various additive producers needing base fuel information could work cooperatively for these purposes. EPA also requests comment on the appropriateness of this proposed method for distinguishing the emissions effects of fuel additives from the emission effects of the base fuel.

Section V.A presented another alternative for comment, in which six vehicles would be used to generate emissions both for the additive/base fuel mixtures being tested and for the applicable base fuel. While this approach would reduce the problem of vehicle-to-vehicle emissions variability, it depends on the validity of the assumption that carryover effects from fuels and additives used previously in the vehicles would be negligible. To the degree that this assumption is valid, the use of the same vehicles to generate emissions for comparison might be preferred.

3. Additive Concentration

Prior to emission generation and testing, additives are to be mixed with their associated base fuel to a concentration equal to that recommended by the additive producer as the maximum in-use concentration. One alternative would require mixing of fuel additives in their base fuels at a significantly higher concentration than the recommended amount, i.e., to "dope" the mixture with the fuel additive. Another possible method of doping an additive/base fuel mixture would be to significantly increase the concentration of particular components of an additive product (e.g., the compounds that contain atypical elements). The primary purpose of these approaches would be to enhance the contribution of the additive product (or the particular component of concern) to the emissions produced by the additive/base fuel mixture. This would facilitate the task of detecting and analyzing the additive's emissions and distinguishing them from the emissions produced by the base fuel. It would also effectively increase the dosage of additive emissions during biological exposures to additive/base fuel emissions, increasing the likelihood that observable changes could be detected in comparison with exposures

to emissions of the base fuel alone. EPA asks for comment on the mixing rules that should be adopted and on the validity of doping the base fuel with the fuel additive or active ingredient. Comment is also requested on appropriate additive concentration levels, if a doping procedure were to be adopted for the final rule.

VI. Evaluation of Health and Welfare Effects

The scope and general structure of proposed provisions for evaluating the potential health and welfare effects of fuels and fuel additives were discussed above in sections III.E and F. The program focuses on the contribution of fuels and additives to harmful air pollution, and includes requirements to determine the composition and potential effects of fuel/additive emissions generated by both combustion and evaporative processes. Health effects testing provisions are specifically focused on the effects of inhalation exposure to fuel/additive emissions in regard to the following selected endpoints: carcinogenicity, mutagenicity, developmental effects, reproductive effects, pulmonary toxicity, and neurotoxicity. The impacts of fuel and additive emissions on the public welfare and the environment are addressed by data research methodologies.

As previously described, the required evaluation procedures are organized within three successive tiers. All fuels and additives (or fuel/additive groups) must be evaluated in compliance with the first two tiers. Tier 1 includes requirements for the characterization of fuel or additive emissions, the compilation of existing information on the potential adverse effects of the emissions, and the modeling of exposure, reactivity, and environmental partitioning. Tier 2 is comprised of short-term biological screening tests for the specified endpoints. Both the Tier 1 emission characterization and the Tier 2 biological testing requirements may be mitigated by the demonstration of adequate existing testing. The information from these two tiers, together with other available toxicity and exposure data, will be assessed by EPA to determine when further study is needed to provide adequate information for regulatory decision-making. In that instance, additional testing requirements will be imposed under the provisions of Tier 3.

The specific requirements of each health/welfare evaluation tier are described in more detail in the following sections.

A. Tier 1: Characterization of Emissions

1. Scope of Characterization Requirements

The proposed requirements for emission characterization are intended to satisfy the provisions in Section 211 to "determine the emissions" of fuels and additives, and to provide a partial inventory of potentially harmful emission products for further study and evaluation in support of programs such as the Mobile Source Related Air Toxic Program (section 202(1)(l) of the Clean Air Act). In general, the required procedures are directed toward the detection and measurement of selected chemical classes and compounds. A complete and precise characterization of all emission products would require test protocols specific to all possible compounds, a nearly impossible task. For this reason, the proposed program focuses on measurement of regulated emissions and on the identification of specified classes of compounds of interest.

For most fuels and fuel additives, proposed emissions analysis requirements are limited to the determination of the emission rate of regulated emissions and the speciation of volatile hydrocarbons, aldehydes, ketones, ethers, alcohols, polycyclic aromatic hydrocarbons (PAH), (the subset of polycyclic organic material [POM] that includes only hydrocarbons) and nitrated polycyclic aromatic hydrocarbons (NPAH). These requirements are summarized in Figure 4. For fuels and additives that contain "atypical" elements (as defined in section IV), the chemical fate of the atypical components must be determined. Comments are solicited on the adequacy of these proposed areas of analysis for characterizing the emissions of fuels and fuel additives.

Comments are specifically requested on whether speciation of nitrogen-containing emissions should be included as a requirement for fuels and additives which contain appreciable quantities of this element. Such information might be of value in determining the chemical basis for toxic effects which might be observed during *in vivo* biological testing.

FIGURE 4.–EMISSION CHARACTERIZATION REQUIREMENTS

Emission type	RE	HC	Ket and Ald	Alc and Eth	PAH	NPAH
Combustion emissions:						
Vapor phase emissions	X	X	X	X [1]		
Semi-volatile phase emissions					X	X
Particulate phase emissions	X				X	X
Evaporative emissions: [2]						
Diurnal emissions	X	X		X [1]		
Hot soak emissions	X	X		X [1]		

[1] Required if alcohols or ethers exist in the uncombusted fuel.
[2] Only applicable to fuels/additives required to measure evaporative emissions RE=regulated emissions, HC=hydrocarbons, Ald and Ket=aldehydes and ketones Alc & Eth=alcohols and ethers, PAH=polycyclic aromatic hydrocarbons, NPAH=nitrated polycyclic aromatic hydrocarbons.

As proposed in section V, the generation of both combustion and evaporative emissions would generally involve equipment and procedures normally applicable to the certification of new vehicles. Three bags of vapor phase and three filters of particulate phase combustion emissions would be collected for each light-duty vehicle. For heavy-duty vehicles, one bag and one filter of combustion emissions would be collected during the cold start and one bag and one filter during the hot start segments of the transient test cycle. For fuels and additives subject to evaporative emission requirements, one bag of diurnal emissions and one bag of hot soak emissions would be collected from the SHED.

Unless otherwise noted, each speciation protocol is to be performed on each sample of combustion emissions. Speciation requirements for evaporative emissions are limited to the analysis of hydrocarbons, ethers, and alcohols (if the latter are present in the fuel/additive formulation). To provide an indication of the variability of emissions, EPA proposes that the entire

emission generation and characterization process be performed three times.

Collection and speciation of background samples is not required. However, if background samples are not speciated, the emissions that are measured in the speciation protocols will be assumed to be entirely due to the fuel or additive of interest.

2. Emission Characterization Protocols

The Clean Air Act authorizes EPA to require information to characterize fuel/additive emissions, while giving EPA discretion to specify the particular protocols which must be used for this purpose. Thus, the following sections identify the general emission product categories of interest and discuss currently available protocols which are suitable for these purposes. However, scientific methods can be expected to advance in the next few years, and the use of these protocols is not mandated. Rather, EPA will hold producers accountable for state-of-the-art methods and good analytical chemistry and laboratory practices. These practices are described in the article "Principle of Environmental Analysis", found in The Journal of Analytical Chemistry, 1983, Volume 55. The regulated emissions need to be measured by EPA approved methods. Current methods are described in 40 CFR 86; however, if these methods are revised or new compounds regulated, then methods in force at the time the regulated emissions testing is performed are the methods that must be used for this program.

a. *Characterization of regulated emissions.* The term "regulated emissions" for this program refers to emission products for which standards have been established for the purpose of the certification of new motor vehicles (40 CFR part 86). Vehicles of three fuel families (gasoline, diesel, and methanol) are presently required to undergo certification testing. The regulated emissions applicable to each family are shown in Figure 5. Oxides of nitrogen and carbon monoxide are regulated combustion emissions common to all three fuel families. Organic material is regulated in various forms depending on the vehicle and fuel type. Particulate emissions, already regulated for diesel cycle vehicles, will be regulated for light-duty Otto cycle vehicles beginning in 1994. Methanol-fueled vehicles are tested for methanol and formaldehyde as part of the organic material standards. Evaporative emissions from otto cycle vehicles and methanol-fueled vehicles are regulated for organic material, including methanol measurement when relevant.

FIGURE 5.—REGULATED EMISSIONS

Fuel cycle	Combustion emissions							Evaporative Emissions	
	Total HC	NMHC	OMHCE	OMNMHCE	NOx	CO	PM	Total HC	OMHCE
Gasoline/Otto	1	2			1	1	2	1	
Methanol/Otto			1	2	1	1	2		1
Diesel/Diesel	1	2			1	1	1		
Methanol/Diesel			1	2	1	1	1		1

Notes:
1 = Always.
2 = After 1994 for light-duty vehicles/trucks only.
Total HC = Total Hydrocarbons.
NMHC = Non-Methane Hydrocarbon.
OMHCE = Organic Material Hydrocarbon Equivalent (includes tests for HC, methanol, and formaldehyde).
OMNMHCE = Non-Methane OMHCE.
NOx = Oxides of Nitrogen.
CO = Carbon Monoxide.
PM = Particulate Matter.

The regulated emissions are to be measured for fuel/additive registration purposes in the same manner and with the same degree of accuracy as specified in 40 CFR part 86 for vehicle certification, including evaporative emissions and combustion emissions of both vaporous and particulate phases. Only those regulated emissions included in the certification requirements for the vehicle type and model year used to generate emissions for testing (selected according to the criteria in section V.A) need to be determined for this program. The results of these tests are to be reported in the manner specified for vehicle certification. Comments are requested on these requirements.

b. *Hydrocarbon characterization.* Speciation of hydrocarbons in the vapor phase of emissions is to be performed using methods that identity and determine the concentration of all hydrocarbon compounds containing twelve or fewer carbon atoms. An acceptable speciation method, available in docket A–90–07, is described in the document "Research Protocol Method for Analysis of Detailed Hydrocarbons Emitted from Automobiles by Gas Chromatograph" (June, 1991). The procedure is to be performed on both combustion and evaporative emissions. Hydrocarbon compounds of higher molecular weight (i.e., more than twelve carbon atoms) tend to condense and/or adsorb onto particulate surfaces at dilute exhaust temperatures and concentrations and are therefore not amenable to this type of analysis. EPA asks for comment on possible requirements for identifying chromatographic peaks using mass spectroscopy when peak identity is questionable and when coelution is suspected.

c. *Aldehyde and ketone characterization.* Speciation of aldehydes and ketones is required only for the vapor phase of combustion emissions, collected using the equipment and methods prescribed in 40 CFR part 86 for formaldehyde measurement. A currently available procedure which can accurately analyze aldehydes and ketones is the ASTM D5197–91, "Standard Test Method for Determination of Formaldehyde and Other Carbonyl Compounds in Air (Active Sampler Methodology)". The speciation procedure involves the reaction of aldehydes with 2,4-dinitrophenylhydrazine to form stable derivatives that are analyzed by high performance liquid chromatography (HPLC) using an ultraviolet light detector.

d. *Alcohol and ether characterization.* Alcohols and ethers are to be analyzed in combustion and evaporative emissions whenever the fuel or additive under evaluation or the base fuel mixed with the additive contains alcohols or ethers. The emissions are to be collected and analyzed using the procedures

prescribed in 40 CFR part 80, appendix F, entitled "Test Method for Determination of C1–C4 Alcohols and MTBE in Gasoline by Gas Chromatography". This procedure can be used for the identification of ethers in addition to MTBE, but will require appropriate modifications for application to gas phase samples.

e. *PAH and NPAH characterization.* PAH and NPAH are mutagenic compounds which have been designated as a topic for study by the Clean Air Act (section 202(1)(1)) to determine if their emission by motor vehicles should be regulated. PAH and NPAH are typically found in combustion emissions, and their identification in evaporative emissions will not be required under Tier 1 provisions. In the past, PAH and NPAH have been analyzed primarily in the particulate phase. However, evidence now suggests that the quantity of these compounds in the semi-volatile phase at the temperatures encountered in dilute exhaust may be important. For this reason, PAH and NPAH will be speciated in both semi-volatile and particulate phase emissions.

At this time, EPA is proposing that these PAH and NPAH characterization requirements be applied to all organic-based fuels and additives. However, it has been argued that the combustion of low molecular weight fuels such as methane, propane, ethanol, and methanol will not generate PAH and NPAH in significant quantities if the vehicles that generate the emissions are in proper operating condition. Comments and supporting data are thus requested on the necessity of imposing PAH and NPAH characterization requirements for these fuels.

Particulate and semi-volatile phase emissions are to be collected as specified in section V.B. The soluble organic fraction (SOF) is to be extracted from the filter and polymer bed separately and used in separate testing procedures. Protocols suitable for characterizing PAH and NPAH have been published by the Coordinating Research Council[4] Both methods 1 and 2 described for PAH speciation in this reference are acceptable, but the alternate method given for the detection of NPAH is not. EPA requests comments and suggestions regarding these proposed procedures.

f. *Characterization of emissions with atypical elements.* As discussed in section IV, fuels and fuel additives which contain chemical elements other than those included in the base fuel formulation for their respective fuel family are classified as "atypical" formulations. For the most part, atypical products are those with elemental components other than carbon, hydrogen, oxygen, nitrogen, and a limited amount of sulfur. Some of the atypical elements contained in such products are the following: Aluminum, Bismuth, Bromine, Cadmium, Cerium, Chlorine, Chromium, Cobalt, Copper, Fluorine, Iodine, Iron, Manganese, Molybdenum, Nickel, Lead, Platinum, Selenium, Sulfur (if present in amounts exceeding 1,000 ppm in gasoline formulations or 0.05 percent in diesel formulations), Titanium, Vanadium, Zirconium, and Zinc. In addition to the emission characterization requirements described in subsections a-e above, producers of "atypical" fuels and additives will be required to identify and measure the emission products containing the associated atypical elements. Because of the variety of potential elements and reaction products involved, all of the necessary chemical analytic procedures cannot be specified in this proposal. However, the procedures used must be state-of-the-art and based on sound analytical chemistry principles.

Generation of the emissions used for speciation of the emission products containing atypical elements was discussed in section V of this notice. To summarize briefly, EPA proposes that combustion emissions must be in steady state prior to sampling, such that essentially all (at least 90 percent) of the atypical elements entering the combustion chamber also exit in the vehicle exhaust. Steady state is to be determined by a mass balance using analytical protocols determined by the fuel/additive manufacturer. Mileage accumulation driving will be used to condition the vehicle until steady state is reached. If the atypical element has not reached steady after the minimum 25,000 mile requirement, mileage accumulation must continue. The producers involved will determine when to conduct additional testing to see when steady state has been reached. If the emission rate of the atypical compounds has not reached steady state within 80 percent of the useful life of the vehicle or engine, one final emission collection will be performed and the emissions analyzed for combustion products containing the atypical elements. The special Tier 1 emission characterization requirements for "atypical" fuels and additives will be considered complete at this point, under the assumption that elements not emitted during most of the useful life of the vehicle probably do not pose a significant health threat.

EPA asks for comments on whether the fate of all elements other than carbon, hydrogen, oxygen, nitrogen, and sulfur should be determined, or whether a select group of such elements should be subjected to these requirements. Also, comments are requested on the proposed requirements for determining the fate of atypical elements and whether initial steady state determinations should be allowed prior to 25,000 miles.

3. Quality Assurance

The accuracy of a testing program is a reflection of the repeatability and reproducibility of test results. Repeatability is a measure of the variation of results when tests are repeated on one set of equipment with all other variables constant, while reproducibility is a measure of the variation of results when an experiment is performed on different sets of equipment with all other variables constant.

This section proposes the adoption of some methods to ensure a high degree of accuracy for the emission characterization program.

a. *Repeatability.* While today's proposal suggests that repeatability should be determined by replicating each test or calibration, the emissions from a given vehicle are themselves subject to some variation. Thus, replicating vehicle-based tests to measure the repeatability of experimental equipment and procedures might yield misleading results. A more controlled approach would entail testing a set of known compounds periodically to determine the repeatability of test procedures. For this purpose, a prepared mixture of appropriate chemical compounds would be subjected to the protocols prior to testing the actual emission sample. These calibration tests would also be performed at intervals throughout the testing of fuel/additive emissions to assure continual satisfactory performance. Such tests are commonly used for calibrating chromatograph equipment. Comments are requested concerning the use of this or other proposed methods for assuring repeatable speciation results, including what compounds should be used for each procedure.

b. *Reproducibility.* Reproducibility is sometimes ascertained by implementing round robin testing of a given sample by a number of laboratories. The results of the round robin can determine the inherent procedural variation along with

[4] CRC Report No. 551 (1987) Chemical Methods for the Measurement of Unregulated Diesel Emissions. Coordinating Research Council, Inc. 219 Perimeter Center Parkway, Atlanta, GA 30346.

the quality of the labs performing the test. For example, if four labs obtained similar results for a known solution and one lab produced results that were significantly different, the reproducibility could be evaluated by the results of the four similar labs and the fifth lab could be excluded from further testing until the differences were resolved.

EPA asks for comments on possible arrangements for participating labs to perform speciation protocols in the context of a round robin program in order to determine test reproducibility and identify those labs capable of performing the required protocols with sufficent accuracy. To this end, labs wishing to take part in the testing program could voluntarily test a vehicle's emissions or analyze an unknown sample provided by EPA. If the results were accurate, EPA would have some assurance that the data generated by the lab would be acceptable.

c. *Audits.* EPA will reserve the right to audit testing facilities involved in the generation and characterization of emissions for purposes of fuel/additive registration so that the quality of results is assured. Such audits would be organized and administered by EPA at its own expense. The audit procedures could include a requirement that facilities submit a completed questionnaire in which equipment and procedural information would be described. EPA could make recommendatioins based on the submitted information and follow up with a visit to observe the performance of the protocols. The audit could also include EPA distribution of "blind" samples for analysis at participating laboratories. The audit would not have the purpose of certifying that the laboratory is "EPA approved". Rather, it would have the purpose of determining the weaknesses of labs and the acceptability of the lab's current performance. Comments would be appreciated on the implementation of laboratory auditing practices.

4. Other Emission Characterization Issues

a. *Emissions modeling.* The Reformulated Gasoline program (56 FR 31176, July 9, 1991) requires the extensive use of emissions modeling in place of actual speciation procedures to determine emission products. These models predict the combustion emissions from the fuel's composition. This approach was adopted because of its convenience, cost, and expected comparable accuracy for purposes of the program.

The "Simple Model" of the reformulated gasoline program uses a fuel's RVP, oxygen, benzene, and aromatic weight percents to predict the emission rate of non-methane volatile organic compounds, benzene, 1,3-butadiene, formaldehyde, acetaldehyde, and POM. In 1993, other fuel parameters will be included in the program's "Complex Model". However, these models fall far short of the speciation requirements proposed for this program. For example, benzene and 1,3-butadiene are only two of more than 100 hydrocarabons determined by the hydrocarbon speciation protocol proposed in section VI.A.2.b.

Given the differences in the goals and requirements of the two programs and a general lack of emission data to develop broader models, it may not be possible to meet the requirements of the present rulemaking using emissions modeling. This rulemaking involves the determination of various emissions from a wide variety of fuels and fuel additives. Some of the fuel additives contain compounds that are not common in fuels. Thus, emissions modeling does not appear to be adequate for this program and is not being proposed as an alternative means for determining emissions. Until models are capable of accurately predicting individual chemical species for entire classes of compounds, EPA regards emission generation and testing to be the only viable alternative. Nevertheless, EPA requests comment on the possible role of emissions modeling for fulfilling the emission characterization requirements in this proposed rulemaking, especially in regard to evaporative emissions, which seem somewhat more suited to modeling approaches. If use of the Simple or Complex Models is supported, EPA requests that a full justification be provided as to why the model results should be deemed to be equivalent to the results achieved under this program.

b. *Raw product testing.* Under the current fuel/additive registration program, fuel and fuel additive manufacturers are required to determine and report the composition of their products. However, few regulations have been promulgated governing the accuracy of this information and the procedures for raw product analysis. Particular short coming in the existing program are the underreporting of impurities which may be present in the fuels and fuel additives and the relatively broad reporting catgegories/criteria permitted for petroleum fuel constituents. With extensive emission speciation requirements now being proposed, it may be important to more clearly prescribe raw product analysis. A thorough raw product analysis along with the speciation results would provide a better picture of the combustion of fuels and fuel additives than the speciation results alone. Because one source of emissions is uncombusted fuel and additives, better information on the components of the raw products might identify potential emissions that are not measured in the standard emission characterization requirements. In addition, raw product testing would give more accurate information by which products could be grouped.

B. Tier 1: Data Research and Analysis

In addition to the emission characterization procedures described above, the requirements of Tier 1 include a comprehensive search and summary of available information sources concerning the emissions-based effects of fuels and fuel additives on the public health and welfare. Data modeling applications are also included. These requirements are discussed below.

1. Data Search and Summary

The major functions of the data search are twofold. The primary purposes is to furnish EPA with a useful compilation of existing information obtained from previous studies on the composition and potential toxicologic and environmental effects of fuel/additive emissions. This body of information is expected to provide a contextual overview as well as specific factual input for future regulatory decision-making by the Agency. For this purpose, the data search is to encompass available information on the chemical composition of the fuel/additive emissions and on all emissions-based health effects. That is, the required information is not restricted to the particular endpoints and experimental protocols included in Tier 2. The secondary function of the data search is to enable producers of fuels and additivies to document the extent to which the emissions characterization requirements of Tier 1 and the health effects endpoints included in Tier 2 have already been addressed by previous adequate testing. To mitigate the testing requirements of Tiers 1 and 2, reports of such previous testing will need to be sufficiently detailed to allow EPA to judge the adequacy of protocols, techniques, experimental design, statistical analyses, and data interpretation.

To the extent that such information is available, the data search should

address the chemical composition and potential adverse effects of whole combustion emissions, evaporative emissions, and relevant emission fractions (e.g., vapor phase and particulate phase). In addition, information should be sought for each of the individual emission products identified by the required emission speciation procedures, with the exception of the regulated emissions. In this regard, EPA requests comment on the necessity of requiring the data search to be done on identified emission products which are designated CAA title II or III air toxics.

Information considered applicable to a given fuel or additive includes data obtained from the testing of emissions from that specific product or from other similar products. Products would be considered similar to each other if they are members of the same fuel/additive group (as defined above in section IV) or if they qualify to be members of the same fuel/additive group. Thus, producers who choose to participate in group functions should pool information about all member products for purposes of their joint submission and should also make use of available data on other products which are not enrolled in the group but share the designated formulation characteristics of group members. Similarly, a producer who chooses not to participate in the grouping system should include any test results which may be available for products which could theoretically be assigned to the same group as the producer's own product.

Information on the health and environmental effects of fuels and additives is to be compiled from peer-reviewed scientific journals and other literature as well as internal industry studies, government-sponsored reports and assessments, proceedings of scientific meetings, and other documented sources. Reports of studies will be evaluated for adequacy using standard EPA guidance documents and basic toxicologic and ecologic principles. In general, EPA will place greater confidence in studies that have been subject to peer review.

Applicable studies may fall into a variety of categories. Evidence for potential toxicity or lack of toxicity in exposed humans may be available from epidemiologic studies, clinical studies, or case reports. More often, data will be available from experiments conducted with laboratory animals. In general, referenced experiments should be concerned with the health effects of inhalation exposure to fuel/additive emissions. However, data collected from studies using other routes of exposure may be included if there is sufficient justification to extrapolate the results to inhalation exposure. Short-term in vitro tests, comparative metabolism studies, structure-activity analyses, and the results of exposure modeling approaches are also considered relevant.

If available, data from field studies, monitoring exercises, accident evaluations, or environmental simulation experiments should be included to characterize the potential impact of fuel/additive emissions on vegetation, livestock, companion animals, wildlife, aquatic species, soil organisms, and natural and synthetic materials. Field and/or modeling studies on the environmental and atmospheric fate of fuel/additive emissions should also be included. In addition, the data search should cover studies concerning the contribution of the fuel/additive emissions to odor and visibility nuisances.

Proposed guidelines for conducting a comprehensive data search and policies for assessing the adequacy of various categories of referenced studies have been drafted in conjunction with the proposed petition process for adding or deleting pollutants to the lists of air toxics under CAA Section 112(b) (available in Central Docket Section A-130, EPA Docket No. A-90-48). EPA proposes to apply these general guidelines, instructions, and policies to the data search and summary requirements of the fuels/additives registration program. Consistent with these guidelines, a search of appropriate commercially available toxicologic and environmental data bases must be conducted to locate information from published sources. The search must go back for at least fifteen years prior to the date of submission, and must be current as of six months prior to the beginning of testing. Lists of appropriate commercially available data bases and suggested database search terms are provided in the draft air toxics petition guidelines referenced above. Given the long history of scientific experimentation with some fuel emissions, comment is requested on whether the data search period should extend back for a longer period of time, e.g., thirty years, rather than for only fifteen years.

The information to be submitted to EPA as a result of the data search includes the following items: (1) A brief text summary of the general findings and conclusions, (2) a printed copy of the outputs from the database searches, including reference list and associated abstracts, (3) complete documentation in scientific journal format of unpublished inhouse or other privately-conducted studies, and (4) tables summarizing the protocols and results of all cited studies, organized by health or environmental endpoint and type of emission (e.g., combustion, evaporation, and individual emission product). In addition, the person(s) or contractor(s) conducting the literature search and summary must be identified.

2. Modeling Approaches

EPA proposes to require the application of modeling or other analytic methods to provide estimates of ambient exposures to fuel/additive emissions, expected atmospheric reactivity of various emission products, and potential environmental partitioning of the emissions. The principles and parameters to be considered in implementing modeling approaches for vehicle emissions have been reviewed in the Health Effects Institute's publication, Air Pollution, the Automobile, and Public Health [5]. The choice of which models to use is left to the applicant, provided that the applicability, assumptions, limitations, and uncertainties of the models are clearly delineated. Several examples for consideration are described briefly below. However, new models are under development by scientists at EPA and elsewhere and the potential registrant would be required to use up-to-date techniques when conducting the analyses needed to meet Tier 1 requirements. Comments and suggestions from the public concerning the selection and application of analytic methods would be appreciated.

Ambient exposures. A microenvironmental model developed by Melvin N. Ingalls and Robert J. Garbe [6] is one possible method identified for deriving preliminary estimates of ambient exposures to emission products. This model estimates ambient concentrations of fuel/additive emissions, for each gram of emissions produced per vehicle mile (or vehicle minute), for "typical" and "severe" situations in six different microenvironments: Residential garage,

[5] Sexton, K. and Ryan, B.P., Assessment of Human Exposure to Air Pollution: Methods, Measurements, and Models and Russell, A.G., Mathematical Modeling of the Effect of Emission Sources on Atmospheric Pollutant Concentrations. In: Air Pollution, the Automobile, and Public Health. (1988) Health Effects Institute, National Academy Press, Washington, DC.

[6] Ingalls, M.N. and Garbe, R.J. (1982) Ambient Pollutant Concentrations for Mobile Sources in Microscale Situations. SAE Technical Paper Series 820787.

parking garage, roadway tunnel, street canyon, expressway, and expressway vicinity. Under this approach, the ambient concentration factors provided by the models could be used in conjunction with the measured emission rates for each fuel/additive emission product to estimate the exposure potential for each emission compound.

Specific population exposure characterizations are provided by the SIMSYS [7] [8] and SHAPES [9] models. Each of these methods uses both statistical and physical approaches to estimate emission exposures to individuals and to defined populations. SIMSYS can characterize high exposure situations and SHAPES can be used to model exposures to maximally-exposed or sensitive individuals. Once modelled, actual exposure data specific to the microenvironments could be used to validate the physical conditions predicted in these models.

EPA's Office of Mobile Sources is now completing the development of a new hybrid exposure model specific to mobile source emissions. The new model (HAPEM–MS) incorporates elements of both the Hazardous Air Pollutant Exposure Model (HAPEM),[10] which is more pertinent to stationary source air pollution, and another EPA model, the National Ambient Air Quality Standards Exposure Model (NEM).[11] [12] While based on carbon monoxide emissions, HAPEM–MS can be used to estimate the average annual exposure to any mobile source pollutant compound of interest, and expected to be highly applicable to the emissions exposure information needs of this program. A report describing HAPEM–MS and its uses is available in the public docket for this proposed rulemaking.[13]

Atmospheric transformation. EPA's OZIPM4 [14] and Urban Airshed [15] models are useful for calculating an ozone cost or benefit from specific emissions. In addition, a model developed for EPA and the California Air Resources Board by William Carter [16] provides estimates of the ozone-forming potential of volatile organic componds (VOCs) emitted by vehicles. The Carter model provides a set of scales representing the projected incremental effects of 140 different VOCs on the formation of photochemical ozone under a variety of urban airshed scenarios. Knowing the weight-percent concentration of individual fuel/additive emission products, the "maximum incremental reactivity" scales can be used to estimate the amount of ozone formed by these chemical species under conditions favorable to ozone production. However, uncertainties in the atmospheric chemical mechanisms related to many of the emitted VOCs may significantly affect the accuracy of these estimates. The usefulness of these models is also limited by the fact that they fail to provide information on potentially harmful atmospheric transformation products other than ozone. Thus, EPA is also considering an alternative approach. Rather than using mathematical models, a requirement could be established for analysis by a qualified chemist of the likely atmospheric fate of the emission species as a result of chemical reactions, deposition, and other processes. EPA would welcome comments from the public on the suitability of these or other approaches for estimating the atmospheric reactivity of fuel/additive emissions.

An argument can be made that requirements for the modeling of atmospheric reactivity would lead to redundant efforts by many manufacturers, since considerable overlap would be expected in the emission products of different fuels and additives (or groups). According to this argument, the duplicate efforts could be avoided if EPA itself were to run the models when needed, using the emission speciation data submitted by the fuel and additive manufacturers. Under this line of reasoning, once the data on primary emission products has been submitted, EPA would be in the best position to compare the emission profiles of different fuels and additives, and to use appropriate models to predict the implications for atmospheric reactivity.

While this argument appears to have some validity, it also contains some drawbacks. First, different manufacturers' submissions would be received by EPA at different times, interfering with EPA's ability to compare the emission profiles of various fuels and additives. Such comparisons would be difficult to perform in any case, and it is likely that EPA's attention would be drawn to fuels or additives which appear to generate unusually high concentrations of known precursors to harmful transformation products. As a result, fuels and additives which might provide a relative advantage in terms of atmospheric reactivity would tend to be overlooked. Such favorable results could be important in the overall evaluation of a fuel or additive for which certain adverse effects were also demonstrated. In addition, if EPA were to perform the modeling procedures, manufacturers would lost the initial opportunity to analyze and interpret the modeling results and conclusions for their products. Comments are requested on this possible approach.

Environmental partitioning. Examples of models which could be used to evaluate the environmental partitioning of emission products are the Spatial Multimedia Compartmental Model (SMCM), [17] [18] developed by the National Center for Intermedia Transport Research at UCLA, and Exposure and Ecotoxicity Estimation for Environmental Chemicals (E4CHEM), [19] [20] developed by Gesellschaft fuer Strahlen (GSF) of Munich, Germany. These publicly available models predict the concentration and mass fraction of pollutants in air, soil, water, sediment, and biota, thus indicating whether terrestrial or aquatic organisms are potentially at risk based on the

[7] Letz, R., et al. (1984) Estimated Distributions of Personal Exposure to Respirable Particles. Environ. Monit. Assess. 4:351–59.

[8] Ryan, P.B., et al. (1986) Estimating Personal Exposures to Nitrogen Dioxide. Environ. Int. 12:395–400.

[9] Ott, W.R. (1983–84) Exposure Estimates Based on Computer-Generated Activity Patterns. J. Toxicol. Clin. Toxicol. 21:97–128.

[10] Johnson, T., et al. The Assessment of Commuting Patterns in Applications of the Hazardous Air Pollutant Exposure Model. 84th Annual Meeting of the Air and Waste Management Association, Vancouver, BC, June 16–21, 1991.

[11] Johnson, T. and Paul, R.A. (1983) The NAAQS Exposure Model (NEM) Applied to Carbon Monoxide. PEDCo Environmental, Inc., Durham, NC. EPA–450/5–83–004.

[12] Ingalls, M.N. (1985) Improved Mobile Source Exposure Estimation. Southwest Research Institute, San Antonio, TX. EPA–460/3–85–002.

[13] Johnson, T., Paul, R.A., and Capel, J.E. (1992) Application of the Hazardous Air Pollutant Exposure Model (HAPEM) to Mobile Source Pollutants. International Technology Corporation, Durham, NC. EPA Contract No. 68–DO–0062.

[14] Hogo, H. and Gery, M.W. (1990) User's Manual for OZIPM4 (Ozone Isopleth Plotting with Optional Mechanisms), Volume I. Systems Applic, Inc, San Raphael, CA. EPA–450/4–89–009a.

[15] Morris, R.E., et al. (1990) User's Guide for the Urban Airshed Model, Volume I. Systems Applic Inc, San Raphael, CA. EPA–450/4/90–007A.

[16] Carter, W.P.L. (1990) Development of Ozone Reactivity Scales for Volatile Organic Compounds. Statewide Air Pollution Research Center, Riverside, CA. U.S. EPA Contract CR–814396–01–0.

[17] Cohen, Y. et al. (1990) Dynamic Partitioning of Organic Chemicals in Regional Environments: A Multimedia Screening-Level Approach, Environ. Sci. Technol. 24:1549–1558.

[18] Tsai, W., et al. (1991) Hydrogen Peroxide Levels in Los Angeles: A Screening-Level Evaluation. Atmos. Env. 25B:67–78.

[19] Trenkle, R. (1988) Fate Simulation of Organic Substances in the Atmospheric Mixing Layer. In: Environmental Meteorology, K. Grefen and J. Lobel (eds), Kluwer Academic Publishers.

[20] Matthies, M. et Al. (1989) Exposure and Ecotoxicity Estimation for Environmental Chemicals (E4CHEM): Application of Fate Models for Surface Water and Soil. Ecol. Model. 47:115–130.

environmental partitioning of the pollutants to these specific environmental media.

C. Tier 2 Requirements

The second tier of health effects evaluation consists of short-term screening tests which address the health endpoints previously described. These tests will be required for all fuels and additives to the extent that the results of the data search activities in Tier 1 do not include comparable existing information from adequately performed and properly documented previous studies. Criteria for assessing the adequacy of such studies were addressed in section III.E.3 of this proposal. EPA requests comment on whether there are other circumstances or product characteristics which would indicate that certain fuel families (e.g., methane or propane) should be exempted from particular Tier 2 testing requirements.

The proposed health effects testing guidelines are included in the regulatory text for this proposal, available in the public docket or by request to EPA (see the section of this Notice entitled, "For Further Information"). Most of these testing guidelines are modified versions of guidelines previously published under TSCA (40 CFR part 798). Methods for performing animal inhalation exposures to fuel/additive emissions are also included in the proposed regulatory text. Comments and suggestons are solicited on the adequacy of these proposed guidelines and methodologies for promoting valid study design and adquate technical performance. EPA believes that these guidelines (perhaps amended for the Final Rule as a result of submitted commentary), together with published laboratory practice standards (referenced below), are sufficient to ensure that Tier 2 testing done in conformance with these guidelines will be acceptable upon subsequent evaluation by EPA. However, comments are requested on whether an optional review mechanism should nevertheless be established, enabling manufacturers to submit detailed protocols to EPA for approval before beginning Tier 2 testing. Under such a review process, protocols reviewed by EPA would earn a presumption of technical adequancy, but in view of the large number of individual protocols which might be submitted for review, significant testing delays could occur. Thus, respondents who believe that a review mechanism is necessary or useful are asked for suggestions on how to make the process operate efficiently and effectively, given the statutory time constraints for program compliance.

Similar requirements among the various test guidelines in regard to animal subjects, exposure scenarios, and general technical principles provide opportunities for concurrent test performance at considerable cost savings. These shared study parameters include the following:

Laboratory Practices

To ensure the quality and integrity of test results, the performance of all studies will be required to conform with the Good Laboratory Practice Standards (GLPS) published in 40 CFR part 792, or with comparable standards which may be developed specifically for this program. These GLPS include facility, equipment, organization, quality assurance, and personnel requirements, as well as specifications for proper care of laboratory animals, handling of reagents and test substances, and conduct of studies. In addition, the provisions of subpart J of part 792 are to be followed for record keeping and reporting of results.

Animal Models

With the exception of the Ames Salmonella assay, the proposed test requirements entail the exposure of live laboratory animals to fuel/additive emissions. Mammalian species are required, with rodent species recommended. The developmental toxicity study calls for the exposure and assessment of two species, while the other studies require only one species to be tested. Animal facilities must be operated in compliance with the Animal Welfare Act as amended and in compliance with all pertinent USDA regulations.

Exposure Routes

Most of the proposed tests are based on the inhalation exposure of laboratory animals to diluted whole exhaust and evaporative emissions. Such studies require an exposure system designed to ensure the controlled generation, dilution, and delivery of emissions to the laboratory animals. To this end, a section of the proposed regulations provides a discussion of methodologies for conveying either combustion or evaporative emissions to the test animals, exposure parameters which need to be monitored and documented during the course of the inhalation exposure period, and animal care issues. Additional information on the hardware requirements, maintenance, and use of emission generation and inhalation systems can be found in "General Health Testing Guideline for Inhalation Exposure to Fuels and Fuel Additives", (Cheng and Barr, 1991), available in public docket A-90-07.

In the case of the in vitro Ames assay, bacterial cell cultures rather than live animals are exposed to the test emissions. This assay is to be performed using prepared fractions of combustion emissions, including an extract of filtered particulate matter [21] and an extract of a sorbent resin which traps semi-volatile gases [22]. The Ames assay will not be required for evaporative emissions.

Exposure Duration, Dosages, and Controls

The results of recent studies on inhaled vehicle exhaust mixtures, as compared with similar tests using concentrated solutions of single chemicals, indicate that exposure durations of five weeks or less may not be sufficient to induce observable toxicologic changes. Traditionally, the next step up in exposure duration is to a 90-day subchronic test. Because of cost considerations, however, the proposed test guidelines generally call for a minimum six week (42 day) exposure period for at least six consecutive hours per day, seven days per week. EPA requests comment on the adequacy of the proposed exposure and on the potential importance of extending these tests to 90 days for comparability to historical data.

Each study requires exposures to be conducted at a minimum of three dilutions, corresponding to low, midrange, and overtly toxic concentrations. A control group exposed to filtered conditioned air is also required. The objective is to choose exposure levels that will provide a lowest-observed-adverse-effect level (LOAEL) and a no-observed-adverse-effect level (NOAEL). In recognition of the possibility that even high levels may be nontoxic, provisions are made for "limit tests", where appropriate.

Tests conducted specifically for determining the emissions effects of additives, which involve mixing the additive with an appropriate fuel prior to emission generation, require additional control studies using the emissions of the base fuel alone. A possible means of meeting the

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[21] Huisingh, J. L., et al. Mutagenic and Carcinogenic Potency of Extracts of Diesel and Related Environmental Emissions: Study Design, Sample Generation, Collection, and Preparation. In: Health Effects of Diesel Engine Emissions, Vol. II, W. E. Pepelko, et al. [Eds.]; US EPA, Cincinnati, 1980, EPA-600/9-80-057b, pp. 788-800.

[22] Stump, F., Snow, R., et al. (1982) Trapping Gaseous Hydrocarbons for Mutagenic Testing. SAE Technical Paper Series No. 820776.

requirement for base fuel control testing without duplicative effort was discussed previously in section V.

Brief descriptions of the proposed test guidelines for each health endpoint are provided in the following sections. A possible alternative testing approach is also described.

1. Carcinogenicity and Mutagenicity Screens

A battery of three screening studies is proposed, as described below. In these studies, mutagenic and/or carcinogenic activity is indicated by a statistically significant concentration-related increase in positive responses after exposure to fuel/additive emissions as compared to controls (i.e., animals exposed to filtered air and, in the case of additive testing, animals exposed to emissions of the base fuel). The detection of a reproducible and statistically significant positive response to at least one concentration of emissions may also be interpreted as a positive result.

Ames reverse mutation assay. The Ames assay is an in vitro test for mutagenicity and, by implication, for carcinogenicity. The assay makes use of five mutant strains of the bacterium Salmonella typhimurium which cannot grow in a medium deficient in histidine due to an inherited inability to produce this amino acid. Exposure to mutagenic (and possibly carcinogenic) subtances can elicit reverse mutations, such that the bacteria regain their ability to grow in a histidine-deficient medium. In this test, bacteria will be exposed to the soluble organic (semi-volatile) and particulate extracts of fuel/additive combustion emissions. (Ames tests will not be required for evaporative emissions or for the gaseous fraction of combusion emissions.) After exposure, the cells will be plated on histidine/deficient media, both with and without metabolic activation, and incubated for a designated period of time. The number of colonies (revertants) growing on the plates will then be compared to the number of spontaneous revertants in control cultures.

In vivo micronucleus assay. Micronuclei are sub-cellular structures containing chromosomes and chromosome fragments not incorporated into the main nucleus during cell division. While micronuclei do form under natural conditions, exposure to potentially carcinogenic agents can cause an increase in micronucleated cells. In this assay, live rodents will be exposed by inhalation to the fuel/additive emissions. Subsequently, erythrocytes obtained from the peripheral blood (or, in rats, from the bone marrow) will be sampled, stained, and viewed under a light microscope. The number of normochromatic erythrocytes containing micronuclei will then be counted and compared with normochromatic erythrocytes from untreated animals. The use of erythrocytes in this procedure facilitates the visualization of micronuclei, since their primary nucleus is normally extruded during cell development.

In viro sister chromatid exchange (SCE). SCEs are believed to be caused by chromosome strand breakage resulting in exchanges of genetic material between the halves of a chromosome "pair" (i.e., the chromatids). While some SCEs occur normally, an increase in the frequency of such exchanges may be indicative of mutagenic/carcinogenic activity. In this assay, animals which have undergone inhalation exposure to vehicle emissions will be sacrificed and peripheral blood lymphocytes as well as cells from lung tissue will be isolated and cultured. The cells will be treated with a DNA base analog (bromodeoxyuridine, BrdU) and with a spindle inhibitor such as colchicine. After appropriate staining for labeled DNA, sister chromatid exchanges will be scored from cells arrested in the second mitotic division and the results compared with appropriate controls.

2. Developmental Toxicity (Teratogenicity) Study

This study is designed to provide information on potential dangers to the unborn which may arise from inhalation exposure of the female to fuel/additive emissions during pregnancy. Pregnant animals will be exposed to emissions during the major organ development period in the fetus (e.g., days 6–15 for rats and mice). The dams will be sacrificed on the day prior to normal parturition and the uterus examined for embryonic or fetal deaths. Viable fetuses will be examined for skeletal and soft tissue anomalies. These results will be evaluated relative to the number of spontaneous embryonic or fetal deaths and abnormalities in appropriate controls. The initially proposed test guidelines for developmental toxicity calls for two different species to be examined. However, EPA asks for comment on whether one species would be sufficient for the screening purposes of Tier 2.

3. Reproduction and Fertility Screen

The purpose of this test is to determine the potential reproductive toxicity to adult male and female animals caused by inhalation of fuel/additive emissions. Both males and females will be exposed to the emissions throughout an initial 42-day exposure period. In females, vaginal cell smears will be examined throughout this time, to track effects on the estrous cycle. At the end of the initial exposure period, a sufficient number of females will be mated to obtain at least ten pregnant females. Histopathological examination of the uterus and ovaries will be performed on the non-pregnant females, while the adult males will be evaluated by gross and histopathological examination of the reproductive organs and by assessing the number, morphology, and motility of sperm. Pregnant females will continue to be exposed to the test atmosphere throughout the pregnancy, and will be examined, along with their offspring, at the time of birth and at four days post-partum.

As compared with appropriate control animals, positive results would include changes in the number and type of cells seen in vaginal smears, decreases in sperm number or motility or abnormalities of sperm structure, and pathologic changes found during gross or microscopic examination of male or female reproductive organs. A decrease in the number or viability of offspring would also be evidence of toxicity.

4. Pulmonary Toxicity Screen

This study involves a six-week inhalation exposure of laboratory rodents to fuel/additive emissions, with subsequent examination of lung tissues and cells. A satellite group of rodents (with control animals) will be exposed to the highest concentration of emissions in the study for only one week. Lung lavage will be performed on the satellite group to obtain alveolar macrophages for assay of phagocytic activity and fluids for biochemical analysis. Positive results at the end of the exposure period would be indicated by elevated enzyme or total protein levels, elevated numbers of cell types normally found in the lungs, a low index or lack of phagocytic activity, and abnormal gross or histopathological findings relative to appropriate control animals. Persistence or delayed occurrence of toxic effects beyond the exposure period would also indicate positive results.

5. Neurotoxicity Screen

The proposed screen for neurologic effects is a functional observational neurotoxicity battery (FONB) which is to be performed on live animals periodically throughout a six-week period of inhalation exposure to fuel/additive emissions. Using standardized

procedures and both positive and negative controls to minimize observer variablility, the functional battery will include the assessment of autonomic activity, alertness, gross movement, behavior, gait, grip strength, and reactivity to general stimuli. As compared with the controls, positive results would include any of the following responses and changes: Unusual body position, activity level, coordination, gait or behavior, tremors or convulsions, increased lacrimation or salvation, piloerection, pupillary changes, unusual respiration, diarrhea, increased of decreased urination, unusual vocalization, and decreased grip strength.

To completely assess the neurotoxic potential of complex fuel/additive emissions, additional functional and neurohistochemical tests would be necessary. Used alone, the FONB may overlook adverse effects at the celluar level. Thus, EPA requests comment on whether an in vitro assay for determining the level of glial fibrillary acidic protein (GFAP) [23,24] should be required in addition to the FONB to broadly assess sensitive neurohistopathologic effects in test animals. Another alternative is to delete the FONB and to address neurotoxicity by requiring only the GFAP assay. The GFAP assay is a sensitive indicator of adverse neurotoxicologic effects. Because it is an *in vitro* test which can make use of brain tissue harvested from exposed animals used in other studies, it is also a relatively inexpensive option. EPA requests comment on these alternative approaches for Tier 2 testing of neurotoxic effects.

6. Optional Histopathology

If the Tier 1 literature search or emissions characterization suggest the potential for toxicity to other organ systems, then histopathology of the indicated organs should be performed, using the animals exposed in the pulmonary toxicity screen. For example, if adverse effects to the liver appear likely, as suggested from the literature or the presence of high levels of PAHs in the emissions, then it would be advisable to perform histopathology of the liver. On the other hand, if scientifically sound studies reported in the literature indicate no or very minimal potential for hepatic effects, then liver examination would not be necessary. Other organ systems likely to be of concern include the kidneys and the endocrine glands. These additional examinations are suggested because findings of potential adverse health effects in Tier 1 might require follow-up at the Tier 3 level, and if performed as adjuncts to required Tier 2 testing, these optional histopathology examinations might provide substantial incremental information at a relatively low incremental cost. At a minimum, organs of potential concern should be removed, weighed, and saved in storage for potential histopathological examination at a future time. However, the length of time which organs can be stored and still be of use is limited. EPA requests comment on whether histopathological examination of the liver, kidneys, and endocrine glands as an adjunct to the pulmonary toxicity screening test should be required rather than optional.

7. Alternative Testing Approach

An alternative approach under consideration by EPA in place of some of the proposed Tier 2 tests described above is a modified version of a protocol developed for use by the Organization for Economic Cooperation and Development (OECD). The protocol, which was developed for use in the OECD's Screening Information Data Set (SIDS) testing program on high volume chemicals, is a screening test which was initially developed in the U.S. by experts from the government, industry, academia, and environmental groups. It is presently in use for certain toxicology applications by 14 countries which are members of the OECD as well as by EPA's Office of Toxic Substances. The standard protocol is designed as a single-study screen for repeat dose, reproductive, and developmental effects. Currently, efforts are underway at EPA to add neurotoxicity measures to the protocol, as well. Documentation about the SIDS protocol is available in the public docket for this rulemaking.

While the SIDS protocol might need some further modification to accommodate exposures by inhalation to fuel/additive emissions, it could potentially be used in place of the pulmonary, reproductive, developmental, and neurotoxicity screening tests described previously. In performing the SIDS test, both male and female rats would be exposed for a 45-day period. Males would then be examined for repeat dose (including pulmonary) effects, reproductive effects (sperm number, sperm morphology, histopathology of the testis, etc.), and neurotoxicity. Females would be evaluated for reproductive performance, developmental effects and, possibly, pulmonary effects.

While some of the proposed individual tests could be performed simultaneously in order to reduce emission generation and exposure costs, the SIDS study evaluates the four specified health effects endpoints in a single protocol, and might offer additional cost savings. On the other hand, the SIDS study is more complex and the results would include somewhat less information for each endpoint in comparison with the proposed individual tests. Comments are requested concerning the use of the modified SIDS study as a single-protocol substitute for the four specified individual screening tests.

D. Tier 3 Requirements

Fuels and additives would be subject to additional testing under the proposed Tier 3 provisions of the registration program as determined on a case-by-case basis by EPA. The endpoints to be addressed and the nature of the studies to be performed would depend on the case at hand. Since the overall objective of the program is to adequately characterize the risk of exposure to fuel and fuel additive emissions, the applicable Tier 3 requirements could include chemical analyses, health studies, and/or exposure studies. As discussed in Section III, these tests would most often be required to further explicate the results of the screening batteries performed under Tier 2, but might also address other areas of concern highlighted by the Tier 1 literature search or emission characterization procedures. The need for Tier 3 testing would depend on whether sufficient toxicity and exposure information were available to determine whether use of a fuel or fuel additive presents an unacceptable health risk. The criteria for this determination are discussed below.

When a determination has been made that Tier 3 testing will be required, EPA will inform the responsible producer(s) by certified mail of the purpose and nature of the testing to be performed. Subsequently, relevant study guidelines and a timetable for completion of all requirements will be specified. The producer(s) will be expected to submit detailed protocols for review and approval by EPA prior to beginning the tests. Tier 3 testing performed in full conformity with a protocol pre-approved by EPA for the given product(s) and test objective will be deemed satisfactory compliance with the Tier 3 testing requirement.

[23] In: Pesticide Assessment Guidelines, Subdivision F, Neurotoxicity Test Guidelines (1991). EPA-540/09-91-123.

[24] O'Callaghan, J.P. (1991) Quantification of Glial Fibrillary Acidic Protein: Comparison of Slot-Immunobinding Assays with a Novel Sandwich ELISA. Neurotoxicology and Teratology, 13:275-281.

1. Need for Discretionary Tier 3 Determinations

Given the variety of evaluation methodologies and subjects included in Tiers 1 and 2 and the wide range of possible interrelated outcomes which could be obtained, EPA believes that it is neither practical nor necessarily desirable to specify precise and exclusive criteria which would automatically cause fuels and additives to be subject to Tier 3 requirements. In nearly all cases, decisions on the need for Tier 3 will ultimately depend on expert scientific judgment as to the quality of the evaluation of potential health risks which would be possible from the available data and the need for more definitive information in developing future regulatory strategies.

Case-by-case judgments would be expected to play a significant role in determining if Tier 3 is required even at the extremes of possible Tier 1 and 2 outcomes. For example, a high potential exposure combined with positive Tier 2 test results might not necessarily call for Tier 3 follow-up if literature search or other supporting information were available to adequately characterize the potential public health risks involved. Conversely, relatively low estimated exposures and equivocal test results might not remove the need for further evaluation if the test results were inconsistent with other available information or with known emission product toxicities or if exposures were expected to rise significantly in the future. In general, because of their potentially widespread distribution and use, most fuels and high-volume bulk additives would have a sufficiently high exposure potential to indicate a need for Tier 3 testing, provided that Tier 1 and 2 data suggested the likelihood of adverse health effects.

The discretionary nature of the decision process means that the elevation of a product (or group of products) to Tier 3 need not invariably lead to studies of chronic duration. Depending on the endpoints and protocols involved, additional short-term analyses, subchronic toxicity tests, and/or pharmacokinetic studies might be sufficient to clarify risks or allay concerns.

Because Tier 3 requirements are proposed to be applied on a discretionary basis, and because the scope of such requirements could be tailored to address individual circumstances, the Tier 3 mechanism would help to ensure that financial resources and laboratory capacity would be invested in areas of real concern. A possible alternative approach would involve the establishment of automatic "triggers", i.e., specific outcomes of Tiers 1 and 2 which would make Tier 3 testing mandatory. Associated Tier 3 testing requirements would also be specified in advance for each trigger. To ensure that significant concerns would not be overlooked under this approach, however, relatively conservative conditions would need to be designated to serve as the Tier 3 triggers, and relatively stringent testing scenarios specified as automatic follow-up regimens. As a result, Tier 3 might be triggered more frequently and might include more rigorous testing requirements that would occur under the proposed discretionary approach. On the other hand, a system of automatic Tier 3 triggers and test requirements would better enable manufacturers to predict and plan for their maximum registration responsibilities and would simplify EPA's data evaluation tasks. EPA requests comment on the relative merits of the discretionary vs. automatic approaches for determining Tier 3 applicability. Respondents who prefer the automatic approach are also asked for suggestions as to the specific "triggers" and follow-up tests which should be established.

While EPA proposes to retain discretion in the decision to require Tier 3 testing, it is possible to predict some sets of circumstances which would indicate that Tier 3 will *not* be required. These factors are discussed in the sections which follow. EPA requests comments on these circumstances, and asks for suggestions on other combinations of criteria ("bright lines") which could be established to determine that consideration for elevation to Tier 3 is unnecessary.

2. Criteria for Escalation to Tier 3

This section presents some of the guidelines and considerations which EPA would use in determining the necessity for additional testing under a discretionary Tier 3 testing approach. Consistent with the proposed discretionary decision-making process for Tier 3, this discussion is not intended to provide an exhaustive or definitive listing of relevant criteria. Rather, the major purpose of this discussion is to help furnish a basis for meaningful public comments and suggestions on the proposed Tier 3 provisions.

The decision to require manufacturers to submit additional testing on the health effects of fuel and fuel additive emissions would take into account the cumulative information provided by Tiers 1 and 2, including previous scientific data, emissions characterization data, modeling outcomes, and biological test results. Thus, decisions to require Tier 3 would be made only after the requirements of Tiers 1 and 2 have been adequately filled. Adherence to this principle will prevent unnecessarily costly or poorly targeted decisions based on piecemeal, out-of-context information, and will promote more precise identification and evaluation of data gaps and more cost-efficient coordination of potential test requirements.

Ultimately, EPA must be able to decide whether the use of a fuel or additive is likely to create unacceptable health risks. If this decision is made possible by the information from Tiers 1 and 2, then Tier 3 would not be needed. However, if such a risk decision cannot be made on the basis of the Tier 1 and 2 data, then Tier 3 testing would be required. Therefore, to make a determination on the need for Tier 3 testing, EPA scientists would evaluate the extent to which the results of Tiers 1 and 2 were adequate for such decisions, guided by the basic principles of risk assessment. A risk assessment involves the merging of a health effects assessment (including hazard identification and dose-response relationships) and an exposure assessment. Such an assessment can range from a qualitative to a highly quantitative analysis, depending upon the extent of the available data.

In most cases, a highly quantitative assessment would probably not be possible at the end of Tier 2. However, Tiers 1 and 2 might indicate that little hazard is present and that such exposures are quite low and limited geographically. In such a case, there would be little reason to pursue further testing at the Tier 3 level to improve dose-response information. In another example, Tiers 1 and 2 might suggest that a hazard is likely and that exposures appear significant, but the data may still be inadequate for a quantitatively advanced risk assessment. In this case, Tier 3 testing, targeted to provide the missing information, would be indicated.

In this way, the principles and critical data elements of the risk assessment process would provide a useful guide for identifying significant information gaps and determining the specific objectives of potential Tier 3 testing. However, EPA does not intend to conduct a formal risk assessment as part of its decision on whether to promote a fuel or fuel additive (or group) to Tier 3. Rather, EPA would evaluate the quality and certainty of available toxicity and dose-response data and consider qualitatively

whether estimated exposure weighs in favor of or against further testing. On this basis, EPA would determine whether additional information is necessary to adequately assess the risk of fuel or additive. A formal risk assessment would be more likely to be developed later if there was a need for action to control or prohibit a product under the regulatory authority of section 211(c).

The following section discuss the key factors which EPA would consider in identifying the need for and content of Tier 3 testing.

a. Statistical issues. As previously mentioned, scientific judgment will be exercised in determining whether Tier 3 tests are necessary and, if so, which ones. An important factor in such judgments will be the interpretation of and significance ascribed to "negative" results obtained in Tiers 1 and 2. Evaluating negative data (i.e., no-effect data) can be more difficult than evaluating positive data, because questions often arise as to the reason for the negative result: Did aspects of the experimental design (e.g., very small numbers of animals) lead to the negative outcome or was the test substance inherently of very low or no toxicity?

This specific question is addressed statistically by considering the probability of Type I and Type II errors. A Type I error occurs when a false positive conclusion is made, while a Type II error is a false negative conclusion. The acceptability of a specific Type II error is related to the acceptability of false negatives in the particular study being performed. For example, from a toxicological perspective, screening assays often have a relatively high probability of producing false negative outcomes, since some major aspects of organ or tissue toxicity are not being examined. Thus, an acceptable Type II error for screening assays would typically be low. However, the level of Type II error considered acceptable should be tempered by the goal of the study. A higher false negative conclusion (e.g., Type II error of 0.2) would generally be acceptable if it referred to an effect of minimal severity at a high-exposure test level relative to ambient concentration and if few people were likely to be exposed. The converse would also hold true.

A number of factors increase the complexity of these statistical issues. For example, the design of the study will influence the Type I and II levels obtained and the standard statistical methods chosen. Therefore, the scientific quality of the statistical analyses and their relationship to the experimental design are quite important. For example, although minimum sample sizes are specified in the proposed regulations, these are only general guidelines. Variability between laboratories and the specifics of the study methods may allow a decrease or require an increase in sample size. These possibilities should be evaluated properly before the start of the study.

In summary, scientifically sound statistical analyses are a crucial part of any good study and will provide key information for EPA to use in forming judgments on whether or not Tier 3 testing is needed. While it is not feasible to list all possible scenarios and results for each Tier 2 endpoint, the foregoing discussion elucidates how some of the statistical factors will be incorporated in EPA's decisions.

b. Exposure assessment. A number of the proposed Tier 1 and 2 requirements will provide EPA with information on population exposures to fuel and additive emissions. This information includes (1) historical and/or projected production volumes, (2) types and emission rates of speciated emission components, (3) estimated urban, rural, and/or microenvironment exposures obtained through exposure modeling approaches, (4) evidence for bioconcentration from environmental modeling results, and (5) possible literature search findings on ambient, occupational, or epidemiological exposures. As mentioned above, this information will be considered qualitatively by EPA in determining whether Tier 3 testing is needed.

Significant public health concerns might sometimes be revealed by the exposure information itself. This might be the case, for example, if there were an anticipated release in excess of, say, 1,000 kg per year of individual emission compounds (in addition to "criteria" pollutants) with known toxicities, or if the anticipated exposure scenarios approached or exceeded current estimates of apparently safe levels of known toxicants. In the case of fuels and their associated high-volume bulk additives, EPA will generally assume that human and environmental exposures will be of sufficient level and extent that significant observed adverse effects would indicate a need for follow-up in Tier 3. This exposure assumption reflects the high production and consumption of these products, either at the present time or as anticipated in the future. Thus, decisions to promote these products to Tier 3 would be based on the degree to which additional testing is needed to clarify the results and potential health effect implications of Tier 1 and Tier 2 data. It cannot be assumed, on the other hand, that fuel additives used in relatively low concentrations or produced in relatively low volumes would automatically be excused from Tier 3. For these products, test results indicative of severe health effects and/or high exposure levels in circumscribed areas might be cause for escalation to Tier 3.

c. Health assessment. General criteria for evaluating the potential public health effects associated with fuel and additive emissions would include (1) the number of positive and negative outcomes related to each endpoint, (2) the identification of concentration-effect relationships, (3) the statistical sensitivity and significance of such studies, (4) the severity of the observed effects (e.g., whether the effects would be likely to lead to incapacitating or irreversible conditions), (5) the number of species involved in the reported tests, and (6) the consistency and clarity of apparent mechanisms, target organs, and outcomes. Additional parameters which would influence the decision on whether to require Tier 3 would include (1) findings of environmental persistence of the emissions and/or the ability of the emissions to accumulate in living organisms, (2) the nature and amount of known toxic agents in the emissions stream, and (3) the observation of lesions which specifically implicate inhalation as an important exposure route for inducing adverse health effects.

These criteria would be evaluated in conjunction with the results of the exposure assessment to determine whether or not higher level testing was needed. In this decision, both the biological and statistical significance of the results of Tiers 1 and 2 would be taken into account. Generally, escalation to Tier 3 would be considered when remaining uncertainties about the significance of observed outcomes and/or exposures interfered with EPA's ability to make reasonable estimates of the attendant public health risks. On the other hand, if no statistically significant effects were obtained at any exposure level in a scientifically sound Tier 2 study (or existing test submitted in lieu of Tier 2 testing and not contradicted by other published reports of equal or greater reliability), and if other major sources of concern did not arise (e.g., toxic effects of structurally related compounds), then Tier 3 testing would not be required for the endpoint in question. This assumes that relevant, high-quality statistical analysis had been done to permit the negative test results to be properly evaluated and interpreted. The statistical analyses

recommended for Tier 2 in an earlier discussion, including determination of Type I and II error, should enable reasonable conclusions to be drawn as to the significance of negative findings. Factors to be taken into account include the toxicological nature of the findings and the exposure levels used in the test. For example, if the statistical analyses were applied to a "severe" endpoint (e.g., major fetal abnormalities, major lung pathology, etc.) and the exposure in question was moderate, then 0.1 would be an appropriate Type II error level. In contrast, if a high concentration limit test caused a relatively minor effect (e.g., a small change in lung lavage protein), a higher Type II error would be allowed (e.g., 0.2), effectively increasing the chance of false negative conclusions.

Evaluation of Tier 2 results. The specific outcomes which would be considered positive and negative results for each proposed Tier 2 test are mentioned briefly in the previous descriptions of Tier 2 requirements and are defined and interpreted more precisely in the proposed regulatory text. For example, three primary studies are included in Tier 2 which relate to carcinogenicity and mutagenicity: the Ames, SCE, and micronucleus assays. As compared with appropriate controls, a statistically significant dose-related positive response in any one of these assays could be cause for concern, as would positive outcomes for at least one concentration in two or more of these tests. Such outcomes would be indicative of mutagenic risk; however, depending on the internal and historical consistency of these results and their relationship to projected exposures, further testing might be required to determine the significance of this mutagenic activity in human populations exposed by inhalation. These outcomes would also indicate that the emissions could initiate some of the mechanisms involved in carcinogenesis. However, the production of malignancy is a multi-step process, and these results would generally not in themselves be sufficient to determine whether the emissions were in fact carcinogenic. Thus, additional testing might be required under Tier 3 to better evaluate the associated cancer risks. In contrast, if no statistically significant results were obtained in these three assays and no conflicting results found in the literature or in other Tier 2 tests, then Tier 3 follow-up for carcinogenicity/mutagencity would not be required.

To take another example, determination of the need to further investigate teratogenic risks would take into account the results of both the inhalation developmental toxicity study and the reproduction and fertility assessment of Tier 2. If negative results were obtained in both of these tests (according to statistically sound principles), and if these results were not refuted by the existing literature, then additional testing would not be required at the Tier 3 level for developmental or reproductive effects. Positive results would include a decrease in neonatal viability relative to that in control studies, a significant change in the proportion of viable male vs. female fetuses or offspring, the presence of soft tissue or skeletal abnormalities, and an increased rate of embryonic or fetal resorption. Other positive outcomes of the reproduction and fertility assessment, such as abnormal changes in sperm structure or function, vaginal cytology, or reproductive organ histopathology, would be indicative of hazards to the adult reproductive systems. The need for additional evaluation under Tier 3 would depend on the number of species from which positive results were obtained, the specificity, severity, and consistency of results, the presence or absence of a concentration-effect relationship, and the significance of these outcomes in view of projected exposure scenarios. The greater the remaining uncertainty regarding the risk of teratogenic or reproductive effects after analysis of such factors, the higher would be the likelihood that Tier 3 would be required.

Similarly, consistent negative results (according to statistically sound principles) obtained in other Tier 2 tests, in the absence of significant related concerns raised in the literature, would make Tier 3 unnecessary. On the other hand, if adverse effects are found at Tier 2 and/or reported in the literature, EPA would determine if Tier 3 follow-up is required by attempting to evaluate the nature, severity, and significance of the findings in light of the likely exposures. If EPA determines that Tier 3 testing is required to resolve the remaining uncertainties, the Tier 3 requirements would reflect both positive and negative results. For example, if the results of Tier 2 were positive for pulmonary effects but negative for neurotoxicity (according to criteria discussed earlier), and if these results were consistent with the literature, only pulmonary toxicity would be a likely candidate for Tier 3 follow-up testing.

Acute health assessment. Under the assumption that emissions exposures will generally be low and thus more likely to cause longer-term effects, this proposed rulemaking does not focus on acute effects. However, the purpose of CAA section 211 is to protect the public health, whatever the exposure duration, and potential acute effects could also be a consideration in the Tier 3 decision.

EPA is currently developing a standardized method of assessing acute noncancer health effects, and this method might be useful for evaluations under this proposal program. The new method will estimate levels of exposure which are expected to pose no or minimal health risk to susceptible subpopulations as well as levels posing incrementally higher risks. A draft of this method is expected in early fiscal year 1993. After a period for comment by EPA's Scientific Advisory Board (SAB) and the public, a final draft is expected in fiscal year 1994. Thus, the new methodology may be available for use in a time frame consistent with the needs of this program. If acute risk must be assessed prior to the availability of the approved methodology, then expert judgment approaches could be applied. EPA seeks comment on these possible methods for taking acute health effects into account in the determination of Tier 3 requirements.

Inhalation reference concentrations. Another standardized methodology under development by EPA might also be applicable to decisions on whether to require Tier 3. This process, the inhalation reference concentration (RfC) methodology, is currently in draft form. After incorporation of revisions based on SAB and public comments, the report is expected to be finalized in fiscal year 1992. From time to time, EPA will be revising this methodology to reflect advances in the state of the art.

While the present RfC methodology recognizes subchronic data, it focuses on chronic data, since the RfC is intended to address health risk due to lifetime exposures. Specifically, a chronic RfC is an estimate of a daily inhalation exposure to humans (including sensitive subpopulations) thought to be without appreciable noncancer risk over a 70-year lifetime. The minimum data base required to develop a chronic RfC includes at least a 90-day inhalation exposure that thoroughly addresses the potential for respiratory tract toxicity and establishes a lowest-observed-adverse-effect level (LOAEL) and a no-observed-adverse-effect level (NOAEL) for a "critical effect." This is a sensitive endpoint that plausibly protects against other less sensitive effects. The NOAEL and LOAEL are adjusted with dosimetric extrapolation factors to derive a human equivalent NOAEL or LOAEL. Various uncertainty factors are then applied to operationally derive the RfC. A draft

methodology and minimal verification criteria for the RfC are available in "Interim Methods for Development of Inhalation Reference Doses, U.S. EPA, 1989 (EPA/600/8–88/066F).

Assuming the RfCs applicable to fuel and fuel additive emissions could be derived from Tiers 1 and 2 information, they could potentially be used to determine testing needs. For example, if exposures were in the vicinity of or significantly above the RfC, the emissions would be considered to have toxic potential and Tier 3 would probably be invoked. If exposures were substantially lower than the RfC, public health concerns would generally be allayed. However, the RfC methodology would not remove the need to temper these conclusions with expert scientific judgment. For example, if the adverse health effects appeared severe or exhibited the potential to progress significantly with duration of exposure, and if the potentially exposed population were large, then signficant concern might persist even if preliminary estimates of the exposure levels were low relative to the RfC. Comments are requested concerning the possible application of the RfC methodology to Tier 3 decision-making in the proposed program.

3. Potential Tier 3 Testing Requirements

To be most cost-effective, Tier 3 testing would be designed to specifically address data gaps regarding the endpoints of concern. Thus, Tier 3 requirements could potentially include further emission characterization procedures, perhaps involving additional vehicles, to identify and quantify harmful emission products with greater precision. Higher-order modeling calculations or exposure field studies could be required to resolve uncertainties in the Tier 1 emissions exposure information. Health effects testing requirements would be aimed at providing sufficient information to make sound conclusions about the degree of health risk. If more than one endpoint were of concern, EPA would attempt to reduce testing costs by permitting combined protocols and/or inhalation exposures insofar as possible. Emission characterization or health effects testing using emissions generated from miscalibrated vehicles or under other non-FTP conditions might sometimes be included.

For a quantitative risk assessment, health effects test exposures would be chosen to permit the determination of a NOAEL and LOAEL. While Tiers 1 and/or 2 may provide some of this information, Tier 3 would typically require NOAEL or LOAEL determinations for longer duration exposures or additional endpoints. If chronic inhalation studies are required, they would generally be preceded by subchronic range-finding studies. These would avoid the possibility of designing a chronic inhalation test with exposure levels so high that excessive mortality occurs or so low that a LOAEL is not identified. Depending on the endpoints under evaluation, consideration would also be given to including a mid-duration examination in the case of chronic inhalation tests. A mid-duration evaluation would be useful for affirming the adequacy of exposure levels and, in some cases, might enable interim risk conclusions to be drawn which would avoid the need for further examination. Inhalation studies would generally make use of rodent species, but higher order mammals might occasionally be required.

While Tier 3 testing requirements would be targeted to critical areas of concern, EPA would also exercise its judgment to avoid the false economy of establishing overly narrow requirements. Just as requirements for too many assays would be wasteful of resources, requirements for too few assays might result in inconclusive findings, creating needs for still further testing at greater total expense than would have been necessary at the start. Similarly, EPA would consider the value of including secondary evaluations as useful and low-cost adjuncts to tests already required. For example, if the histopathology of a specified target organ were the primary examination required at the conclusion of an inhalation exposure, other organs could be weighed and saved in storage for a limited time period, at low incremental expense. If indicated, these other organs would then be available for subsequent examination, avoiding the possible need to repeat the chronic inhalation procedures to assess the effects on these other organs.

Because the specific health testing requirements which would be imposed in Tier 3 would be tailored to individual circumstances, precise test guidelines cannot be provided in advance. However, some of the likely testing scenarios which might be required in Tier 3 are cited below. Where possible, existing TSCA guidelines for these tests are referenced. It should be recognized, however, that such guidelines might need to be revised to accommodate emission inhalation requirements and/or to evaluate certain structures or functions which the current guidelines do not adequately address. Study parameters which might require modification include exposure routes and concentrations, species selection, number of animal subjects, examination procedures and frequencies, and analytic requirements. Furthermore, interim advances in the underlying science and testing technology may provide superior approaches which could be available for use by the time Tier 3 requirements would be implemented.

Tier 3 follow-up for mutagenicity and carcinogenicity concerns raised in Tiers 1 and 2 would often include a cancer bioassay of chronic duration (e.g., 40 CFR 798.3300 or 798.3320). However, this would generally be preceded by short-term studies to investigate the mechanisms involved and, in some cases, these shorter tests might be sufficient to allay concerns or clarify the nature of the risks. Among these possibilities is a mutagenicity battery, which might include a biochemical specific locus test, bacterial DNA damage or repair tests, and heritable translocation test (40 CFR 798.5195, 798.5500, and 798.5955). Newer procedures, such as cell transformation, DNA adducts, and gene amplification, would also be considered. In addition, physiologically-based pharmacokinetic (PBPK) or metabolic studies (e.g., 40 CFR 798.7100) might be required.

Tier 3 evaluation of reproductive and developmental toxicity would generally involve two generation breeding studies (40 CFR 798.4700) and/or reproductive assays by continuous breeding (RACB) [25]. Each of these approaches entails approximately 9–12 months of exposure.

Additional evaluation for neurotoxicity might include metabolic analyses (40 CFR 798.7100), subchronic neurotoxicity (including histopathology) tests (40 CFR 798.6400), and/or one- to two-year chronic inhalation tests (e.g., 40 CFR 798.3260). Such studies might involve neurobehavioral, neurochemical, pharmacokinetic, and/or histopathological assessments. Because fetuses and infants may be particularly sensitive to neurotoxicants, special studies involving in-utero and neonatal exposures might be indicated.

The follow-up required for pulmonary toxicity concerns would frequently involve subchronic and/or chronic inhalation studies (40 CFR 798.2450 and 798.3260), emphasizing histopathology of the respiratory tract. If indicated, pulmonary function measurements, host

[25] A protocol developed by the National Toxicology Program of the National Institute of Environmental Health Sciences is available in the public docket.

defense assays, immunotoxicity tests, and enzyme assays of lavage cells and fluids might be required in conjunction with these exposures. If both chronic toxicity and carcinogenesis were of concern, then a combined protocol (40 CFR 798.3320) would be in order.

Tier 3 testing to follow up on Tier 1 findings would depend on the specific identified concerns. EPA anticipates that such concerns, identified by previous scientific studies in the literature or by the occurrence of known toxic chemicals in the emissions, would most often pertain to potential hepatic, renal, or endocrine toxicity, but effects on other organ systems or physiologic processes are also possible. Potential testing might include metabolic, subchronic exposure, and/or chronic exposure studies (40 CFR 798.7100, 798.2450, and/or 798.3260), but specialized functional, immunologic, and enzyme studies might also be required.

As previously mentioned, Tier 3 requirements could also include additional work to improve the exposure estimates submitted in compliance with Tier 1. The need for additional exposure data would depend in part on the limitations of the Tier 1 estimates, and in part on the nature of the associated health effects information. That is, highly precise and accurate exposure information would not be cost effective if the health assessment were based on limited and/or uncertain results, and vice versa.

The approach which EPA plans to use in determining the potential need for greater precision and accuracy in the exposure information is to consider the slope of the toxic response. If the slope is steep within the range of potential human exposures, then a small change in exposure is likely to have a major impact on the eventual risk assessment. Greater precision would thus be required in the exposure calculation. If adverse health effects appear likely within the projected range of exposures, improved estimates might also be needed to determine the conditions and locations under which these exposures might occur as well as the size of the potentially affected populations. On the other hand, if only minor health effects occur at levels well above ambient concentrations and only a relatively small number of people are likely to be exposed, then additional refinements of the exposure calculations would not be warranted.

Tier 3 exposure assessment could include physical monitoring studies or the application of more sophisticated modeling techniques, some of which are described in Section VI.B.2. However, the precise nature of these studies would be strongly influenced by interim advances that are expected in the growing science of exposure assessment. The general topic of gasoline exposure is receiving increased attention by the scientific community as a topic for research, in recognition of the limited knowledge base currently available for determining the risks from mobile source emissions and from the use of motor vehicle fuels.[26] Thus, new information and new scientific methodologies for monitoring and estimating population exposures are expected to emerge in a time frame which will be useful for guiding the types of exposure assessments which might be required at the Tier 3 level.

EPA requests comments on the possible scenarios and test guidelines outlined above, and solicits suggestions on other health effect and exposure studies which should be considered. An alternative approach for determining Tier 3 testing requirements would permit the responsible manufacturers to propose testing scenarios which would address the areas of concern identified by EPA as requiring Tier 3 follow-up evaluation. Such proposals would be subject to review and approval by EPA scientists prior to their implementation by the manufacturer in compliance with Tier 3. Comments are requested about this alternative approach.

VII. Reporting Requirements

The materials to be submitted to EPA following completion of all Tier 1 and Tier 2 requirements are divided into three major categories: Basic registration data, a summary report, and appendices. Producers who must conduct additional testing under Tier 3 will be required to submit a final report when the designated Tier 3 testing is complete. The nature of the information to be included in each reporting category is described below.

A. Basic Registration Data

The information mandated by existing regulations under section 211(b)(1) must be submitted (or resubmitted) individually for each product being registered, using EPA forms which are in effect at the time of the submittal. This requirement pertains to all previously registered fuels and additives, including relabeled products, as well as those for which first-time registration is sought. However, if the basic registration data previously submitted for an existing fuel or additive is accurate and complete, then a statement asserting that this is so will suffice in lieu of the submittal of duplicate information. A finding by EPA that this information is not, in fact, accurate and complete as claimed will result in the report being considered inadequate.

The basic information currently required for fuel and additive registration includes product and manufacturer identification, concentration and purpose-in-use, and specific compositional data. In addition to these items, information on the production volume of each product will be required. If the producer has participated in group efforts to satisfy Tier 1 and Tier 2 requirements for the product, then identifying information for the group must also be provided. Similarly, if the producer is relying on another manufacturer's (or group's) previous registration materials in compliance with the testing requirements for a new product, then the other manufacturer and product (or group) must be identified. In addition, the producer must certify and provide evidence that the first manufacturer has been notified.

B. Summary Report

This document will provide a text summary of the evaluation procedures, results, and conclusions pertaining to Tiers 1 and 2. A cover page should be included, identifying the subject product, the manufacturer's name and address, and a designated contact person and phone number. For group submissions, all products and manufacturers to which the report pertains must be named, and a contact person, address, and phone number for the group must be identified. If a group submission has been prepared under the aegis of a trade or other umbrella organization, this organization must also be identified. The body of the summary report should be divided into the following sections:

1. Executive Summary

This should consist of a brief description of the general results and conclusions of Tier 1 and Tier 2 activities, emphasizing information and test data which provide evidence for potential adverse health and/or welfare effects.

2. Tier 1 Report

This section of the summary report is intended to provide an overview of the information provided by Tier 1. Detailed procedural descriptions, tables, and other outputs are to be included in the appendices.

Literature search. The search methods should be described, including the identity of data bases, search terms, and

[26] Journal of Exposure Analysis and Environmental Epidemiology, January–March, 1992.

time periods accessed. Any in-house and/or other unpublished studies included in the literature search should also be described briefly. The results and conclusions of the literature search with respect to potential health and welfare effects of the subject fuels/additives should be summarized. If test documentation provided by the literature search has been used to satisfy some or all of the other program requirements, the relevant studies should be discussed and their adequacy to fulfill the specific purposes of the associated program requirements should be justified. Finally, the person(s) or contractors conducting the search are to be identified.

Emission generation and characterization. This section of the summary report should identify the vehicle selected and describe the procedures followed in vehicle preparation and maintenance and in the generation, storage, and processing of emissions for testing. A description of the analytic methods used to characterize the fuel/additive emissions products should also be provided. Problems encountered in generating and/or characterizing the emissions should be discussed, including attempts to resolve the problems and their potential effects on testing outcomes. The laboratories performing these procedures should be identified.

Modeling. The underlying principles, functions, and limitations of the chosen modeling or other analytic methods should be explained, and a summary of results and conclusions provided.

3. Tier 2 Report

For each study, the objectives, principles, and general procedures should be outlined and the findings and conclusions summarized. Discussion should be included regarding problems encountered during the performance of the tests and the methods used to resolve them. This discussion should include the impact which such problems may have had on the study outcomes.

4. Conclusions

Further testing needs should be identified or else a discussion should be provided explaining why the results of Tiers 1 and 2 should not trigger Tier 3 testing requirements.

C. Appendices

Detailed information in support of the general discussions contained in the summary report are to be submitted as appendices to that report. In regard to the literature search, the appendices will contain (1) summary tables, using the format for Table IV suggested within the draft petition process guidelines associated with the air toxics program (available in Central Docket Section A-130, EPA Docket No. A-90-48), (2) a complete printed copy of reference lists and associated abstracts obtained from database searches, (3) complete documentation of in-house studies and other unpublished information sources, and (4) complete documentation (e.g., copies of journal articles) of previous studies which are being cited in satisfaction of emission characterization and/or Tier 2 test requirements. Appendices to the emission characterization section will contain detailed protocols, copies of all relevant laboratory reports, a list of all speciated emission products and their emission rates, and documentation of calibration/verification procedures. For the section on modeling methods, an appendix should be provided for detailed calculations and results.

An appendix is also required for each of the tests conducted in compliance with Tier 2 requirements. These appendices should contain the full detailed study protocol, complete laboratory report, statistical analysis of the findings, and scientific conclusions. These materials should conform to the reporting requirements of the individual study guidelines as well as the general standards for record keeping and reporting specified in 40 CFR part 792, subpart J. A final appendix should be provided, containing laboratory certifications and associated personnel credentials.

D. Tier 3 Report

Reports for additional tests required under the provisions of Tier 3 should include a cover page with identifying information as described above for the Tier 1 and 2 summary report. The report should begin with discussion of the concerns arising under the previous tiers which led to the Tier 3 requirements, the specific objectives of the additional studies, and a summary of pertinent results and conclusions. This summary discussion should be supported with appendices containing the kinds of documentation discussed above with respect to Tier 2: Full protocols, lab reports, statistical analyses, discussion of problems and findings, and conclusions. The laboratory conducting the required tests must be identified, and relevant certifications and personnel credentials provided.

VIII. Special Provisions

A. Exemption for Relabeled Products

A company's product is registered as "relabeled" if it is simply a repackaged and rebranded version of a formulation which is also registered by the original manufacturer. As previously discussed, requiring companies which sell relabeled products to conduct the health and welfare effects assessments proposed in today's rulemaking would clearly duplicate the efforts of the original manufacturer. Thus, under the authority of section 211(e)(3)(C), which provides that the Administrator may exempt from the rule any fuel or fuel additive upon a finding that any testing of that fuel or fuel additive would be duplicative of adquate existing testing, relabeled products will be exempt from the evaluation and testing requirements of the registration program. For relabeled products, only basic registration information will be required, as described above in section VII.A. Of course, this presumes that the registration requirements proposed in this NPRM would be satisfied for the original product by the original manufacturer.

Among the total of 1,160 manufacturers with one or more registered fuel additives as of mid-1990, over half (604) registered only relabeled additives, and will therefore not be required to comply with the health and welfare effects assessment provisions of the registration program. Relabeled additives account for approximately 30 percent of all additive products currently registered.

B. Applicability of Evaporative Emission Testing

As discussed fully in section III.C, requirements for the chemical characterization and toxicologic testing of evaporative emissions are proposed to apply only to those fuels and additives for which vaporization is expected to be significant. Fuels which are supplied by way of sealed containment and engine delivery systems would thus be exempt from evaporative emission requirements, as would liquid fuels with RVP less than 2.0 psi. Methane, propane, and diesel fuels would be exempt from evaporative emissions testing under this guideline.

The proposed criteria for determining the applicability of evaporative emission testing requirements to additives are based on (1) the change in RVP of the appropriate additive/base fuel mixture relative to the RVP of the base fuel alone, and (2) the partial pressure of the additive in the additive/base fuel mixture. If the presence of the additive does not increase the RVP of the base fuel by at least 0.1 psi, and if the partial pressure of the additive in the additive/fuel mixture in the vapor phase at 100

degrees Fahrenheit and atmospheric pressure is less than 0.1 psi, then evaporative emission testing would not need to be performed.

C. Small Business Provisions

Section 211(e) grants EPA discretionary authority to provide program exemptions, deferments, or modifications for small businesses. However, in developing the proposed registration program, EPA has carefully balanced the desire for rigorous scientific evaluation with consideration for the associated costs, and has included a number of provisions designed to decrease the cost burdens to all manufacturers. These general cost-reduction provisions include: (1) The tiered program structure which imposes rigorous testing requirements only when needed to further explicate significant identified concerns, (2) the opportunity to share program costs and burdens with other manufacturers, (3) the ability to rely on existing adequate information for compliance with testing requirements, (4) the exemption for relabeled products, and (5) the general reliance on existing regulatory programs for evaluating potential emission control system effects. In consideration of these provisions, EPA is not initially proposing to implement the authority to make special allowances for small businesses.

EPA's economic analyses indicate that the financial impact of the proposed program on most fuel and fuel additive producers would be relatively modest. The median cost per producer is estimated to be about $2,000 for compliance with Tiers 1 and 2. Furthermore, the costs for about 85 percent of small fuel companies and 70 percent of small additive companies (as defined by the Small Business Administration) would be less than $10,000. Nevertheless, the estimated total costs per manufacturer vary widely, from about $500 to over $2 million, depending on each manufacturer's number and type of products and opportunities for cost-sharing with manufacturers of similar products. Thus, as one might expect, the financial impact of the proposed program could be significant for some small companies.

As discussed further in section XIV, below, a Regulatory Flexibility Analysis conducted by EPA indicates that small fuel producers would not be jeopardized by the proposed rule, but that nearly six percent of small additive manufacturers (about 1.5 percent of all fuel/additive manufacturers) might experience financial distress. However, size alone does not predict which additive manufacturers would be adversely affected, and EPA has not yet been able to identify what, if any, common factors place certain small companies at risk. Further analysis is expected to clarify these factors and, if appropriate, EPA may elect to implement special provisions for such companies in the final rule.

Various alternative provisions are under consideration for this purpose. First, the vulnerable companies could be excused from one or more of the program's requirements. For example, they could be excused from all Tier 2 biological testing or could be required to conduct only those Tier 2 tests which address the endpoints mandated by statute (carcinogenicity, mutagenicity, and teratogenicity). Another alternative would be to require only the Tier 1 literature search for such companies. To ensure that no small additive companies would be financially stressed by the regulations, complete program exemptions might be necessary. However, the potential health and environmental effects associated with an additive product are generally not related to the size of its producer, and EPA does not favor this alternative. On the other hand, because risk is partly a function of exposure, and potential exposure to an additive's emissions is related to the volume produced and sold, appropriate measures of volume in conjunction with other relevant financial parameters may be reasonable to consider in determining possible small business allowances.

Public comment is requested concerning these small business issues and alternative ideas for possible small business allowances or exemptions.

D. Possible Exemption for "De Minimis" Factors

EPA is considering the creation of program exemptions for certain fuel additives which are expected to have only a *"de minimis"* impact on the composition and biological effects of motor vehicle emissions. These exemptions are contemplated under two sets of circumstances, described below. EPA requests comment on each of these possible exemptions.

The first exemption under consideration would relate to additives which are recommended for use at less than 2,500 ppm maximum concentration in fuel and which fall into the "baseline conventional" categories described above in section IV. Because the elemental composition of these additives is the same as their associated base fuels, and because some degree of emissions variability is inevitable, it may be extremely difficult to distinguish the emission products or the emissions-based biological effects of these additives (as mixed in base fuel) from the emission products or effects of the base fuel alone. These factors are reflected in the proposed grouping scheme, in which baseline conventional additives and fuels are grouped together and share the same representatives. However, an argument can be made that test requirements for these additives would be duplicative of the requirements for the related fuels, and that a testing exemption for the additives might be justifiable under section 211(e)(3).

If the exemption for baseline conventional additives were put into effect, then the second exemption possibility would arise. This potential exemption would apply to those additives in the "atypical" formulation classes (see section IV) which had such small concentrations of the atypical components that their emission products could be judged to be of negligible toxicologic significance. The specific concentration criterion for this exemption could be established by assuming that the toxicity of the atypical component was similar to that of a known toxic agent (e.g., lead or benzene) and then estimating the maximum concentration of such a toxicant which would result in an insignificant exposure risk.

Comments are solicited in regard to possible exemptions under these *"de minimis"* circumstances. Suggestions for the specific concentration which could be used as the threshold for granting atypical additive exemptions, and the underlying rationale for selecting that threshold, are also welcome.

E. Possible Temporary Exemption for Experimental Fuels and Fuel Additives

As part of the August 7, 1990 ANPRM for this action, EPA requested comment on whether special provisions should be included for low volume fuels and additives. In general, commenters on the ANPRM did not support a long term or permanent exemption for low production volume fuels/additives due to equity and public health considerations.

Nevertheless, EPA believes that, under certain circumstances, a temporary exemption for low production volume, experimental fuels and additives may be appropriate, similar to the provisions for experimental chemicals under the Toxic Substances Control Act (TSCA). Authority for this possible provision would be based on CAA section 211(e)(3)(A), which permits EPA to exempt, defer, or modify the program requirements for any small

business, with "small business" to be defined within the regulations. Given that compliance costs for this proposed program could exceed a million dollars for new or unique fuels and additives, the proposed testing and evaluation requirements could pose a substantial barrier to innovation and development at a time when both environmental and energy concerns are generating significant public and private sector interest and activity in this area.

Thus, EPA requests comments on the possibility of providing a temporary program exemption or deferment for experimental fuels and additives. Eligibility for this possible exemption would be limited to new products, i.e., those which were not registered as of the effective date of the final rule or, if already registered, had not yet been placed into wholesale or retail commerce. Instead of meeting the program requirements immediately, the interested producer would apply to EPA for a deferment. The application would provide details on the chemical, physical, and functional properties of the fuel or additive involved, the purpose of the requested temporary exemption, the anticipated volume of use, and the expected toxicity and exposure related to the product and its combustion and evaporative emissions. Information required under 40 CFR 723.50 covering exemptions for Premanufacture Notification under TSCA would also be required. The temporary exemption would require EPA approval following submittal of the application and review by EPA.

The temporary exemption would be available only when the use of the fuel or additive was restricted to experimental (research, development, and evaluation) purposes. No product in commercial application, i.e., wholesale or retail sale, would be eligible for the deferment of testing requirements. In addition, a volume limitation could be established. For example, the exemption could apply only to experimental fuels not exceeding, say, 500,000 pounds per year or experimental additives not exceeding 2,500 pounds per year of production or consumption. Alternatively, similar to 40 CFR 720.36 and 40 CFR 790.42(a)(5) promulgated under TSCA, no volume limit would be placed on production and use, provided that the use of the fuel or additive was restricted to experimental purposes. The temporary exemption would be good for a period of 5 years after the exemption was approved by EPA, but would expire if the annual use exceeded any potential volume limitations or if the product was offered for wholesale or retail sale. EPA asks comment on whether additional annually renewable exemption periods should be permitted. Comment is also requested on whether volume restrictions should be established and, if so, what limitations would be most appropriate.

IX. Compliance Considerations

As discussed above, the Tier 1 and Tier 2 information proposed in this rulemaking must be submitted prior to registration in the case of fuels and fuel additives which are not registered on the date of promulgation of the final regulations (expected June 1, 1993). Fuels and additives already registered on the date of promulgation must comply with the regulations within three years following the effective date of the final rule. If further testing and information submittal is required under Tier 3 provisions, a separate timetable would be established for compliance with such requirements.

Failure to comply with the requirements of the rule could result in revocation of a product's registration. In addition, direct financial penalties are specified in section 211(d) of the statute. According to this provision, persons who fail to submit any information or conduct any tests required by the Administrator under section 211(b) shall be liable to the United States for a civil penalty of not more than $25,000 for every day of such violation plus the amount of economic benefit or savings resulting from the violation. Each day after the due date for submission of data shall constitute a separate day of violation. Civil penalties shall be assessed in accordance with sections 205(b) and (c), which permit EPA to proceed either in court or in an administrative action. In addition, the district courts of the United States have jurisdiction to compel the furnishing of information and the conduct of tests required under section 211(b).

EPA would consider failure to submit information, or submission of information that does not comply with the requirements of this rule, to constitute a violation of sections 211 (b) and (e). If a group of manufacturers commits to performing joint testing, each manufacturer would separately be in violation of the rule. However, the Administrator would retain the authority to remit or mitigate any penalty.

Because EPA recognizes that unusual circumstances outside the control of the manufacturer may occasionally interfere with the ability to comply with all of the provisions of the rule, the proposed regulations contain mechanisms to allow manufactuers to request modification of the requirements. However, EPA expects persons subject to this rule to submit comments about the feasibility of the proposed testing requirements during the comment period, and does not intend the modification process to be used in place of such commentary. Instead, the purpose of the proposed modification process is to allow only persons who experience unforeseen difficulties or accidents in conducting the needed tests to request modification of the requirements in order to avoid being in violation of the rule. However, section 211(e) requires the requisite (Tier 1 and Tier 2) information to be submitted to EPA for previously registered products within three years after the effective date of the rule. Accordingly, EPA proposes that modification requests must be submitted as soon as the manufacturer is aware of the difficulty, thus prohibiting persons from waiting until the deadline before informing EPA of circumstances which might prevent EPA from receiving the data on time.

X. Confidential Business Information

A provision under section 211(b)(2) states that the results of health effects tests "conducted in conformity with test procedures and protocols established by the Administrator" shall not be considered confidential. Thus, information supplied to EPA in compliance with testing requirements will be available to the public. However, the statute specifically differentiates between health effects test data and other information submitted for registration. Thus, data on product composition and other registration information not integral to the testing program will continue to be held in confidence.

XI. Public Participation

EPA strongly encourages full public participation in its decision-making processes. In addition to those areas where specific comment has been requested, EPA solicits comments on all aspects of today's proposal from all interested parties. Whenever applicable, full supporting rationale, data, and detailed analyses should also be submitted to allow EPA to make maximum use of the comments. Commenters are encouraged to provide specific suggestions for improvements to any aspect of the proposal, especially in regard to modifications which could reduce the costs and burdens of fuel and fuel additive registration without unduly compromising the scientific accuracy of the program or compliance with the statutory intent. All comments should be

directed to the EPA Air Docket Section, Docket No. A–90–07 (see "ADDRESSES"). Comments will be accepted for 30 days after the public hearing (see "DATES" and "SUPPLEMENTARY INFORMATION" in section I).

XII. Statutory Authority

The statutory authority for this proposal is provided by sections 205(b) and (c), 211, and 301(a) of the Clean Air Act as amended (42 U.S.C. 7524(b) and (c) 7545, and 7601(a), Public Law 95–95).

XIII. Administrative Designation and Regulatory Analysis

Under Executive Order 12291, EPA must judge whether a regulation is major and therefore subject to the requirement that a Regulatory Impact Analysis (RIA) be prepared. Major regulations are defined to be those which have an annual impact on the economy of $100 million or more, have a significant adverse impact on competition, investment, employment, or innovation, or result in a major price increase for the affected product.

A regulatory support document which presents EPA's analysis of the costs and economic impacts of the proposed rule is available for review in the public docket. EPA estimates that the costs to industry for submittal of the proposed requisite data for Tiers 1 and 2 would total approximately $83 million incurred over the first three year period after promulgation of the final rule. Thus, the average annual cost during this period would be about $27 million. In the subsequent three years, Tier 3 requirements might cost an additional $10 million annually. These projected overall costs are far less than the $100 million annual cost criterion which defines a "major rule". Also, the proposed rule would not be expected to significantly impact competition, investment, employment, or innovation, or result in major price increases in the industry.

This proposed regulation was submitted to the Office of Management and Budget (OMB) for review as required by Executive Order 12291. Any written comments from OMB and any EPA response to OMB's comments are available in the public docket for this rulemaking.

While the costs of the proposed program would be expected to vary widely between various fuel/additive groups and amoung individual manufacturers, a hypothetical example may help to clarify the proposed scope, time frame, and costs of the program. Based on the analysis provided in the regulatory support document, a possible testing scenario and the associated compliance costs for a hypothetical group of products is discussed below and summarized in Figure 6. These costs would pertain to the evaluation and testing of a fuel selected to represent the hypothetical group. The total costs would subsequently be shared by all of the manufacturers with products enrolled in the group. The requirements and costs assume that the group consists of 40 fuels and additives which contain no "atypical" elements, that the group does not qualify for exemption from evaporative emission testing, and that adequate existing studies are not available to fulfill any of the speciation or biological test requirements. Therefore, under this hypothetical situation, all of the potential requirements of Tiers 1 and 2 must be conducted. Combustion emission generation procedures are assumed to be performed using one light-duty vehicle, for both emission characterization and biological testing purposes.

FIGURE 6: HYPOTHETICAL COST SCENARIO

	Cost
Tier 1 requirements	
Data Research and Analysis	$16,500
Vehicle Costs	32,500
Combustion Emission Generation/Speciation	27,000
Evaporative Emission Generation/Speciation	4,000
Total Tier 1 Costs	80,000
Tier 2 requirements	
Combustion Emission Generation	59,000
Biological Tests on Combustion Emissions	294,000
Evaporative Emission Generation	16,000
Biological Tests on Evaporative Emissions	286,000
Total Tier 2 Costs	655,000
Administrative and Reporting Costs	157,000
Total Tier 1, Tier 2, Administrative Costs	892,000
Estimated Costs of Tier	32–2,500,000
Total Costs	3–3,500,000

Under this scenario, the cost of conducting all requirements of Tier 1 is estimated at approximately $80,000. Of this, EPA estimates data research and analysis (literature search and data modeling) costs to be about $16,500, and vehicle-related costs (acquisition/operation/mileage accumulation) to be about $32,500. EPA estimates a cost of $27,000 for generation and speciation of combustion emissions, and approximately $4,000 for generation and speciation of evaporative emissions.

Further, EPA estimates the costs of conducting all Tier 2 test requirements to total nearly $655,000 under this hypothetical example. Including set-up costs, combustion emission generation costs are estimated at about $59,000, while biological testing of combustion emissions is estimated at nearly $294,000. The cost of generating adequate evaporative emissions to conduct all Tier 2 screening tests would be approximately $16,000, and conducting Tier 2 tests on these emissions is estimated to cost $286,000.

The administrative costs for organizing and administering the group and for reporting the Tier 1 and 2 results to EPA is judged to be nearly $157,000. Adding this to the Tier 1 and Tier 2 costs provided above yields a total cost of approximately $892,000 for the group as a whole. Assuming these costs are incurred over a three-year period and are divided equally among the 40 products in the group, the cost to a manufacturer with a single product in this group would be about $7,300 annually for three years, or $22,000 in total.

Let us assume further that, within 18 months of receiving the group's report, EPA determines that the submittal is complete and that the required Tier 1 and 2 evaluations have been adequately performed. However, a number of health concerns are raised by the results. The literature search suggests a high potential for toxic liver effects to be caused by chronic exposure to the combustion emissions of fuels similar to those in the group, and the Tier 2 results indicate a need for further evaluation of possible carcinogenic and pulmonary effects of three emissions. In addition, a large and widespread population is expected to be exposed to the emissions of products in this group. Thus, EPA determines that more rigorous testing is necessary under Tier 3 to clarify the potential risks posed by this group of products.

Under this hypothetical scenario, two tests are likely to be required to address the identified areas of concern: A two-year combined chronic toxicity/carcinogenicity study conducted in two species, and a metabolism study to elucidate the potential carcinogenic mechanisms. The group is given three years in which to complete these tests. The total cost, including costs for emission generation and biological testing, is estimated at 2 to 2.5 million dollars. When divided equally among the 40 products in the group and spread over the three-year compliance period, the Tier 3 testing cost per product in this

group would be in the range of $17–21,000 annually for three years.

In sum, EPA estimates that the total costs to this hypothetical group would range from approximately 3 to 3.5 million dollars, incurred over a seven or eight year time period. The total cost for each product would range from about $75,000 to $87,500, averaging about $10–12,000 per year. EPA seeks comments on these estimates, given such a scenario.

The above discussion illustrates the compliance costs which the proposed program might entail for a group of fuel/additive producers. However, the proposed program could have some indirect cost implications, as well. For example, if the costs of compliance represented a significant barrier to entry into the fuel/additive marketplace, real social costs (including potential environmental costs) could be incurred as a result of delayed or deterred innovation. These potential social costs have not as yet been quantified, and EPA requests comment, along with supporting data, on how to evaluate and quantify such indirect impacts of the program.

XIV. Compliance with Regulatory Flexibility Act

Under section 605 of the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, the Administrator is required to assess the economic impact of this proposed regulation on small business entities. Accordingly, a Regulatory Flexibility Analysis (RFA) has been prepared and is available in the public docket. The RFA compares the estimated financial effects of the proposed programs on large and small companies as defined by the Small Business Administration.

Using weighted average financial statistics based on a sample of current fuel and additive manufacturers, the RFA analyzes the impacts of the proposed program by projecting the effects which the estimated compliance costs would have on each company's return on assets (ROA). For both fuel and additive producers, the analysis shows that changes in ROA directly attributable to the proposed regulations would be greater for small companies than large ones. On the average, small companies tend to have lower compliance costs than large companies, but this tendency is outweighed by the relatively greater vulnerability of small companies resulting from their much lower levels of assets and earnings.

Among fuel manufacturers, these ROA effects do not appear to have a significant impact. Only two small fuel producers in the sample would experience a reduction in ROA by as much as one percent, and none would be driven into severe financial distress or closure. Among additive manufacturers, however, the impacts of the proposed regulations appear more significant. While the impacts on large additive companies would be extremely minor, the analysis projects that 23 (almost six percent) of small additive companies might experience a reduction in ROA to less than 2.5 percent, which is indicative of financial stress. In addition, 18 small companies might be pushed into severe financial distress (ROA < -4 percent), and two into closure (ROA < -30 percent). Additional analysis will be needed to identify the specific factors which cause this subset of small additive companies to be at particular financial risk. Potential allowances for small businesses are discussed above in section VIII.C.

XV. Compliance with the Paperwork Reduction Act

The information collection requirements in this proposed rule have been submitted for approval to the Office of Management and Budget (OMB) under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* An information Collection Request document has been prepared by EPA (ICR No. 309.06) and a copy may be obtained from Sandy Farmer, Information Policy Branch; EPA; 401 M St., SW. (PM–223Y); Washington, DC, 20460 or by calling (202) 260–2740.

Public reporting burden for this collection of information is estimated to vary from 1 to 1,768 hours per response with an average of 440 hours per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing the collection of information.

Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Chief, Information Policy Branch; EPA; 401 M St., SW., (PM–223Y); Washington, DC, 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC, 20503, marked "Attention: Desk Officer for EPA". The final rule will respond to any OMB or public comments on the information collection requirements contained in this proposal.

List of Subjects in 40 CFR Part 79

Fuel, Fuel additive, Gasoline, Motor vehicle pollution, Penalties, Incorporation by reference.

Dated: April 1, 1992.

William K. Reilly,

Administrator.

[FR Doc. 92–8066 Filed 4–14–92; 8:45 am]

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Part III

Environmental Protection Agency

40 CFR Parts 80, 86, and 600

Control of Air Pollution From New Motor Vehicles and New Motor Vehicle Engines; Refueling Emission Regulations for Gasoline-Fueled Light-Duty Vehicles and Trucks and Heavy-Duty Vehicles; Proposed Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 80, 86, and 600

[AMS-FRL-4120-1]

RIN 2060-AC04

Control of Air Pollution From New Motor Vehicles and New Motor Vehicle Engines; Refueling Emission Regulations for Gasoline-Fueled Light-Duty Vehicles and Trucks and Heavy-Duty Vehicles

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final agency action pursuant to section 202(a)(6) of the Clean Air Act regarding onboard control of refueling emissions.

SUMMARY: On August 19, 1987 (52 FR 31162), EPA published a proposal to require vehicle-based (onboard) control of refueling emissions from gasoline-powered light-duty vehicles, light-duty trucks, and heavy-duty vehicles. This notice announces EPA's decision not to promulgate onboard control requirements at this time and explains the rationale for that decision.

ADDRESSES: Materials relevant to this action are contained in public dockets A-87-11 and A-84-07, located in the Air Docket of the U.S. Environmental Protection Agency, 401 M St., SW., Washington, DC and are available for review in room M-1500 between the hours of 8:30 a.m. to 12 p.m. and 1:30 p.m. to 3:30 p.m. on weekdays. As provided in 40 CFR part 2, a reasonable fee may be charged for copying.

FOR FURTHER INFORMATION CONTACT: Mr. James Bryson, U.S. Environmental Protection Agency, Regulatory Development and Support Division, 2565 Plymouth Rd., Ann Arbor, MI 48105, telephone: 313-741-7828.

SUPPLEMENTARY INFORMATION

I. Background

For over 15 years, the control of vehicle refueling emissions has been the subject of a complex debate. Two technologies exist to control these emissions: Onboard (vehicle-based controls) and Stage II (controls at the dispensing pump). Each approach has certain advantages and disadvantages, but if implemented properly, either would be effective at controlling refueling emissions.

Section 202(a)(6) of the 1977 Clean Air Act (CAA) Amendments directed EPA to study the relative merits of the two control strategies for refueling emissions. If, based on the study, EPA found onboard vapor recovery feasible and desirable, it was to prescribe standards requiring the use of such technology after consulting with the Secretary of Transportation with respect to motor vehicle safety. EPA began the study of onboard and Stage II controls in 1983, and in 1984 released a draft gasoline marketing study for public comment (49 FR 31706, August 8, 1984) (see public docket A-84-07). In the same time frame, EPA also initiated consultation with the Department of Transportation (DOT) (through the National Highway Traffic Safety Administration (NHTSA)) regarding onboard safety. In these discussions, NHTSA expressed concern that the implementation of onboard canister systems would cause an unquantifiable increase in the risk of crash and non-crash vehicle fires. Docket Number II-D-05 and -10. Entries of this nature throughout this document indicate where such material can be found in public docket A-87-11.

Following review of the comments on EPA's draft gasoline marketing study, EPA concluded that the control of vehicle refueling emissions was appropriate and that onboard controls were feasible and desirable, and a rulemaking was begun. As part of the proposed rulemaking analysis, EPA prepared a technical report assessing NHTSA's concerns. (II-A-17) In August, 1987, EPA published a proposal to require onboard canister systems for gasoline-powered motor vehicles, seeking comment on concerns raised regarding vehicle safety issues (52 FR 31162, August 19, 1987).

Following publication of the proposal, EPA received public comment reflecting both sides of the safety issue. Auto industry interests and several safety organizations expressed concerns similar to NHTSA's, while gasoline marketing interests and other safety and environmental groups thought such concerns were not significant. After the comment period closed, discussion between EPA and NHTSA continued, as technical staff attempted to resolve their differences.

As the consultation continued, Congress began debate in earnest about revisions to the CAA. As it became clear that the amendments would address the control of refueling emissions, EPA postponed making any final decisions pending the new legislation.

The CAA Amendments of 1990 contain provisions addressing both Stage II and onboard. As is discussed more fully below, sections 182(b)(3), (c), (d) and (e) require Stage II in moderate, serious, severe, and extreme ozone nonattainment (NA) areas. Under section 182(b)(3) and 184(b)(2) State II might also be implemented in marginal ozone NA areas and attainment areas in the Northeast U.S. section 202(a)(6) requires action on onboard controls:

> (6) ONBOARD VAPOR RECOVERY.—Within 1 year after the date of enactment of the Clean Air Act Amendments of 1990, the Administrator shall, after consultation with the Secretary of Transportation regarding the safety of vehicle-based ("onboard") systems for the control of vehicle refueling emissions, promulgate standards under this section requiring that new light-duty vehicles manufactured beginning in the fourth model year after the model year in which the standards are promulgated and thereafter shall be equipped with such systems. The standards required under this paragraph shall apply to a percentage of each manufacturer's fleet of new light-duty vehicles beginning with the fourth model year after the model year in which the standards are promulgated. The percentage shall be as specified in the following table:

IMPLEMENTATION SCHEDULE FOR ONBOARD VAPOR RECOVERY REQUIREMENTS

Model year commencing after standards promulgated	Percentage [1]
Fourth	40
Fifth	80
After Fifth	100

[1] Percentages in the table refer to a percentage of the manufacturer's sales volume.

> The standards shall require that such systems provide a minimum evaporative emission capture efficiency of 95 percent. The requirements of section 182(b)(3) (relating to Stage II gasoline vapor recovery) for areas classified under section 181 as moderate for ozone shall not apply after promulgation of such standards and the Administrator may, by rule, revise or waive the application of the requirements of such section 182(b)(3) for areas classified under section 181 as Serious, Severe, or Extreme for ozone, as appropriate, after such time as the Administrator determines that onboard emissions control systems required under this paragraph are in widespread use throughout the motor vehicle fleet.

II. Outcome of Consultation With DOT

As directed by the CAA Amendments of 1990, EPA has consulted with DOT regarding the safety of vehicle-based (onboard) canister systems for the control of refueling emissions. During the first half of 1991, several meetings and discussions were held between EPA and NHTSA officials regarding the consultation process, and correspondence was exchanged regarding both the consultation process and technical matters related to onboard safety. (IV-B-20; IV-C-170, 171, 172; IV-D-689, 691, 698, 699, 749; IV-H-06, 07) As part of that process, in August 1991 NHTSA released an updated report

on onboard safety entitled "An Assessment of the Safety of Onboard Refueling Vapor Recovery Systems". (IV–D–701) As stated in the report's Executive Summary, the purpose of the report was "to establish NHTSA's consultation position concerning onboard safety, in accordance with statutory direction, to be used by EPA in its rulemaking deliberations concerning ORVR [onboard system] safety." The principal conclusion of the NHTSA report is that onboard canister systems—the only onboard system design beyond the most preliminary stages of development and, therefore, the only design capable of being evaluated in the report—will result in an increase in safety risk and thus have a negative impact on safety.

In response to the release of NHTSA's report, EPA published a Federal Register notice (56 FR 43682, September 3, 1991) announcing the availability of the report and seeking comment on the content and findings of the NHTSA study. A public hearing was held on September 26 and 27, 1991, and NHTSA officials participated on the hearing panel. Sixteen parties provided oral testimony at the public hearing and over 30 written comments were received. Copies of all of these materials are also available in the docket.

On October 31, 1991, based on NHTSA's review of the presentations made at the public hearing and submissions made to the public docket, the NHTSA Administrator sent EPA a letter stating that the conclusions of its July 1991 report were unchanged. (IV–H–08) In a November 8, 1991 letter, EPA asked NHTSA to provide specific responses to comments on the NHTSA report and to provide the technical basis for the statement that the comments received on the report had not changed NHTSA's views regarding onboard canister system safety. (IV–H–9) NHTSA replied in a November 27, 1991 letter to EPA which included a technical evaluation of, and response to, the comments on the NHTSA report. (IV–H–10) The technical evaluation reaffirmed the conclusions expressed in NHTSA's report and in the NHTSA Administrator's October 31, 1991 letter.

The NHTSA report contained several conclusions. As mentioned above, the principal conclusion of the report is that onboard systems will result in an increase in safety risk and thus have a negative impact on vehicle safety. This conclusion is based on three supporting conclusions. First, canister-based onboard systems would be more complex in design and operation than current evaporative systems (i.e. canister systems currently used to capture evaporative emissions (not refueling emissions)), and this greater complexity would lead to greater risk. Second, canister-based onboard systems would entail the handling and storage of greater amounts of flammable vapor on the vehicle, leading to greater crash and non-crash fire risks. Third, NHTSA's analysis of its data indicates that vehicle fire risks would increase with onboard canister-based systems. NHTSA did not quantify the increase in risk, but concluded that some risk was inherent in canister-based onboard technology and noted that Stage II technology does not present this concern.

Concerns regarding design and operating complexity and increased safety risk were supported by a number of findings in the NHTSA report:

—As compared to current and future evaporative systems, the increase in the number of parts and connections with canister-based onboard systems will make canister-based onboard systems more vulnerable to failure in collisions and in normal use.

—Some onboard system components, such as filler pipe nozzle sealing devices and vapor vent valves, will need to be placed in areas of potential collision damage, adding to the likelihood of fuel and vapor release in collisions.

—As compared to current and future systems, many onboard system components will be larger and therefore more difficult to locate in areas less likely to sustain damage in collisions.

—The larger onboard system components, particularly during operation in high ambient temperatures, will carry much larger inventories of fuel vapor than current evaporative systems, increasing the likelihood of fires if a release of this vapor should occur in the presence of an ignition source.

Concern that vehicle fire risks would increase with onboard canister systems was also supported by several findings:

—During the refueling process, vapor flow from the fuel tank to an onboard system canister for vapor storage can be 45 to 65 grams per minute. This is much greater than current evaporative flow rates, which rarely exceed 6 to 8 grams per minute and are generally less than 1 gram per minute. The flow is also greater than that contemplated by the type of enhanced evaporative controls being considered under section 202(k) of the CAA. Should this vapor escape, due to a design or manufacturing error, improper maintenance, or tampering, uncontrolled vapor would flow into the engine compartment or under the vehicle and ignite, should an ignition source be present.

—NHTSAlaboratory tests simulating a failed refueling vapor vent hose indicated that vapor flowing through this hose, if exposed to ignition sources characteristic of the motor vehicle environment, would ignite and result in a sustained flame.

—High vapor flow during vehicle refueling will result in a significant increase in the fuel vapor stored onboard the vehicles in canisters, compared to existing vehicles.

—Full scale laboratory vehicle crash tests indicate that even current evaporative canisters can lose their integrity in crashes and expose the charcoal/vapor contents of the canister to possible ignition sources. NHTSA test simulating a canister broken due to collision forces indicated that the vapor in canisters, if exposed to ignition sources characteristic of the motor vehicle environment, would ignite and result in significant, self-sustaining fires.

Finally, it is worth noting one other finding of the NHTSA report regarding the status of onboard technology:

—There are no onboard prototype systems that function satisfactorily under all vehicle operating conditions and that meet current evaporative and tailpipe emission requirements. Further, there are no onboard prototypes that can meet the more stringent tailpipe and enhanced evaporative emissions requirements of the 1990 Clean Air Act Amendments.

In addition to this principal conclusion and the supporting findings, NHTSA notes that, according to EPA and other studies, Stage II vapor control systems are an effective existing technology which presents no incremental risk and are thus a viable alternative to onboard controls. NHTSA then concludes that EPA should consider the risk differences of onboard and Stage II in the regulatory decision concerning onboard controls, and that it would be reasonable for EPA to conclude that onboard systems constitute an unreasonable safety risk.

III. EPA's Discretion To Determine Whether to Require Canister-Based Onboard Controls

1. Whether EPA Has Discretion Not To Issue an Onboard Requirement

Before discussing EPA's evaluation of and response to NHTSA's report and related documents, an initial question is

whether EPA has discretion not to require onboard controls, in light of the results of the consultation process. The Agency believes it apparent from the statutory text and structure, as well as from the legislative history to section 202(a)(6), that EPA retains discretion not to require onboard controls due to concerns regarding their safety. The words of command together with the deadline found in section 202(a)(6) establish a mandatory duty for the Agency to take action regarding onboard controls by the specified dates. The consultation requirement in section 202(a)(6), however, leaves the statute ambiguous about what action EPA may take in light of that process. Congress would not have mandated imposition of onboard controls if the Department of Transportation and EPA find, after consultation, that these systems pose unreasonable safety risks. To have meaning, the consultation requirement must allow EPA to decline to impose requirements based on the results of the consultation process.

EPA also rejects the contention that any safety concerns with onboard control systems noted in the consultation process should only be redressed during the vehicle certification process pursuant to section 206(a)(3)(A). This would mean, potentially, that automakers would be required to comply with a requirement to install a device that they would be subsequently prohibited from using. The Agency does not believe that Congress intended to mandate this irrational result. Moreover, as discussed below, the legislative history to section 202(a)(6) states that Congress intended EPA to resolve the issue of onboard control system safety in this rulemaking.

A second statutory indication that EPA is not mandated to issue a rule requiring onboard controls occurs in the portion of section 202(a)(6) describing Stage II controls, in which Congress recognized the possibility that onboard requirements would not be promulgated. Section 202(a)(6) provides that only after EPA issues an onboard requirement would states be relieved of the requirement (in section 182(b)(3)) that Stage II controls be installed in moderate ozone nonattainment areas. If the imposition of onboard requirements were mandatory, however, this language (indeed, the section 182(b)(3) requirements themselves) would be unnecessary. Moreover, if EPA had a mandatory duty to issue onboard controls as of November, 1991, then it would make little sense for Congress to have required states to submit State Implementation Plan revisions by November, 1992, requiring Stage II controls in ozone moderate nonattainment areas.

The legislative history to section 202(a)(6) confirms that EPA retains discretion not to require onboard controls based on the consultation process with DOT. The House Report states:

> Paragraph 202(a)(6) directs the Administrator, in consultation with the Secretary of Transportation, to determine that onboard vapor recovery systems are safe. It is expected that this determination will be made before the promulgation of the regulations under this paragraph. The determination is an independent duty and shall not affect the Administrator's mandatory duty to promulgate regulations, subject to paragraph 202(a)(4), which provides that emission controls may not cause an unreasonable risk to safety.
>
> Refueling emissions control has been a contentious issue for many years. This provision will resolve the safety issue * * *.
>
> The Committee wants onboard controls that are effective and safe. No one wants a rule that requires controls for the consumer that present safety problems. These problems need to be resolved in the rulemaking under section 202(a)(6). The bill provides the mechanism for this to occur. It should. H. Rep. No. 490, 101st Cong. 2d Sess. at 303, 304.

Since section 202(a)(6) is based on the House bill (Cong. Rec. of Oct. 27, 1990, at S 16935), the House Report is a principal source of legislative history for the provision.

The legislative language to which the House Report refers, however, is somewhat different from that eventually enacted. The House bill included the consultation requirement in a separate sentence following the initial sentence directing the Agency to issue an onboard requirement. That separate sentence provided that "[t]he Administrator shall determine, in consultation with the Secretary of Transportation, that such systems are safe." (Cong. Rec. of May 23, 1990 at H 2798). This separation of the promulgation requirement from the consultation requirement may explain the statement in the legislative history that the safety determination "shall not affect the Administrator's mandatory duty to promulgate" the onboard requirement. See also fn.[1] *infra*. The provision as enacted by Congress, however, does not explicitly require the Administrator to determine that onboard systems are safe, and instead provides for the determination to be made as part of the rulemaking requirement process. This linking of the safety determination with the rulemaking is more in keeping with Congress' intent as expressed in the rest of the House Report—that "[n]o one wants a rule that requires controls for the consumer that present safety problems. These problems need to be resolved in the rulemaking under section 202(a)(6)." Indeed, a summary of the Clean Air Act conference agreement submitted by Senator Baucus as an aid to the floor debates on that agreement states explicitly:

> Auto manufacturers are required to install canisters on vehicles to capture hydrocarbons that would otherwise be emitted * * * during refueling * * * if these devices are determined to be safe by the EPA and the Department of Transportation. Cong. Rec. of Oct. 24, 1990 at S 18038.

Senator Baucus, as chairman of the Senate Subcommittee on Environmental Protection at the time the CAA Amendments of 1990 were being drafted, had a leading role in the development of the conference agreement and his summary may thus be considered authoritative. Clearly, the legislative history evinces a Congressional intent to leave EPA with the discretion not to require onboard controls based on the outcome of consultation process with DOT.

2. The Standard That Should Apply to EPA's Exercise of Discretion

EPA concludes that it has discretion not to require onboard controls based on the safety consultation with DOT. The standard by which this discretion should be exercised remains to be determined. Here again, the statute and legislative history provide assistance. Section 202(a)(4), a provision referred to in the legislative history of section 202(a)(6) (see H. Rep. No. 490 at 303, quoted above), provides that "no emission control device * * * shall be used in a new motor vehicle * * * for purposes of complying with requirements prescribed under this title if such device * * * will cause or contribute to an unreasonable risk to public * * * safety in its operation or function." In determining what constitutes an unreasonable risk, EPA is to consider "the availability of other devices * * * which may be used to conform to requirements prescribed under this title without causing or contributing to such unreasonable risk" (section 202(a)(4)(B)(iii)).

At the least, the general goals and principles of section 202(a)(4) can be considered in deciding whether to promulgate an onboard canister-based requirement.[1] Thus, the Agency will first

[1] Section 202(a)(4) by its own terms applies to use of emission control devices, rather than to promulgation of standards requiring such devices.

Continued

examine (guided by the DOT recommendation as to safety) if canister-based onboard controls pose a safety risk, ascertain to the extent possible the extent of the risk, and determine if the risk is unreasonable based in large part on the availability and safety of comparably effective refueling control measures, namely Stage II controls.

IV. EPA Findings and Conclusions

A. Response to Conclusions of the Consultation

A review of the record for this proposal (public docket A–87–11) shows a lengthy and detailed consultation process between EPA and DOT regarding the potential safety implications of canister-based onboard systems. The process began in March of 1986, more than a year before publication of the proposal, and has continued to varying degrees over the past six years. The consultation has occurred through a number of means. EPA and DOT management and technical staff held meetings and exchanged correspondence on issues related to onboard system safety. The agencies exchanged technical information on the fuel vapor control system safety of current vehicles and the emission performance requirements for future vehicles. Both agencies have prepared or commissioned numerous technical reports and similar documents raising or assessing various aspects of the onboard system safety issue. EPA also developed and tested a prototype onboard system which was installed on a vehicle and evaluated by NHTSA. (IV–A–06; IV–E–93,94)

NHTSA's July 1991 report and its response to the oral and written comments thereto mark the last (and culminating) phase of the consultation process. EPA has been heavily involved in assessing the technical aspects of onboard safety over the course of this consultation. However, since NHTSA is the Federal agency charged with ensuring motor vehicle safety, NHTSA's findings on safety issues are entitled to special consideration. NHTSA, in its report and related correspondence, including the technical evaluation of comments, has concluded that onboard canister systems will unavoidably increase vehicle safety risk and has recommended that EPA forgo requirements for canister-based onboard controls and instead proceed with Stage II for the control of refueling emissions.

The Agency has reviewed the NHTSA report, including the comments (both written and oral) to it and NHTSA's response to those comments. EPA's review of the rulemaking record indicates that NHTSA has persuasively responded to all of the significant comments made regarding the safety issue. In light of NHTSA's safety expertise and EPA's review of the NHTSA response, EPA adopts NHTSA's response for purposes of addressing those comments in this rulemaking.

After carefully reviewing the comments and the record, the Agency believes that NHTSA's conclusions and supporting analyses are reasonable. NHTSA's analysis shows that canister-based onboard systems are potentially subject to additional failure modes compared to current systems, or enhanced evaporative systems under 202(k), due to added size and components and increased rate of vapor flow during refueling. Further, NHTSA's analysis shows that onboard canisters must necessarily result in vehicles handling, storing, and transporting increased amounts of gasoline vapor which in turn increases the risk of vehicle fires and the seriousness of such fires. Also NHTSA's report includes crash studies and analyses which indicate the potential for self-sustaining vehicle fires to result if canisters are damaged by collision. For many of these same reasons, NHTSA's conclusion that increased safety risk is inherent to canister-based onboard systems appears reasonable. Again, in light of NHTSA's safety expertise and EPA's review of the record, EPA adopts NHTSA's conclusions and supporting analyses that canister-based onboard systems will increase the risk of vehicle fires.

Given the absence of experience with onboard canisters in a large number of vehicles in real world operation, and the availability of the Stage II alternative, NHTSA did not quantify the increased safety risk posed by onboard canister systems. Nor has EPA. However, any vehicle condition posing a potential increase in risk of vehicle fires must be viewed seriously, because of the increased risk of fire and of harm whenever vehicle fires occur. NHTSA consequently was of the view that onboard canister controls posed an unreasonable risk given that an alternative emission control system exists, namely Stage II, that d)es not present any of these risks. In the case of this decision, EPA agrees that this is the relevant inquiry. Thus, in the following sections, EPA discusses the potential safety risks associated with Stage II controls, the degree to which Stage II controls provide refueling emission reductions comparable to onboard canister control systems, and the relative costs of the two systems.

B. Stage II Safety and Effectiveness

1. Stage II Safety

Stage II control systems were first installed in the mid-1970's in California. Since that time they have undergone a number of developmental generations in which improvements have been incorporated. Although some operational difficulties were encountered in the very early years of the use of this technology, leading to limited safety concerns, such problems have been notably absent in the more recent generations of this equipment produced over the past 5–10 years. Contacts with local fire marshals and review of national statistics on service station fires such as those provided by the National Fire Incident Reporting System indicate no evidence of greater risk with Stage II dispensing equipment than with conventional dispensing equipment. (IV–H–04) Stage II nozzles incorporate several features designed to address potential safety problems (e.g., secondary liquid shut off, emergency breakaway, and liquid removal systems). Also under California Air Resources Board procedures recommended by EPA in recent Stage II guidance documents, the State fire marshall must preapprove and certify all Stage II equipment designs. (IV–A–8) Comments in the record indicate that Stage II dispensing equipment is at least as safe as conventional dispensing equipment, and suggest that the addition of Stage II controls would marginally reduce the annual rate of service station fires due to control of refueling vapors. (IV–D–725)

2. Comparison of Refueling Emission Control Effectiveness

The second point to be addressed is how a decision not to implement onboard controls would impact the overall control of refueling emissions. To answer this question we must first review the provisions of the 1990 CAA Amendments with regard to onboard and Stage II controls. With this information, we can then examine the refueling emission control benefits with and without onboard controls, consistent with the statutory scheme for the implementation of onboard and

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and its prohibition against the use of unsafe devices applies durint the vehicle certification process pursuant to section 206(a)(3). In this case, however, EPA believes that Congress intended EPA to refer to the standards set forth in section 202(a)(4) (see, e.g., the House Report), in determining whether regulations that require onboard controls are safe and should be promulgated.

Stage II control approaches. This will be examined for both the nonattainment areas subject to Stage II and on a nationwide basis.

a. Statutory Provisions. The provisions governing onboard controls are contained in section 202(a)(6) of the CAA as amended in 1990. As detailed above, these provisions provide for onboard controls to be installed on light-duty vehicles only, beginning with the fourth model year after the year in which the onboard standards are promulgated. Controls would be phased-in as follows: 40 percent of the vehicles manufactured in the fourth model year, 80 percent in the fifth model year and 100 percent thereafter. Since section 202(a)(6) provides for EPA action on the onboard provision during the 1992 model year, were EPA to issue a rule, controls would presumably have started in the 1996 model year and been required on all new light-duty vehicles by 1998. Light-duty trucks and heavy-duty vehicles are not covered by the provisions of section 202(a)(6), although EPA could potentially include them under section 202(a)(1) authority.

The relevant provisions of the Act regarding Stage II controls are found in sections 182(b)(3), (c), (d) and (e); 323; 324; 184(b)(2); and 202(a)(6). The section 182 provisions require Stage II controls in moderate or worse ozone nonattainment areas and prescribe a schedule for the installation and operation of those controls at gasoline dispensing facilities within those areas. The schedule is based on the date of construction of the facility and the amount of fuel throughput per month. The provisions of section 182(b)(3) apply to facilities that dispense more than 10,000 gallons per month (gpm) of gasoline; however, independent small business marketers of gasoline (as defined in section 324), which dispense less than 50,000 gpm of gasoline, may be exempted from the Stage II requirements. The provisions of section 324 reiterate the exemption criteria mentioned above for independent small business marketers, define the term "independent small business marketer", and provide a 3-year phase-in for non-exempt independent marketers. Section 324 also permits each State to incorporate more stringent exemption levels than those discussed above. Section 323 establishes the general requirements for who is responsible for paying for installation of Stage II systems.

Section 184 also contains provision relating to Stage II. Section 184(a) creates an ozone transport region comprised of the States of Connecticut, Delaware, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, and Vermont, and the CMSA (Consolidated Metropolitan Statistical Area) which includes the District of Columbia. Under section 184(b)(2), EPA is to complete a study identifying alternative control measures capable of achieving emission reductions camparable to Stage II. The study is to be completed within three years after enactment of the 1990 CAA Amendments. After completion of the study, States in the ozone transport region would be required to adopt, within one year, the alternative measures or Stage II for all areas of the States that do not have such controls. To the extent that an area was already subject to Stage II, the State would not be required to adopt new measures for that area. In these States, Stage II may expand to some areas now in attainment with the ozone NAAQS or classified as marginal for ozone nonattainment.

Finally, as detailed above, section 202(a)(6) provides that the requirement for Stage II controls shall not apply in moderate ozone NA areas after promulgation of an onboard requirement. In addition, if an onboard rule is promulgated, EPA may also revise or waive Stage II requirements for serious, severe, or extreme ozone NA areas after EPA determines that onboard control systems are in widespread use throughout the motor vehicle fleet.

To summarize, the statute envisions either an integrated control strategy involving LDV onboard nationwide and Stage II in serious and worse ozone NA areas or a broader program of Stage II in moderate or worse ozone NA area. For ease of discussion, the former strategy will be referred to as the "onboard case" (even though it includes Stage II in serious or worse NA areas as well) and the latter will be referred to as the "Stage II case".

Having determined the statutory schedules and specifications for each of the two strategies, the next step is to determine the emission reductions afforded by each strategy. EPA has performed this anlaysis for the 55 ozone nonattainment (NA) areas that are required to install Stage II controls and for the nation as a whole. An analysis of the relative benefits in the nonattainment areas is appropriate in light of the fact that onboard would reduce emissions that contribute to ozone nonattainment. A nationwide analysis is also appropriate because onboard controls are a nationwide requirement and would reduce exposure to toxic emissions when onboard-equipped LDVs are refueled anywhere in the nation.

As presented below, EPA's analyses indicate that the emission reduction benefits of the onboard and Stage II cases differ in several ways. The onboard case would eventually produce large emission reductions overall. In the early years, however, onboard control requirements would make only a small contribution to the overall emission reductions achieved by the onboard case. Most of those reductions would be associated with Stage II controls in the worst ozone NA areas and in those States that have voluntarily adopted Stage II controls. The Stage II case, on the other hand, would produce faster and larger reductions in the areas with the greatest need for reductions in ozone-producing emissions and with greater population exposure to toxic emissions.

In light of Congress' concern with the safety of onboard controls, EPA believes it has discretion to accept some tradeoffs in emission reduction benefits to avoid a safety risk. Here, EPA is faced with a finding that canister-based onboard controls would increase the risk of vehicle fires. Stage II would safely provide greater benefits to the areas in greatest need in the most expeditious manner. As explained more fully below, under the circumstances EPA finds it reasonable to accept the risk-free reductions that Stage II would provide to avoid the risk onboard would pose. The earlier, targeted benefits of Stage II will afford more time for either safe onboard technologies to be developed or for EPA to take action under other provisions of the Act to reduce toxic emissions nationwide.

b. Methodology. Before describing the details of how the analysis is to be structured to assess the relative emission reductions achieved by the two statutory control strategies, information is needed on the implementation details and control effectiveness of each control technique. This is presented below for Stage II and onboard. Much of the data referred to below is taken from various reports in the record, and EPA has also compiled this information separately in a document in the public docket. (IV–B–21).

The information cited below for Stage II controls was taken in its entirety from the recently released EPA report entitled: "Technical Guidance—Stage II Vapor Recovery Systems for Control of Vehicle Refueling Emissions at Gasoline Dispensing Facilities," volume 1, EPA 450/3–91–022a. (IV–A–8) Among other topics, this report contains a detailed

discussion of the legislation implementing Stage II, the NA areas affected by the statute, current Stage II programs around the country, and the effectiveness of Stage II in controlling refueling emissions under several exemption/enforcement scenarios. The report takes into account the various studies on Stage II efficiency submitted as part of this rulemaking.

Under the provisions of section 182, 55 ozone NA areas would be affected by Stage II: 1 extreme, 9 severe, 14 serious and 31 moderate (see Table 2–2 of the EPA Stage II report). If fully implemented, Stage II would apply to areas that distribute 43 percent of the nation's gasoline; 27.5 percent is in serious or worse areas (see Table 2–3 of the EPA Stage II report). Taking into account a range of exemption scenarios, Stage II would reduce refueling emissions in the areas where Stage II has been installed from 77 percent, assuming the 10,000/50,000 gpm exemptions are adopted, to 84 percent, assuming States adopt the more stringent provision and permit only 10,000 gpm exemptions for all facilities. This information is presented in Figure 4–15 of the EPA Stage II report. Both percentages assume annual enforcement, the most likely scenario according to the authors of the study.

The emission reduction benefits of equipping LDVs with onboard systems were determined using the leadtime, phase-in, and efficiency specifications of section 202(a)(6) as described above and the future gasoline use projections for 1996 and later model year vehicles and all gasoline vehicles from EPA's Mobile 4.1 fuel consumption model. (IV–A–9) The results of the fuel consumption model are shown in Table. 1.

The potential reductions provided by onboard-equipped LDVs are small at first and increase as fleet turnover occurs. As was discussed above, the onboard case also includes the additional reduction benefits of Stage II in serious or worse ozone NA areas. Stage II in these areas would provide reductions in addition to those provided by onboard, because Stage II would control refueling emissions from all current and future vehicles without onboard systems. The EPA Stage II report uses an efficiency of 77 to 84 percent. However, for modeling purposes under the onboard case, Stage II was assumed to have an efficiency of 80 percent.

TABLE 1.—MOBIL 4.1 FUEL CONSUMPTION

[Consumption figures are in billions of gallons per year]

Cal year	Fuel consumption			
	Nationwide		55 NA areas	
	LDGV*	All GV	LDGV*	All GV
1996	2.364	126.244	1.017	54.285
1997	8.469	128.439	3.642	55.229
1998	16.742	130.838	7.199	56.260
1999	25.122	133.335	10.802	57.334
2000	33.150	136.077	14.255	58.513
2001	40.921	138.832	17.596	59.698
2002	48.356	141.676	20.793	60.921
2003	54.846	144.622	23.584	62.187
2004	60.312	147.508	25.934	63.428
2005	65.209	150.521	28.040	64.724
2006	69.952	153.616	30.079	66.055
2007	74.711	156.735	32.126	67.396
2008	79.326	159.873	34.110	68.745
2009	83.535	163.068	35.920	70.119
2010	87.031	166.262	37.423	71.493
2011	89.707	169.133	38.574	72.727
2012	92.219	172.394	39.654	74.129
2013	94.578	175.692	40.669	75.548
2014	96.823	179.003	41.634	76.971
2015	98.942	182.348	42.545	78.410
1	2	3	4	5

*Represents the portion of total fuel consumption that would be consumed by onboard-equipped vehicles if onboard were implemented in 1996.

c. Nonattainment Areas. To conduct the analysis for the 55 ozone NA areas, the emission reduction benefits of the onboard and Stage II cases must be determined for those areas. The onboard case is discussed immediately below, followed by discussion of the Stage II case.

Under the provisions of the statute, for the onboard case the emission control benefits would be the sum of the reductions from: (1) Stage II controls in the serious and worse ozone NA areas; (2) LDV onboard systems in the moderate ozone NA areas; and (3) LDV onboard systems in the serious and worse NA areas, incremental to the reductions from Stage II in those areas, due to differences in control efficiency and exemptions from Stage II.

In assessing the onboard case benefits, EPA believes it appropriate to go beyond the statutory minimum and recognize that under State provisions, Stage II is present in six of the 31 moderate ozone NA areas. Given the fact that these Stage II systems are already in place, and the comments indicating the importance of these controls (IV–F–17), this analysis assumes that these Stage II controls would remain in place. Thus, if onboard controls were implemented, Stage II would be in place in a total of 30 ozone NA areas (6 moderate NA areas plus 24 serious or worse NA areas). According to Table 2–2 of the EPA Stage II report, these 30 areas represent 32.5 percent of the nationwide gasoline consumption; about five percent of this comes from the six moderate areas (i.e., those in the States of Florida, New Jersey, California and Missouri) and 27.5 percent comes from the 24 serious or worse ozone NA areas.

Finally, with regard to Stage II controls under the onboard case, as was mentioned above, the statute allows EPA to revise or waive Stage II requirements for serious or worse ozone NA areas after EPA determines that onboard controls are in widespread use throughout the motor vehicle fleet. As will be discussed below, the removal of these controls in the 55 NA areas would reduce the overall effectiveness of the onboard case.

For the Stage II case, the analysis is much simpler. Stage II is required to be in all 55 moderate or worse ozone NA areas. The percent of nationwide gasoline consumption covered (43 percent) and the emission reductions efficiency (77 to 84 percent) are as detailed in the EPA Stage II report.

Based on the implementation details and approaches discussed above, Table 2 compares the emission control effectiveness in the 55 ozone NA areas for the onboard and Stage II cases. The comparison is discussed below first on an annual basis and then on a time average annual basis.

1. Annual Basis. As is shown in columns 4 and 5 of Table 2, the State II case (no onboard) provides a constant annual reduction of 77 to 84 percent throughout the entire period. This is the case because, pursuant to section 182(b)(3), Stage II would be fully implemented by the time onboard controls began in the 1996 model year.

The onboard case includes LDV onboard controls and Stage II in 30 NA areas. Control would begin in 1996 with Stage II in place in the 30 NA areas discussed above; the remainder of the control would come from LDV onboard systems and would phase in as the fleet turns over. As is shown in column 11 of Table 2, even though the annual effectiveness of the onboard case eventually approaches that achieved in the Stage II case, it does not occur until more than ten years into the program. Depending on the exemption level assumed for the Stage II case, the onboard case may never achieve the same level of effectiveness as the Stage II case. Also, columns 9 and 10 of Table 2 provide information on the portion of the reduction in the 55 NA areas which is attributable to onboard controls. Onboard controls provide at most only about 25 percent of the reductions achieved in the onboard case; the

remaining 75 percent comes from the Stage II in the 30 NA areas. Also, in the early years, the Stage II cases provides greater reductions than the onboard case because Stage II would be in place at the outset in all 55 NA areas and would control refueling emissions from all three vehicle classes.

2. Time Average Basis. Since under the Stage II case controls would be fully implemented in the 55 NA areas prior to the start of the onboard case, the average emission reductions that the Stage II case would achieve over time would be the same as the annual emission reductions—77 to 84 percent. For the onboard case, Table 2 shows that the emission reductions would phase in and average reductions by the year 2015 would be approximately 75 percent, a bit less than for the Stage II case. Moreover, as was the case on an annual basis, at least 75 percent of the onboard case reductions would be attributable to stage I in the 30 NA areas. Also, as was the case on an annual basis, the Stage II case provides greater average reductions in the 55 NA areas than does the onboard case.

The greater VOC reductions achieved with the Stage II case would translate into increased reductions in air toxic emissions, as well. These results would be obtained because Stage II would control fuel dispensed to all classes of motor vehicles while, under section 202(a)(6), the onboard requirement would apply to only light-duty vehicles. Based on the Mobile 4.1 Fuel Consumption Model, approximately 40 percent of gasoline is consumed by light-duty trucks and heavy-duty vehicles. Thus, for the NA areas in greatest need of ozone precursor reductions, Stage II provides earlier and more effective control.

TABLE 2—NONATTAINMENT AREA CONTROL EFFECTIVENESS, ONBOARD VS STAGE II

[Consumption figures are in billions of gallons per year]

Cal year	Stage II case (55 areas)				Onboard case						
	Contr consumpt		Contr effectvness (percent)		Controlled consumption*			Control (percent)		Contr effectvns (percent)	
	SII-10/10	SII-10/50	SII-10/10	SII-10/50	O/B incr	STG II (30)	Total	O/B incr	STGII(30)	Total	Time Avg
1996	45.599	41.799	84.0	77.0	0.382	32.823	33.205	1.1	98.9	61.2	61.2
1977	46.392	42.526	84.0	77.0	1.368	33.394	34.762	3.9	96.1	62.9	62.1
1998	47.259	43.320	84.0	77.0	2.704	34.018	36.722	7.4	92.6	65.3	63.2
1999	48.161	44.147	84.0	77.0	4.057	34.667	38.724	10.5	89.5	67.5	64.3
2000	49.151	45.055	84.0	77.0	43.354	35.380	40.734	13.1	86.9	69.6	65.4
2001	50.146	45.967	84.0	77.0	6.609	36.096	42.705	15.5	84.5	71.5	66.5
2002	51.173	46.909	84.0	77.0	7.809	36.836	44.645	17.5	82.5	73.3	67.5
2003	52.237	47.884	84.0	77.0	8.858	37.602	46.459	19.1	80.9	74.7	68.5
2004	53.280	48.840	84.0	77.0	9.740	38.352	48.092	20.3	79.7	75.8	69.3
2005	54.368	49.838	84.0	77.0	10.531	39.135	49.667	21.2	78.8	76.7	70.2
2006	55.486	50.862	84.0	77.0	11.297	39.940	51.237	22.0	78.0	77.6	70.9
2007	56.613	51.895	84.0	77.0	12.066	40.751	52.817	22.8	77.2	78.4	71.6
2008	57.746	52.934	84.0	77.0	12.811	41.567	54.378	23.6	76.4	79.1	72.2
2009	58.900	53.992	84.0	77.0	13.491	42.398	55.889	24.1	75.9	79.7	72.8
2010	60.054	55.049	84.0	77.0	14.056	43.228	57.284	24.5	75.5	80.1	73.4
2011	61.091	56.000	84.0	77.0	14.488	43.975	58.462	24.8	75.2	80.4	73.9
2012	62.269	57.080	84.0	77.0	14.893	44.822	59.716	24.9	75.1	80.6	74.4
2013	63.460	58.172	84.0	77.0	15.274	45.680	60.954	25.1	74.9	80.7	74.8
2014	64.656	59.268	84.0	77.0	15.637	46.541	62.178	25.1	74.9	80.8	75.1
2015	65.864	60.375	84.0	77.0	15.979	47.410	63.390	25.2	74.8	80.8	75.5
1	2	3	4	5	6	7	8	9	10	11	12

*Represents the incremental control attributable to onboard in the 55 areas plus control due to stage II requirements in the 30 nonattainment areas.

Note: Control effectiveness represents emission reductions as a percentage of total consumption controlled by the onboard case in the 55 nonattainment areas. For stage II, it is the percentage controlled for all gasoline vehicles. Stage II scenarios represent 10/10 exemptions or 10/50 exemptions; with annual inspections. Assumes 95% onboard control efficiency.

d. Nationwide Assessment. In assessing the relative nationwide benefits of the onboard and Stage II cases, the appropriate comparison is between the additional benefits achieved by onboard nationwide incremental to the benefits of Stage II in the 30 NA areas described earlier and the benefits of Stage II in all 55 NA areas.

In this analysis, the onboard case is similar to that described for the NA areas, except the scope of coverage is greater. For the onboard case the emission reduction benefits would be based on: (1) Stage II controls in the 30 ozone NA areas as described previously, (2) the onboard system reductions for LDV fuel consumption in the remainder of the country and, (3) the onboard system reductions for LDV fuel consumption in the 30 ozone NA areas with Stage II, due to the incremental differences in overall control effectiveness and exemptions from Stage II.

Regarding the onboard case, as was the situation with the NA area analysis, Stage II in 30 NA areas accounts for 32.5 percent of national gasoline consumption. See Table 3. When adjusted for Stage II efficiency (for convenience, modeled at 80 percent in the onboard case), the effectiveness is 26 percent on a nationwide basis. Onboard systems would capture LDV refueling vapors in moderate and marginal ozone NA areas and in other attainment areas, as well as the LDV portion of those vapors not controlled by Stage II in the 30 ozone NA areas. In all, over the long term, LDV onboard systems could potentially control approximately 40 percent of nationwide refueling emissions beyond those which would be controlled by Stage II systems. However, as was seen with the NA area comparison, the onboard case effectiveness is a function of fleet turnover, and this control would not be achieved in full until fleet turnover is complete.

For the Stage II case, the situation is essentially the same as the NA area

presentation. However, since this is based on nationwide fuel consumption, the overall control effectiveness is reduced because Stage II is statutorily required only in the 55 ozone NA areas. Thus, instead of 77 to 84 percent control as in the NA areas, the Stage II case reduces emissions 33 to 36 percent on a nationwide basis since Stage II would cover only 43 percent of the nationwide gasoline consumption. As was the case with the NA area discussion above, all Stage II would be in place by 1996 so the 33 to 36 percent reductions in emissions is constant.

1. Annual Basis. A comparison of the annual emission reductions, or effectiveness, of the onboard and Stage II cases is shown in Table 3. For the Stage II case, as is shown in columns 4 and 5, annual reductions are a constant 33 to 36 percent. For the onboard case, column 11 shows that annual reductions start out lower than that of the Stage II case, and a comparison of columns 2 and 3 with column 8 shows that reductions from the Stage II case exceed those from the onboard case for the first few years. After that point, annual onboard case reductions meet and surpass those from the Stage II case. At its maximum in 2015, a comparison of columns 4 and 5 with column 11 gives a difference of about 30 percentage points. However, comparing columns 2 and 3 of Table 2 with columns 7, 8 and 9 of Table 3, it can be seen that most of this incremental difference is due to reductions outside of the 55 NA areas.

2. Time Average Basis. Since all expected Stage II controls would be in place in 1996, columns 4 and 5 of Table 3 show that the Stage II case would achieve constant average reductions of 33 to 36 percent. For the onboard case the control would be phased in, so reductions on a time average basis would be less than that on an annual basis. As is shown in column 12 of Table 3, average reductions from the onboard case would be less than that for the Stage II case for the first five years of the program, after which the average reductions of the onboard case would exceed that of the Stage II case. However, once again, most of this increase in average reductions would come as a result of increasing reductions outside of the 55 NA areas.

TABLE 3—NATIONWIDE CONTROL EFFECTIVENESS, ONBOARD AND STAGE II

[Consumption figures are in billions of gallons per year]

Cal year	Stage II case (55 areas)				Onboard case						
	Contr consumpt		Contr effectvness (percent)		Controlled consumption *			Control (percent)		Contr effectvns (percent)	
	SII-10/50	SII-10/10	SII-10/50	SII-10/10	O/B incr	STG II (30)	Total	O/B incr	STG II (30)	Total	Time avg
1996	41.787	45.574	33.1	36.1	1.662	32.823	34.485	4.8	95.2	27.3	27.3
1997	42.513	46.366	33.1	36.1	5.954	33.394	39.348	15.1	84.9	30.6	29.0
1998	43.307	47.233	33.1	36.1	11.770	34.018	45.788	25.7	74.3	35.0	31.0
1999	44.134	48.134	33.1	36.1	17.661	34.667	52.328	33.8	66.2	39.2	33.1
2000	45.041	49.124	33.1	36.1	23.304	35.380	58.684	39.7	60.3	43.1	35.2
2001	45.953	50.118	33.1	36.1	28.767	36.096	64.864	44.4	55.6	46.7	37.2
2002	46.895	51.145	33.1	36.1	33.994	36.836	70.830	48.0	52.0	50.0	39.2
2003	47.870	52.209	33.1	36.1	38.557	37.602	76.158	50.6	49.4	52.7	41.0
2004	48.825	53.250	33.1	36.1	42.399	38.352	80.751	52.5	47.5	54.7	42.6
2005	49.822	54.338	33.1	36.1	45.842	39.135	84.977	53.9	46.1	56.5	44.1
2006	50.847	55.455	33.1	36.1	49.176	39.940	89.116	55.2	44.8	58.0	45.5
2007	51.879	56.581	33.1	36.1	52.522	40.751	93.273	56.3	43.7	59.5	46.8
2008	52.918	57.714	33.1	36.1	55.766	41.567	97.333	57.3	42.7	60.9	48.0
2009	53.976	58.868	33.1	36.1	58.725	42.398	101.123	58.1	41.9	62.0	49.2
2010	55.033	60.021	33.1	36.1	61.183	43.228	104.411	58.6	41.4	62.8	50.2
2011	55.983	61.057	33.1	36.1	63.064	43.975	107.039	58.9	41.1	63.3	51.2
2012	57.062	62.234	33.1	36.1	64.830	44.822	109.652	59.1	40.9	63.6	52.0
2013	58.154	63.425	33.1	36.1	66.488	45.680	112.168	59.3	40.7	63.8	52.8
2014	59.250	64.620	33.1	36.1	68.067	46.541	114.607	59.4	40.6	64.0	53.5
2015	60.357	65.828	33.1	36.1	69.556	47.410	116.967	59.5	40.5	64.1	54.1
1	2	3	4	5	6	7	8	9	10	11	12

* Represents the incremental control attributable to onboard nationwide plus control due to stage II requirements in the 30 nonattainment areas.

Note: Control effectiveness represents emission reductions as a percentage of total consumption controlled by the onboard case nationwide.

For stage II it is the percentage of total consumption controlled by stage II installed in the 55 NA areas. Stage II scenarios represent 10/10 exemptions or 10/50 exemptions; with annual inspections. Assumes 95% onboard control efficiency.

e. Additional Considerations. Analyses, such as this, which use models to compare the effectiveness of emission control strategies, often require that certain assumptions, judgments, and estimations be used in developing the parameters and scenarios for the model. In these situations, a sensitivity analysis is normally undertaken to assess how realistic changes in the key assumptions, judgments, and estimations might affect the results. Such an analysis was prepared for this comparison, and the results are presented below. Except as noted below, the sensitivity analysis applies to both the NA area and nationwide analyses. Overall, the sensitivity analysis indicates that the Stage II case may be more effective, and the onboard case less effective, than the foregoing analysis suggests.

1. Stage II Technology. For the reasons discussed below, the control effectiveness of the Stage II case is probably understated. First, absent an onboard requirement, if Stage II is adopted statewide in the ozone transport states under section 184(b)(2), an analysis of Tables 2–2 and 2–3 of the EPA Stage II report indicates that the percent of nationwide gasoline consumption covered by Stage II would increase by 6 percentage points (43 to 49 percent). This would increase the overall effectiveness of the Stage II case by five percentage points. Thus, the Stage II case effectiveness would increase to 38 to 41 percent nationwide. Second, as has been discussed above, Stage II would be in place prior to 1996. In most cases, installations would be

completed by the end of 1994, which provides two years of additional benefits under the Stage II case for the moderate NA areas which do not presently have Stage II. This increases the overall average effectiveness of the Stage II case as compared to the onboard case. These areas represent about 12.5 percent of the fuel consumption, and applying the 77 to 84 percent control efficiency for Stage II, a 10 percent increase in control effectiveness would be gained for an additional two years under the Stage II case. Third, there are a number of other minor factors to consider. States implementing Stage II controls in moderate NA areas could implement more stringent exemption levels or enforcement programs than those now being used in most States which have Stage II. Also, as is discussed in the EPA Stage II reports, if present trends continue, new service station facilities will tend to be larger than the smaller, lower throughput facilities they replace, and would thus be more likely to be subject to Stage II requirements. In addition, Stage II controls may provide some control of underground storage tank emptying loss emissions, especially in periods of lower vehicle fueling activity. These three points considered together could increase the effectiveness of the Stage II case by 1 to 2 percentage points. Finally, it should be noted that one gasoline marketing company has introduced a vapor recovery nozzle which is not subject to the efficiency losses which can occur due to lack of maintenance on current Stage II hardware. (IV–D–715, IV–A–8) This "bellowless nozzle", would presumably have a control efficiency much closer to the 95 percent certification value suggested for new Stage II nozzles in the EPA Stage II report. If nozzle designs of this type are used widely, this could improve the efficiency of the Stage II controls. Each percentage point increase in the average control efficiency of the Stage II hardware translates into almost a one percentage point increase in the effectiveness of the Stage II case which relies solely on Stage II controls but somewhat less for the onboard case.

2. Onboard Technology. Also, the effectiveness of the onboard case may be overstated. The analysis used the 95 percent control effectiveness called for in the statute. And, while there is data in the record to indicate that this level of control efficiency can be met and perhaps surpassed on new vehicles, there is little data to indicate how the LDV onboard systems would perform in use. In the August 1987 NPRM, EPA discussed the in-use control efficiency for onboard systems and based on the in-use performance of evaporative controls estimated that the reduction in control efficiency could be as high as 2.5 percentage points (52 FR 31185). Using essentially the same data, others have suggested an in-use control efficiency reduction of six percent (IV–H–03). Of course, predicting this impact is problematic since there is little in-use data for onboard systems and initiatives such as RVP control, enhanced inspection and maintenance based on transient testing and evaporative emission control system checks, and onboard emission control system diagnostics could have a salutary effect.

Also, the onboard case includes Stage II in 30 ozone NA areas. If the six moderate NA areas with Stage II were no longer to require such systems, the efficiency of the onboard case would be decreased, especially in the early years. Similarly, under section 202(a)(6), EPA may revise or waive the Stage II requirements in the serious and worst ozone NA areas when onboard systems are in widespread use throughout the motor vehicle fleet. While it is not clear if this would occur and if so, when, an analysis of the information in Tables 2 and 3 indicates that the loss of the Stage II control applied to gasoline-powered light-duty trucks and heavy-duty vehicles would decrease the control effectiveness of the onboard case by about five to ten percentage points depending on when implemented (presumably after 2005 when much of the pre-onboard fleet would have been retired). Thus, the overall control effectiveness of the onboard case could be reduced in the long term.

There thus are a number of factors which could directionally reduce the effectiveness of the onboard case and increase the effectiveness of the Stage II case. Using the information presented above, the effectiveness of the onboard case could be reduced by about 10 percentage points while the effectiveness of the Stage II case could increase by 6 to 8 percentage points or perhaps more if the bellowless nozzle design comes into widespread use. This brings the average nationwide effectiveness value to 44 percent for the onboard case (assuming that Stage II is phased out of the serious and worse ozone NA areas in 2005) and 39 to 44 percent for the Stage II case.

Furthermore, in the later years when the annual effectiveness of the onboard case is projected to surpass that of the Stage II case, the underlying predictions of gasoline consumption are problematic. There is presently a strong interest in alternative fuels and initiatives are now underway through Federal, State, and local legislation to require more use of these fuels. Thus, fuel use characteristics—and the need for and effectiveness of refueling emission controls—could change substantially.

Finally, EPA recognizes that the Stage II case and the onboard case would not provide emission reductions in the same geographic areas. While the Stage II case provides the VOC emission reductions earlier and where most needed, it would not provide reductions in air toxic emissions to the remainder of the nation. Conversely, the onboard case would provide a more even distribution of reductions in air toxic emissions, but would not provide as large or timely a reduction for the ozone NA areas as the Stage II case would provide, especially in the moderate NA areas which would be relieved of Stage II under section 202(a)(6). These NA areas, moreover, are generally urban. While the absence of onboard controls would mean a loss of potential air toxic emission reductions nationwide, the Stage II reductions would come more in urban areas with greater population exposure potential.

When evaluating the need for refueling emission controls, EPA has historically considered health effects concerns related to exposure to benzene and other gasoline vapors. However, the potency of gasoline vapor in causing adverse health effects is unclear. It is presently classified as a B–2 (probable human) carcinogen, but newer evidence suggests that its potency should be downgraded to a class C (possible human) carcinogen. (IV–A–10) While there is no uncertainty about benzene, EPA has direct regulatory authority to control mobile source related air toxics including benzene emissions (consistent with section 202(a)). Section 202(1) requires a study of mobile source related air toxics, followed by regulations to control such toxics applying at a minimum to emissions of benzene, formaldehyde and 1,3 butadiene. The issues of control of benzene exposures from vehicle refueling will be addressed pursuant to these provisions. Thus, the need to focus on air toxics as a central aspect of this analysis is somewhat diminished as compared to the importance of ozone precursors. On balance, EPA believes that the nationwide reduction in air toxics which the onboard case would provide is of less importance than the greater focused reductions in ozone precursors and toxic emissions in ozone NA areas that the Stage II case would provide.

In summary, as was shown above, the Stage II case would provide earlier and more effective control in the 55 ozone NA areas in greatest need of such reductions. While the onboard case provides greater control on a nationwide basis, its reductions in ozone precursors would not be as early or as great in the moderate ozone NA areas. Moreover, there is reason to believe given the sensitivities of the analyses that the Stage II case would achieve average nationwide reductions comparable to the onboard case nationwide reductions.

EPA recognizes that the Stage II case would not provide exactly the same emission reductions as the onboard case. In light of the safety risk posed by onboard controls, however, the Agency believes that the reductions afforded by the Stage II case make it unwise to proceed with onboard requirements at this time. Stage II will safely provide, earlier and more effective control to the areas most in need. Indeed, Stage II may provide reductions measured on a nationwide basis equivalent in quantity to those onboard would have achieved. To the extent Stage II proves not to achieve needed reductions, other means exist to provide reductions, such as controls under section 202(1), and other onboard technologies may be developed in place of the canister systems found to pose an unreasonable safety risk. In light of these considerations, EPA finds that the reductions achievable by the Stage II case are appropriately viewed as comparable to those achievable by the onboard case.

f. Costs and Cost Effectiveness. As a part of the previously mentioned gasoline 1984 marketing study and the subsequent NPRM for onboard controls, EPA conducted an in-depth study of the costs and cost effectiveness of onboard and Stage II controls in both NA areas and on a nationwide basis. This analysis is set forth in the draft Regulatory Impact Analysis (RIA) for the onboard NPRM and is available in the public docket. (II–A–18,19,20).

Subsequent to the NPRM, there have been several developments which must be considered in this discussion. First, the number of areas and the specific NA areas affected by Stage II has changed. This affects the percent of fuel consumption and the number of service stations requiring Stage II. The current situation requires Stage II in 55 NA areas involving 43 percent of nationwide fuel consumption. The previous analysis involved 61 NA areas but only 35 percent of fuel consumption. Second, onboard was phased-in and limited to LDVs only. This reduces the overall costs and emission reductions substantially as compared to those in the draft 1987 RIA. Third, the onboard case involves a limited amount of Stage II as well which requires combination of some portion of the onboard and Stage II analyses.

Furthermore, in response to comments on the August 1987 NPRM, on December 22, 1988 EPA released an updated analysis of onboard costs. (IV–B–19) This analysis indicated that for a simple onboard system, onboard costs incremental to enhanced evaporative emission controls would be less than the $14–$19 estimate in the NPRM (52 FR 31177). These lower costs were due to onboard system design simplications EPA believed to be possible, improved cost estimates for enchanced evaporative controls and fuel recovery credits. However, a number of manufacturers have indicated that simple systems such as suggested by EPA may not be workable and more costly approaches may be needed. If this is the case, costs will be closer to the values presented in the NPRM. Enhanced evaporative controls have not yet been implemented under section 202(k), so it is not clear precisely what will be required. Thus, EPA is not now in a position to determine the costs of an onboard system incremental to the costs of enchanced evaporative control.

Also, as part of the response to section 182(b)(3) requirements for Stage II, EPA updated the assessment of Stage II costs and cost effectiveness. As is reflected in chapter 5 of the previously cited EPA report on Stage II, costs are slightly less and the efficiency is essentially the same as estimated in the 1987 RIA. Thus, the cost effectiveness is still about the same as indicated in the draft RIA (see Table 5–12). Thus Stage II remains a very cost effective VOC control technology.

Nonetheless, the best information now available suggests that much of the data used in the 1987 RIA remains valid. The unit costs and effectiveness remain largely unchanged. The key changes involve the change in the amount of fuel consumption in the 55 NA areas (and of course indirectly the number of service stations), limiting the onboard requirements to only LDV's and a combination of onboard and Stage II controls in the onboard case. For the purposes of this analysis, the figures used in the 1987 analyses will be used with appropriate updating for the changes mentioned above. Costs and cost effectiveness are discussed below for the 55 NA areas, nationwide, and then onboard incremental to Stage II.

First, with regard to the 55 NA areas, the costs and cost effectiveness of the Stage II case are very close to those figures reflected in Table 3–19 of the 1987 RIA. After scaling for increased fuel consumption, annualized costs are approximately $117–$180 million per year and the cost effectiveness is in the range of $1000–$1100 per megagram (Mg) (see Table 3–19 of the 1987 draft RIA or Table 5–13 of the EPA stage II report). For the onboard case, the costs of the Stage II control are reduced in proportion to the fractions of the fuel consumption in these areas (32.5/43). Stage II costs thus are approximately $88 to $121 million. Onboard technology is required on LDVs nationwide but the benefits are counted only in the 55 NA areas. Using the LDV portion of the costs in the 1987 RIA, the annualized costs for LDV onboard are approximately $129 million per year. Thus, the total cost is $217 to $250 million per year and the cost effectiveness increases to about $1750 per Mg. The Stage II case is much more cost effective and less costly. This is primarily the case because onboard and Stage II are largely redundant for LDV's.

Second, on a nationwide basis, the costs and cost effectiveness for the Stage II case are the same as in the NA area analyses above. For the onboard case, the costs are similar to those presented above, but the reductions cover Stage II in 30 NA areas and LDVs nationwide as well. Thus, in this case the costs are approximatley $217 to $250 million per year and the cost effectiveness is about $1250 per Mg. Once again the Stage II case entails less total cost and is more cost effective.

Finally, there are a few additional points worth considering in this comparison. First, Stage II is presently in place in 6 of the 25 moderate NA areas which would have to install Stage II in the Stage II case but not the onboard case. These facilities contribute about 5 percent of nationwide gasoline comsumption and 12 percent of the control which would be achieved in the Stage II case. The investment in Stage II in these areas represents sunk costs which could arguably be subtracted from the total costs under the Stage II case in both the NA areas and nationwide analyses. This would lead to a lower overall cost.

Also, it is important to note that at a minimum Stage II will be in place in 30 NA areas representing 32.5 percent of fuel consumption. If the additional reductions from LDV onboard are viewed incremental to the Stage II that is or will be in place, the marginal cost effectiveness is $5800 per Mg in the NA area analysis and $1400 in the nationwide case. These values are very

high relative to those for the Stage II case alone.

Based on the information available this analysis suggests that both the onboard and Stage II cases have attractive cost effectiveness values, especially compared to other VOC control strategies now required under the 1990 CAA Amendments. However, given the provisions of the statute for onboard and Stage II controls, the analysis indicates that the Stage II case is the more cost effective control strategy.

V. Future Technology

Since NHTSA's safety report covers only canister-based onboard systems, today's decision is based on systems of this design. While other vehicle-based control technologies might be developed to control refueling emissions, this rulemaking has dealt almost exclusively with the question of imposition of canister-based onboard controls. Some commenters suggested that EPA should proceed to require onboard systems now, and work out safety concerns before the rule would take effect. For several reasons, EPA is not adopting this approach. First, as to canister-based systems, the record does not demonstrate that the safety risks are entirely capable of resolution. Other technolgies have been suggested for the refueling control, but they are only in the preliminary stages of development and, therefore, could not be analyzed. Too little is known about these alternatives for EPA to base an onboard requirement on them at this time. Moreover, the 1990 legislation did not purport to apply to alternative, non-canister-based onboard systems. (See H. Rep. No. 490 at 303–04, discussing only the onboard system serving as the basis for EPA's 1987 proposal, namely canister-based controls; see also Cong. Rec. of Oct. 24, 1990 at S 18038, summarizing section 202(a)(6) as requiring installation of canisters provided EPA and DOT find that canister-based technology is safe). Indeed, the capture efficiency specified for onboard controls by section 202(a)(6) is based on a canister system, indicating that Congress intended promulgation of onboard requirements on the prescribed schedule only if canister-based systems were found safe. Finally, since Congress directed EPA to consult with NHTSA before promulgating any onboard requirement, Congress expected NHTSA's advice to relate to currently available technology—i.e., canister-based systems. Thus, EPA is not in a position today to predict reliably when or whether such new (non-canister) technologies might be developed, nor to consider the safety of such as-yet undeveloped technology. As a result, EPA could not reasonably base an onboard requirement on them. EPA will continue to monitor technical developments for other onboard systems, including diaphragms, bladders, and other capture technologies (e.g., activated carbon or chemically activated polymer absorbers impregnated on porous foam filters) which may substantially reduce or control refueling emissions and raise fewer concerns about vehicle safety. (IV–D–762, IV–E–96).

VI. Unique Aspects of This Decision

It is important to distinguish the unique aspects of today's action that differ from other similar regulatory programs. In the decision at hand, an alternative to vehicle-based controls is available which raises no question of increased safety risk. Much of the rationale supporting the decision not to implement onboard requirements hinges on the ready availability of Stage II controls. In this case, however, NHTSA has found that the introduction of onboard canister-based controls would increase the risk of vehicle fires in a manner that could never be entirely redressed. In the context of the section 202(a)(6) requirement that EPA consider the safety of onboard controls before promulgating an onboard rule, EPA finds that the safety risk associated with onboard controls—measured against the availability of an alternative control strategy of comparable effectiveness—leads to the conclusion that onboard controls should not be required.

A second distinguishing factor concerns the degree of risk associated with the introduction of new technology. EPA does not believe that increased risk is an automatic consequence of technological change. It is a broadly accepted fact that today's vehicles, with their highly sophisticated and complex designs, are safer than were the simpler vehicles of the past. Clearly, the degree to which new technology increases total risk is a function of many factors. New hardware introduces new failure modes and less well proven designs; however, they often replace undesirable systems and thus could directionally improve safety. Also, such sources of potential risk are affected to varying degrees by the risk environment into which they are introduced. For example, new hardware to cure an existing safety risk would generally be seen as providing a net reduction in risk. Similarly, new emission controls that replace or upgrade already existing controls could increase risk, have no impact on risk, or even reduce risk, depending upon the balance of their reliability and safety factors compared to the existing controls.

Finally, the existence of risk is not in itself an absolute bar to regulation requiring the introduction of new technology to reduce emissions. The emission reductions themselves are beneficial to society, or they would not be imposed. Thus, a marginal increase in risk may well be appropriate to obtain a given degree of emission reduction. For example, in adopting greatly reduced emission levels for both conventional and clean-fueled vehicles, the Congress clearly believed that any associated risk factors could be adequately controlled in the process of technology development. However, in the case of onboard controls, Congress made the issue of canister safety a critical factor in the Agency's decision to promulgate the onboard requirement. NHTSA and EPA have both found central to that issue the availability of a safe, alternative means of achieving comparable emission reductions. In these circumstances, the Agency believes it appropriate to avoid the risk posed by canister-based onboard controls by not promulgating the onboard requirement and instead relying on Stage II controls to achieve refueling emission control.

In summary, EPA considers this rulemaking to be a unique situation. While safety is always an important consideration, and EPA will continue to review the potential safety implications of all mobile source-related regulatory actions with NHTSA, EPA believes that situations where safety becomes the prime determinant of action will continue to be rare. In this rulemaking, however, where Congress required EPA to consider the safety of the controls before requiring them, and intended EPA to decline to require them if they are found to be unsafe, safety concerns appropriately play a role that is not common in mobile source rulemakings under the CAA.

VII. Finding

As required by section 202(a)(6) of the Clean Air Act, EPA has consulted with the Secretary of Transportation regarding the safety of vehicle-based (onboard) systems for the control of refueling emissions. For the reasons explained above, EPA finds reasonable and adopts NHTSA's conclusion that onboard systems would have a negative impact on safety. Stage II controls are a viable alternative to onboard controls for light-duty vehicles. They provide comparable emission control effectiveness without accompanying concerns about safety risks. In light of

these findings regarding onboard and Stage II controls, EPA concludes that onboard canister controls pose an unreasonable safety risk. Therefore, the Agency has decided not to promulgate the onboard requirements at this time.

Dated: March 27, 1992.

William K. Reilly,

Administrator.

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Wednesday
April 15, 1992

Part IV

Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 314 and 601

New Drug, Antibiotic, and Biological Drug Product Regulations; Accelerated Approval; Proposed rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 314 and 601

[Docket No. 91N-0278]

New Drug, Antibiotic, and Biological Drug Product Regulations; Accelerated Approval

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing procedures under which the agency would accelerate approval of new drugs and biologicals for serious or life-threatening illnesses, with provisions for any necessary continued study of the drugs' clinical effects after approval or with restrictions on use, if necessary. These new procedures are intended to provide expedited marketing of drugs for patients suffering from such illnesses when the drugs provide meaningful therapeutic benefit over existing treatment. Accelerated approval will be considered in two situations: (1) When approval can be reliably based on evidence of the drug's effect on a surrogate endpoint that reasonably suggests clinical benefit or on evidence of the drug's effect on a clinical endpoint other than survival or irreversible morbidity, pending completion of any necessary studies to establish and define the degree of clinical benefits to patients; and (2) when FDA determines that a drug, effective for the treatment of a disease, can be used safely only if distribution or use is modified or restricted. Drugs or biological products approved under this proposal will have met the requisite standards for safety and effectiveness under the Federal Food, Drug, and Cosmetic Act (the act), or the Public Health Service Act (the PHS Act) and thus will have full approval for marketing. These drugs or biological products will, however, be subject to the necessary postmarketing requirements for study or limitations on distribution set forth in the regulations.

DATES: Written comments by June 15, 1992.

ADDRESSES: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: Marilyn L. Watson, Center for Drug Evaluation and Research (HFD-360), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-295-8038.

SUPPLEMENTARY INFORMATION: Because expediting the approval and increasing the availability of promising new drug therapies is important to the public health, in recent years FDA has developed a number of new procedures for regulating these drugs. For example, since 1983, FDA has given special emphasis to the development and review of potential new therapies for rare diseases, under its responsibility to implement the Orphan Drug Act.

In the **Federal Register** of February 22, 1985 (50 FR 7452), FDA comprehensively revised its new drug application (NDA) regulations (called the "NDA rewrite"). The regulations were designed to streamline the process for submitting and reviewing marketing applications. FDA supplemented these regulations with extensive guidelines to sponsors on how to prepare such applications so that they are complete and thus facilitate agency review.

In the **Federal Register** of March 19, 1987 (52 FR 8798), FDA revised its investigational new drug (IND) regulations (called the "IND rewrite"). These regulations were designed to clarify and simplify the rules governing clinical testing of new drugs.

In the **Federal Register** of May 22, 1987 (52 FR 19466), "treatment IND's" were specifically authorized by regulation to permit wide access to promising experimental drugs for serious or immediately life-threatening illnesses. Under this mechanism, more than 20 drugs have since been made available prior to marketing approval to patients for a wide variety of serious diseases: acquired immunodeficiency syndrome (AIDS), cancer, Parkinson's disease, obsessive-compulsive disorder, neonatal respiratory distress syndrome, and others.

In the **Federal Register** of October 21, 1988 (54 FR 41523), FDA announced new regulatory procedures (21 CFR part 312, subpart E). These procedures were designed to expedite the development, evaluation, and marketing of drugs for life-threatening and severely debilitating illnesses. Under these procedures the agency is committed to working closely with sponsors to decide as early as possible in the human testing of the drug what evidence will be necessary for marketing approval and to assist the sponsors in designing trials to evaluate the safety and effectiveness of the drug.

These actions, combined with management innovations made in recent years, have greatly increased patient access to promising experimental drugs and have also significantly shortened the agency's time to review applications for important new drugs and approve the drugs for marketing. Additionally, in the **Federal Register** of May 21, 1990 (55 FR 20856), the Public Health Service (PHS) published a proposed policy to make promising new drugs more widely available to people with AIDS and HIV-related diseases through nonconcurrently controlled studies. These studies would be conducted in parallel with controlled clinical trials; thus the proposed policy became known as parallel track. Under the proposed policy, large numbers of AIDS and HIV-infected patients who are without alternative therapy would have access to investigational drugs as early in the drug evaluation process as possible.

Nevertheless, because, by their nature, life-threatening and other serious diseases represent particularly urgent needs, FDA believes that it should continue to modify its procedures to provide for the approval of new drugs for treatment of these diseases at the earliest time permitted under the law.

I. Introduction

FDA has determined that two additional steps should be taken in its current review process to facilitate the approval of significant new drugs, antibiotics, and biological products (generally referred to as "drugs" in this document) to treat serious or life-threatening illnesses. Accordingly, FDA is proposing regulations that would incorporate these steps into its review procedures for these products.

First, by providing for required postmarketing study to elaborate on the evidence of effectiveness, FDA is proposing to approve new drugs for serious or life-threatening illnesses at the earliest possible point at which safety and efficacy can reasonably be established under existing law.

Secondly, FDA is proposing procedures under which beneficial but highly toxic drugs can be approved for marketing. These drugs are one that the agency believes can be used safely only if distribution and use are restricted in certain ways.

Therefore, FDA is proposing to amend 21 CFR part 314 by adding subpart H, consisting of §§ 314.500 through 314.550, and to amend 21 CFR part 601 by adding subpart E, consisting of §§ 601.40 through 601.45.

II. Scope

The proposal would apply to new drug, antibiotic, and biological products used in the treatment of serious or life-threatening diseases, where the products provide meaningful therapeutic

benefits to patients over existing treatment.

A. Diseases Covered by the Proposal

The terms "serious" and "life-threatening" would be used as FDA has defined them in the past. The seriousness of a disease is a matter of judgment, but generally is based on its impact on such factors as survival, day-to-day functioning, or the likelihood that the disease, if left untreated, will progress from a less severe condition to a more serious one. Thus, acquired immunodeficiency syndrome (AIDS), all other stages of human immunodeficiency virus (HIV) infection, Alzheimer's dementia, angina pectoris, heart failure, cancer, and many other diseases are clearly serious in their full manifestations. Further, many chronic illnesses that are generally well-managed by available therapy can have serious outcomes. For example, inflammatory bowel disease, asthma, rheumatoid arthritis, diabetes mellitus, systemic lupus, erythematosus, depression, psychoses, and many other diseases can be serious for certain populations or in some or all of their phases.

B. Meaningful Therapeutic Benefit Over Existing Therapy

As in past programs for expediting access to new drugs, FDA believes that procedures for doing so should be applied only where a serious medical need is not met by currently available therapies. If such a need does not exist, the agency believes that the usual procedures provide for the most appropriate and thorough approach to ensuring safety and effectiveness of drugs prior to marketing. Accordingly, FDA is proposing that the accelerated approval program should only apply to drugs that provide meaningful therapeutic benefit over existing treatment for patients with serious or life-threatening diseases. For example, if there is an approved treatment for a serious or life-threatening disease, individuals or a defined subset of patients may not respond well to that therapy or be intolerant of it. A treatment shown to be effective in those patients would be eligible for these procedures. Similarly, if a new therapy were a clear improvement over existing therapy in being more effective or better tolerated, that too would be eligible for accelerated approval.

At the same time, however, FDA is aware that drugs useful for one condition can often be useful in a range of other conditions. FDA's risk-benefit analysis in cases of serious or life-threatening diseases necessarily will differ from cases where the majority of a drug's likely application in actual clinical practice will not meet these conditions. Accordingly, FDA reserves the right to apply FDA's traditional approval mechanisms rather than this accelerated process in cases where the agency believes in good faith that the new drug's foreseeable use is reasonably likely to be outside the scope of "life-threatening diseases without meaningful therapeutic benefit over existing therapy." Sponsors are encouraged to meet with FDA early in the drug development process to determine the nature of the regulatory review that FDA will apply.

III. Elements of the Program

For products covered under this program, FDA would grant accelerated marketing approval, with postmarketing requirements, in the following two situations:

A. Reliance on a "Surrogate" Endpoint or Other Appropriate Indicator of Effectiveness (e.g., Evidence of Efficacy Other Than an Effect on Survival or Irreversible Morbidity)

1. Criteria for Approval.

There may be information about the effect of a drug on a "surrogate" endpoint of disease before there is a demonstrated effect on patients' survival or overall well-being, particularly when the disease is one that progresses over a long period. A surrogate endpoint, or "marker," is a laboratory measurement or physical sign that is used in therapeutic trials as a substitute for a clinically meaningful endpoint that is a direct measure of how a patient feels, functions, or survives and that is expected to predict the effect of the therapy. For example, elevated cholesterol and hypertension, two surrogate endpoints, are important because they are risk factors for coronary and cerebral artery disease; but it is the impact of the diseases (e.g., angina, congestive heart failure after a heart attack, paralysis after a stroke, or sudden death) that is important to the patient.

Surrogate endpoints can be established with different degrees of assurance. There is usually at least a theoretical possibility that the marker and the disease are not causally related, but are instead associated with a common underlying factor. For example, fever and respiratory impairment occur with pneumonia, but the fever does not cause the disease, and treating it will not improve the infection. Similarly, frequent premature ventricular beats after a heart attack signal an increased risk of sudden death, but lowering the rate of these beats with antiarrhythmic agents has not been shown to decrease the risk of sudden death. In some cases, however, the evidence of a causal relationship is very persuasive, especially where treatment that changes the surrogate has been repeatedly shown to lead to improvement of clinical outcome. For example, substantially reducing elevated blood pressure has been repeatedly shown to reduce the likehihood of stroke and renal failure. Reliance on a surrogate endpoint is therefore a matter of scientific judgment, a judgment based on the available data, but still a judgment.

Approval of a drug on the basis of a well-documented effect on a surrogate endpoint can allow a drug to be marketed earlier, sometimes much earlier, than it could be if a demonstrated clinical benefit were required. FDA has in the past based approval of drugs on a demonstration of a favorable effect on a surrogate endpoint, where the agency has concluded that a favorable effect on the surrogate endpoint was very likely to predict a clinical benefit. In some cases, however, the judgment as to the likelihood of clinical benefit when the drug affects a surrogate endpoint is so close that it could be influenced by assurance that studies to evaluate actual clinical benefit would be conducted promptly.

Under this proposal, therefore, for drugs to treat serious or life-threatening diseases where there is meaningful benefit to patients over existing treatment, FDA would consider granting approval on the basis of adequate and well-controlled trails establishing that the drug has an effect on a surrogate endpoint that is reasonably likely (based on epidemiologic, therapeutic, or other evidence) to predict clinical benefit. Approval could be granted where there is some uncertainty as to the relation of that endpoint to clincial benefit, with the requirement that the sponsor conduct or complete studies after approval to establish and define the drug's clinical benefit.

It is also often possible to demonstrate a favorable clinical effect of therapy other than an effect on survivual or the ultimate course of the disease that, for serious and life-threatening illnesses, would merit a decision to approve the therapy. For example, an anti-HIV drug might demonstrate that it could provide weight gain and reduce the frequency of opportunistic infections, even through evidence of an effect on long-term survival was not yet available. While

the favorable findings would be a basis for approval, in some instances additional study may be necessary to clearly determine long-term effects.

Finally, as in the past, FDA will continue to approve therapies for serious and life-threatening illnesses, for which there are no adequate therapies, as early in the development process as possible when the statutory standard of substantial evidence of safety and effectiveness is met through evidence on the clinical endpoints of survival or irreversible morbidity. The safety and efficacy determination would be made taking into account the risks to human life and health of the untreated disease. FDA made such a determination for AZT and would grant approval for other such drugs in the same expeditious manner. Approvals of drugs for which there is sufficient evidence of effectiveness on the clinical endpoints of survival or irreversible morbidity would not require postmarking studies under this regulation.

2. Postmarketing Studies

For drugs approved on the basis of an effect on a surrogate endpoint, or other indicator of effectiveness the sponsor would be required to conduct any clinical studies necessary to ascertain the actual clinical benefit of the drug on such endpoints as survival, disease complications, or longer-term symptoms. It is important that the sponsor's postmarketing studies be adequate and well-controlled trials that are carried out in such a way that they are capable of obtaining the confirmatory data being sought. FDA will expect the sponsor to carry out such studies in a timely manner and in consultation with FDA. However, the requirements for any additional study to demonstrate actual clinical benefit will not be more stringent than those that would normally be required for marketing approval, and new studies beyond those already in progress will not necessarily be needed. Indeed, it is anticipated that the requirement for postmarketing studies would usually be met by studies already underway at the time of approval. The plan for timely completion of the necessary studies would be included in the marketing application. FDA would interpret the requirement for conducting the studies with "due diligence" by assessing the sponsor's success in meeting normal developmental goals for a clinical trial. This assessment would include examining the pace of design of studies and the speed with which patients are enrolled.

3. Authority to Require Postmarketing Studies

FDA believes that sections 505 and 701 of the act (21 U.S.C. 355, 371) provide legal authority for the agency to promulgate regulations requiring postmarketing studies for new drugs. New drugs are approved for marketing if they meet the safety and effectiveness criteria set forth in section 505(d) of the act and the implementing regulations (21 CFR part 314). To demonstrate effectiveness, the law requires evidence from adequate and well-controlled clinical studies on the basis of which qualified experts could fairly and responsibly conclude that the drug has the effect it is purported to have. Under section 505(e) of the act, approval of a new drug application is to be withdrawn if new information shows that the drug has not been demonstrated to be either safe or effective. Approval may also be withdrawn if new information shows that the drug's labeling is false or misleading.

Section 505(k) of the act authorizes the agency to promulgate regulations requiring applicants to make records and reports of data or other information that are necessary to enable the agency to determine whether there is reason to withdraw approval of an NDA. Section 701(a) of the act generally authorizes FDA to issue regulations for the "efficient enforcement" of the act.

For new drugs approved under proposed § 314.510 of these accelerated approval regulations, the judgment concerning likelihood of clinical benefit is based upon a demonstrated effect on a surrogate marker reasonably likely to predict clinical benefit. If, however, the surrogate marker turns out not to be such a predictor, then the drug would lack substantial evidence of effectiveness. The risk-benefit analysis of the drug may also be altered so that the drug can no longer be considered safe for use in treating the serious or life-threatening disease. In addition, in such cases the drug's approved labeling may be false or misleading.

When the correlation between surrogate endpoint or other indicator of effectiveness and clinical benefit is uncertain, the agency believes it would not be appropriate to approve drugs under section 505 of the act without the assurance of promptly conducted adequate and well-controlled studies evaluating actual clinical benefit. Evidence from such postmarketing studies evaluating actual clinical benefit (and thus confirming the predictive value of the surrogate marker or other indicator) is necessary for the agency to know whether the drug should remain on the market or whether the NDA should be withdrawn.

Section 351 of the PHS Act (42 U.S.C. 262) provides legal authority for the agency to require postmarketing studies for biological products. Licenses for biological products are to be issued only upon a showing that they meet standards "designed to insure the continued safety, purity, and potency of such products" prescribed in regulations (42 U.S.C. 262(d)(1)). The "potency" of a biological product includes its effectiveness (21 CFR 600.3(s)). When the correlation between surrogate endpoint and clinical benefit is uncertain for a biological product approved under proposed § 601.41, postmarketing studies are necessary to ensure that product's "continued" safety and effectiveness.

B. Restrictions on Use After Marketing

1. Criteria for Approval

Virtually all drug can be toxic to humans, and no drug is completely free of risk. In approving a new drug for marketing, FDA analyzes benefits and risks, and approves a drug if the benefit outweighs the risks. In general, the more serious the illness and the greater the effect of the drug on that illness, the greater the acceptable risk from the drug. If products provide meaningful therapeutic benefit over existing treatment for a serious or life-threatening disease, a greater risk may also be acceptable. FDA alerts health professionals and their patients to adverse effects that may result from drug use through labeling and other warning mechanisms and, where possible, provides advice on measures that can be taken to reduce the risks.

Some drugs, however, are so inherently toxic or otherwise potentially harmful that it is difficult to justify their unrestricted use. In 1990, for example, FDA approved the drug clozapine for schizophrenia when the manufacturer decided to restrict distribution to patients taking part in a monitoring program to guard against a potentially fatal side effect.

FDA has concluded that some clinically beneficial drugs can be used safely only if distribution and use are modified and restricted. In some cases, it is reasonable to expect that careful labeling will accomplish the needed limitations as, for example, is the case for most oncologic drugs, where the toxicity of the drugs is widely appreciated and monitoring for toxic effects is a routine part of patient care. In some cases, however, other kinds of restrictions may be necessary. FDA is

prepared to approve such high risk drugs for early marketing if the agency can be assured that postmarketing restrictions will be in place to counterbalance the known safety concerns.

2. Postmarketing Restrictions

The restrictions FDA may consider when approving drugs under this proposal may include restrictions such as the following:

a. *Restricting distribution to certain facilities or to physicians with special training or experience.* For example, if the drug were known to cause life-threating reactions, it might be necessary to restrict a drug's use to settings in which emergency capabilities and equipment are readily available.

b. *Conditioning distribution on the performance of specified medical procedures.* The approval of clozapine, for example, was accompanied by a commitment to have regular blood tests performed on patients receiving the drug to monitor its toxicity. FDA can envision the need for similar procedures should it approve a drug that can be used safely only if regular monitoring is assured.

The limitation would be tailored to the specific safety issue raised by the particular drug and agreed to by the manufacturer at the time of approval. It should be emphasized that these restrictions will be considered necessary only rarely and in extraordinary cases. FDA believes that the safe use of most prescription drugs will continue to be ensured through traditional patient management by health professionals and through necessary safety warnings on the drug's labeling.

3. Authority To Impose Restrictions on Distribution

Sections 501, 502, 503, 505, and 701 of the act (21 U.S.C. 351, 352, 353, 355, and 372) provide broad authority for FDA to issue regulations to help ensure the safety and effectiveness of new drugs. These provisions reflect the congressional objective of protecting the public health by requiring safety and effectiveness of new drugs under the conditions of actual use, through a variety of mechanisms.

For example, under section 503 of the act drugs may be limited to prescription use when, because of their toxicity or other potentiality for harmful effect, or the methods of use, or the collateral measures necessary to their use, the drugs are not safe for use except under the supervision of a licensed practitioner. Section 502(a) of the act prohibits false or misleading labeling of drugs, including (under section 201(n) of the act) failure to reveal material facts relating to potential consequences under customary conditions of use. Section 502(f) of the act requires drugs to have adequate directions for use and adquate warnings against unsafe use, such as methods of administration, that may be necessary to protect users. In addition, section 502(j) of the act prohibits use of drugs that are dangerous to health when used in the manner suggested in their labeling. Section 501 of the act contains provisions regarding the methods and controls for processing or holding to ensure that the drug is safe and has the quality and other characteristics the drug is represented to possess. (See section 501(a)(1) of the act; see also section 501(c) of the act.)

Moreover, new drugs may be approved under section 505(d) of the act only if safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling. As previously discussed, section 701(a) of the act authorizes FDA to issue regulations for the efficient enforcement of the act.

For drugs approved with restricted distribution or use under proposed § 314.520, FDA will have determined that the particular restriction is necessary for safe use. The appropriate restrictions may vary with the circumstances of each drug. Without the restriction specified in the approval, the drug would be adulterated under section 501 of the act, misbranded under section 502 of the act, or not shown to be safe under section 505 of the act.

For biological products, section 351 of the PHS Act (42 U.S.C. 262) authorizes the imposition of restrictions through regulations "designed to insure the continued safety, purity, and potency" of the products. As with drugs approved under the NDA procedures, biological products will be licensed with restrictions on distribution or use only if FDA determines that such restrictions are necessary for safe use.

C. Promotional Materials

FDA is also proposing to require submission of promotional materials, including promotional labeling as well as advertisements, that the applicant intends to disseminate for drugs approved under the accelerated approval regulations. Because drugs approved under the restricted use provision may be highly toxic or otherwise potentially harmful, FDA is concerned that certain promotional claims could cause inappropriate and, therefore, unsafe use. Similarly, the risk/benefit balance for drugs approved based on evidence of the drug's effect on a surrogate endpoint could readily be adversely affected by promotion that does not appropriately reflect the proper use of the product.

FDA does not intend specifically to approve promotional materials under proposed § 314.550, but does intend to require advance submission of such materials. FDA may therefore consider during the drug approval process and subsequent to approval whether such materials could undercut or counteract the drug's approved labeling so as to affect adversely the risk/benefit assessment. Accordingly, the sponsor must submit promotional materials to FDA during the approval process and subsequent to approval. The agency will determine the extent of review and potential modification on a case-by-case basis. Under section 505(d)(4) of the act, in determining whether a drug is "safe for use" under the conditions proposed, the agency may consider not only information such as data from clinical studies, but also "any other information" before the agency relevant to the determination. In deciding whether the drug's proposed labeling would be "false or misleading" under section 505(d)(7) of the act, the agency is also to evaluate "all material facts." Section 505(k) of the act authorizes FDA to require reporting of information necessary to determine whether there are grounds for withdrawing approval. For biological products, section 351 of the PHS Act authorizes the promulgation of regulations designed to ensure the continued safety, purity, and potency of the products.

For prescription drug products, NDA applicants are ordinarily required to submit mailing pieces and any other labeling or advertising devised for promotion of the drug at the time of initial dissemination of the labeling and at the time of initial publication of the advertisement (21 CFR 314.81(3)). The current prescription drug advertising regulations provide for prior approval of advertisements in specific situations related to potential fatalities or serious damage from drug use (21 CFR 202.1(j)). In rare circumstances in the past, specific FDA approval of promotional materials prior to dissemination has been required.

Because of the special circumstances under which drugs will be approved within these accelerated approval regulations and the likelihood that promotional materials could adversely affect the sensitive risk/benefit balance in this context, FDA will require submission of the promotional material prior to marketing approval. In addition, FDA will require submission of promotional materials developed by the applicant subsequent to marketing

approval at least 30 days prior to the intended time of initial dissemination of the labeling or initial publication of the advertisement. Because promotional claims may adversely affect the risk/benefit assessment or may result in false or misleading labeling, FDA may wish to protect the public health by withdrawing approval as rapidly as possible if inappropriate promotional materials are disseminated. FDA believes that submission of these materials is necessary to enable the agency to determine whether such withdrawal proceedings should be initiated.

If the agency determines after approval that submission of promotional materials is no longer needed, it will so notify the sponsor. For example, if a drug is approved based on a surrogate endpoint, after a postmarketing study has verified the clinical benefit, FDA expects that such advance submission of promotional materials will no longer be required.

D. Withdrawal of Approved Drugs

1. Streamlined Withdrawal Procedures

Because FDA is accelerating the marketing of new drugs under these proposed regulations, the agency also believes it appropriate to propose a streamlined withdrawal process. Under current FDA regulations, holders of approved NDA's or license applications may request a formal evidentiary hearing under 21 CFR part 12 if the agency intends to withdraw the approval of the application (21 CFR 10.50(c), 12.21, 314.200, and 601.7). Part 12 proceedings ordinarily include written and oral testimony before an administrative law judge, who issues an initial decision that may then be appealed to the Commissioner for final decision.

In the agency's experience, such proceedings often take long periods of time, with months to years elapsing before issuance of the final decision. In the past, when significant safety problems have been discovered for marketed drugs, FDA and the sponsors of such drugs have often reached mutual agreement on the need to remove them from the market rapidly. However, sponsors usually have been unwilling to enter into such agreement when doubts about effectiveness have arisen, such as following the review of effectiveness of pre-1962 approvals carried out under the Drug Efficacy Study Implementation (DESI) program.

For drugs approved under these proposed accelerated approval regulations, the risk/benefit assessment is dependent upon the likelihood that a surrogate endpoint will correlate with clinical benefit or that postmarketing restrictions will enable safe use. Without the assurances regarding demonstration of actual clinical benefit or the demonstrated adequacy of distribution restrictions, the risk/benefit assessment for these drugs changes significantly. The agency is proposing a streamlined, expeditious procedure for withdrawing approvals if: (1) A postmarketing clinical study fails to verify clinical benefit; (2) the drug's sponsor fails to perform the required postmarketing study with due diligence; (3) experience with the drug after marketing demonstrates that restrictions on distribution or use are inadequate to ensure safe use; (4) the drug's sponsor fails to adhere to the postmarketing restrictions agreed upon; (5) the promotional materials are false or misleading; or (6) other evidence demonstrates that the drug product is not shown to be safe or effective under its conditions of use. FDA believes that if any of these circumstances exists, continued marketing of the drug to treat patients with a serious or life-threatening disease is inappropriate and marketing approval should be rapidly withdrawn.

Although FDA believes that rapid withdrawal of approval under such circumstances is important to the public health, the agency also believes that the drug's sponsor should have an adequate opportunity to present data and information if the sponsor disagrees with the agency's position regarding the facts of a particular drug. Under FDA's current regulations, persons may waive the opportunity for a part 12 hearing and request instead a hearing before a public board of inquiry under 21 CFR part 13, a hearing before a public advisory committee under 21 CFR part 14, or a hearing before the Commissioner under 21 CFR part 15 (21 CFR 12.32(a)). Each of these alternative approaches can lead to more expeditious resolution of disputed issues.

For resolution of disputes concerning withdrawal of drugs approved under proposed §§ 314.510, 314.520, 601.41, or 601.42, the agency believes that a hearing combining and modifying aspects of part 14 and part 15 procedures would be most appropriate and expeditious. Although not required to do so, in most instances the agency will have consulted with one of its standing advisory committees before approving an application under these accelerated approval regulations. Advisory committee members have relevant technical expertise (a committee will ordinarily have been consulted prior to approval of a drug under these accelerated approval provisions) and are subject to conflict of interest laws and regulations (21 CFR 14.80(a)). Especially if they have reviewed the existing data prior to the drug's approval, the committee members should be well situated to provide advice and recommendations concerning withdrawal based on subsequent information in an efficient manner.

Under the agency's current procedures, the Commissioner decides whether to withdraw a drug's approval after appeal of the Administrative Law Judge's initial decision following a part 12 hearing or, if the applicant requests, after an alternative form of hearing. When part 15 procedures are followed, the Commissioner or a designee presides at a hearing where interested persons may present their views on the pending matter.

In order to provide fair opporunity for presentation of views, as well as expeditious resolution of the issues, the agency proposes that when the agency intends to withdraw an NDA or license application approved under §§ 314.510, 314.520, 601.41 or 601.42, the applicant will have an opportunity for a hearing before the Commissioner (or designee) and an advisory committee. The withdrawal process would begin with a letter from the Director of the Center for Drug Evaluation and Research or the Director of the Center for Biologics Evaluation and Research notifying the applicant that the Center proposes to withdraw marketing approval and stating in general the reasons for the proposed action. This letter would also inform the applicant that unless the applicant requests a hearing within 15 days of receiving the notification, the applicant has waived the opportunity for a hearing.

If the applicant submits a timely request for hearing, the agency will publish a notice of hearing in accordance with § 15.20. Separation of functions (as in § 10.55) would not apply to these proceedings at any point in the withdrawal process. At a hearing under § 314.530 or § 601.43, an advisory committee would be present and would be asked to review information and make a recommendation on withdrawal of the NDA or license. Subsequent to the hearing, the Commissioner would render a final decision concerning the proposed withdrawal.

The Commissioner or designee would preside at such a hearing, which would essentially follow the procedures set forth in 21 CFR part 15, with some modifications. Under ordinary part 14 or part 15 procedures, only the committee members or the presiding officer (or

designated panelists) may question a person concerning that person's presentation at the hearing (§§ 14.29(f) and 15.30(e)). Under the proposed withdrawal procedures, the presiding officer, the committee members, a representative of the applicant, and a representative of the Center that initiates the withdrawal proceedings may also question participants. As with ordinary part 15 hearings, the rules of evidence would not apply to this hearing. No motions or objections relating to the admissibility of information or views could be made, but participants could comment on or rebut information and views presented by others (§ 15.30(f)).

The Commissioner's final decision would constitute final agency action from which the applicant may petition for judicial review under applicable statutes. Before requesting an order from a court for stay of action pending review, the applicant must first submit a petition for stay of action under § 10.35.

2. Authority for Withdrawal Procedures

Section 505(e) of the act authorizes the agency to withdraw approval of an NDA if new information shows that the drug has not been demonstrated to be either safe or effective. Approval may also be withdrawn if the applicant has failed to maintain required records or to make required reports. In addition, approval may be withdrawn if new information, along with the evidence considered when the application was approved, shows the labeling to be false or misleading. Withdrawal for any of the specified reasons under section 505(e) of the act is to follow "due notice and opportunity for hearing to the applicant." As previously discussed, section 701(a) of the act authorizes FDA to issue regulations for the efficient enforcement of the act.

In issuing its general procedural regulations, FDA decided to afford NDA holders an opportunity for a formal evidentiary hearing even though the courts had not decided that such a hearing was necessarily legally required (see 40 FR 40691, September 3, 1975). The agency's procedural regulations permit denial of an applicant's hearing request if inadequately justified (21 CFR 12.28, 314.200(g)). As previously noted, the regulations also allow applicants to request, and the Commissioner to suggest, an alternative form of hearing (21 CFR 12.32).

For drugs approved under proposed § 314.510 the agency will have determined that reports of postmarketing studies are critical to the risk/benefit balance needed for approval. For drugs approved under proposed § 314.520, FDA will have determined that the distribution or use restriction is critical to this risk/benefit balance needed for approval. For drugs approved under proposed § 314.520, FDA will have determined that the distribution or use restriction is critical to this risk/benefit balance. In addition, the agency has determined that the ability to withdraw approval expeditiously for such drugs is critical. If the agency is not able to withdraw approval rapidly in the event it loses the assurances regarding demonstration of actual clinical benefit or the demonstrated adequacy of distribution restrictions are removed, then the agency believes that, under authority of section 505(d) of the act, the drug cannot on an ongoing basis meet the standards of safety and efficacy required for marketing under the act. Otherwise, the risk of continued exposure of patients with serious or life-threatening diseases to ineffective or unsafe drugs outweighs the potential benefits.

For biological products, section 351(d)(1) of the PHS Act authorizes approval of license applications under standards designed to ensure continued safety, purity, and potency. The PHS Act does not specify license revocation procedures, except to state that licenses would be suspended and revoked "as prescribed by regulations" (42 U.S.C. 262(d)(1)). In promulgating its procedural regulations, FDA has determined that a formal evidentiary hearing is not required before withdrawing approval of biological products, but that it would be appropriate to apply the same procedures to biological products as to drug removal (see 40 FR 40691, September 3, 1975). Similarly, FDA is now proposing to revoke licenses for biological products approved under §§ 601.41 and 601.42 following the same procedures proposed for withdrawing NDA's.

The agency believes that the withdrawal procedures under proposed §§ 314.530 and 601.43 satisfy any applicable due process requirements for holders of NDA's and license applications. Through the proposed hearing process, applicants will be afforded the opportunity to present any data and information they believe to be relevant to the continued marketing of the drug. Moreover, as part of the approval process, applicants will have agreed that these withdrawal procedures apply to the drug for which they seek approval; applicants objecting to these procedures may forego approval under these proposed regulations and seek approval under the currently codified regulations. Under such circumstances, applicants would not have the benfit of accelerated approval; however, if the drug were subsequently approved under current regulations, before withdrawal of the approval the applicant would have an opportunity for a part 12 hearing.

E. Additional Safeguards for Patient Safety

The accelerated drug approval program is intended to make significant new drugs available to patients earlier than under existing approval procedures, yet ensure that they are safe and effective for marketing. As with all new drugs, FDA has in place regulations that provide additional safeguards to ensure patient safety. Those regulations will apply to drugs approved under this program as well. Specifically, applicants will be expected to adhere to FDA's longstanding requirements for postmarketing recordkeeping and safety reporting. Those regulations also provide for additional "special reporting," at FDA's request, of other relevant information such as adverse drug experiences. FDA believes these safeguards are sufficient as currently promulgated in regulation and does not intend to develop new regulations imposing additional adverse reaction reporting requirements upon sponsors gaining approval under the accelerated approval procedures.

In addition, FDA's paractices and procedures provide further safeguards to ensure the quality and integrity of the drug development and review process. These include conducting on-site audits of key studies and/or clinical investigators to ensure authenticity of data submitted to FDA, and inspections of manufacturing facilities before marketing approval is granted to ensure that manufacturers are able to produce properly formulated compounds.

IV. Economic Impact

In accordance with Executive Order 12291, FDA has carefully analyzed the economic effects of this proposal and has determined that the final rule, if promulgated, will not be a major rule as defined by the Order. Furthermore, the final rule, if promulgated, is not expected to impose significant economic impact on a substantial number of small entitites so as to require a regulatory flexibility analysis under the requirements of the Regulatory Flexibility Act of 1980.

However, FDA is seeking public comment on the extent to which the contemplated postmarketing requirements would impose an economic impact upon affected drug manufacturers.

V. Envrionmental 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. Paperwork Reduction Act of 1980

This rule would not contain new collection of information requirements. Section 314.540 does refer to regulations that contain collection of information requirements that were previously submitted for review to the Director of the Office of Management and Budget (OMB) under section 3504 of the Paperwork Reduction Act of 1980 (Adverse Drug Experience Reporting, OMB No. 0190–0230).

VII. Request for Comments

Interested persons may, on or before June 15, 1992, 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 314

Administrative practice and procedure, Confidential business information, Drugs, Reporting and recordkeeping requirements.

Part 601

Biologics, Confidential business information.

Therefore, under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR parts 314 and 601 be amended as follows:

PART 314—APPLICATIONS FOR FDA APPROVAL TO MARKET A NEW DRUG OR AN ANTIBIOTIC DRUG

1. The authority citation for 21 CFR part 314 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 505, 506, 507, 701, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 357, 376).

2. Subpart H consisting of §§ 314.500 through 314.550 is added to read as follows:

Subpart H—Accelerated Approval of New Drugs for Serious or Life-Threatening Illnesses

Sec.

Subpart H—Accelerated Approval of New Drugs for Serious or Life-Threatening Illnesses

§ 314.500 Scope.

This section applies to new drug and antibiotic products that have been studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit to patients over existing treatments (e.g., ability to treat patients unresponsive to, or intolerant of, available therapy, or improved patient response over available therapy).

§ 314.510 Approval based on a surrogate endpoint or on an effect on a clinical endpoint other than survival or irreversible morbidity.

FDA may grant marketing approval for a new drug product on the basis of adequate and well-controlled clinical trials establishing that the drug product has an effect on a surrogate endpoint that is reasonably likely, based on epidemiologic, therapeutic, pathophysiologic, or other evidence, to predict clinical benefit or on the basis of an effect on a clinical endpoint other than survival or irreversible morbidity. Such approval will be subject to the requirement that the applicant study the drug further, when determined necessary by FDA, to verify and describe its clinical benefit, where there is uncertainty as to the relation of the surrogate endpoint to clincal benefit, or of the observed clinical benefit to ulitimate outcome. Postmarketing studies would not necessarily be required and would usually be studies already underway. The applicant shall carry out any such studies with due diligence.

§ 314.520 Approval with restrictions to ensure safe use.

(a) If FDA concludes that a drug product shown to be effective can be safely used only if distribution or use is restricted, FDA will require such postmarketing restrictions as are needed to ensure safe use of the drug product, such as:

(1) Distribution restricted to certain facilities or physicians with special training or experience; or

(2) Distribution conditioned on the performance of specified medical procedures.

(b) The limitations imposed will be commensurate with the specific safety concerns presented by the drug product.

§ 314.530 Withdrawal procedures.

(a) For circumstances of withdrawal for new drugs and antibiotics approved under §§ 314.510 and 314.520, FDA may withdraw approval, following a hearing as provided in part 15 of this chapter, as modified by this section, if:

(1) A postmarketing clinical study fails to verify clinical benefit;

(2) The applicant fails to perform the required postmarketing study with due diligence;

(3) Use after marketing demonstrates that postmarketing restrictions are inadequate to ensure safe use of the drug product;

(4) The applicant fails to adhere to the postmarketing restrictions agreed upon;

(5) The promotional materials are false or misleading; or

(6) Other evidence demonstrates that the drug product is not shown to be safe or effective under its conditions of use.

(b) *Notice of opportunity for a hearing.* The Director of the Center for Drug Evaluation and Research will give the applicant notice of an opportunity for a hearing on the Center's proposal to withdraw the approval of an application approved under § 314.510 or § 314.520. The notice, which will ordinarily be a letter, will state generally the reasons for the action and the proposed grounds for the order.

(c) *Submission of data and information.* (1) If the applicant fails to file a written request for a hearing within 15 days of receipt of the notice, the applicant waives the opportunity for a hearing.

(2) If the applicant files a timely request for a hearing, the agency will publish a notice of hearing in the **Federal Register** in accordance with §§ 12.32(e) and 15.20 of this chapter.

(3) An applicant who requests a hearing under this section must, within 30 days of receipt of the notice of opportunity for a hearing, submit the data and information upon which the applicant intends to rely at the hearing.

(d) *Separation of functions.* Separation of functions (as specified in § 10.55 of this chapter) will not apply at

any point in withdrawal proceedings under this section.

(e) *Procedures for hearings.* Hearings held under this section will be conducted in accordance with the provisions of part 15 of this chapter, with the following modifications:

(1) An advisory committee duly constituted under part 14 of this chapter will be present at the hearing. The committee will be asked to review the issues involved and to provide advice and recommendations to the Commissioner of Food and Drugs.

(2) The presiding officer, the advisory committee members, a representative of the applicant, and a representative of the Center may question any person during or at the conclusion of the person's presentation. No other person attending the hearing may question a person making a presentation. The presiding officer may, as a matter of discretion, permit questions to be submitted to the presiding officer for response by a person making a presentation.

(f) *Judicial review.* The Commissioner's decision constitutes final agency action from which the applicant may petition for judicial review. Before requesting an order from a court for a stay of action pending review, an applicant must first submit a petition for a stay of action under § 10.35 of this chapter.

§ 314.540 Postmarketing safety reporting.

Drug products approved under this program are subject to the postmarketing recordkeeping and safety reporting applicable to all approved drug products, as provided in §§ 314.80 and 314.81.

§ 314.550 Promotional materials.

For drug products being considered for approval under this subpart, applicants must submit to the agency for consideration during the approval process copies all promotional materials, including promotional labeling as well as advertisements, intended for dissemination or publication upon marketing approval. Subsequent to marketing approval, unless otherwise informed by the agency, the applicant must submit promotional materials at least 30 days prior to the intended time of inital dissemination of the labeling or initial publication of the advertisement.

PART 601—LICENSING

3. The authority citation for 21 CFR part 601 continues to read as follows:

Authority: Secs. 201, 501, 502, 503, 510, 513–516, 518–520, 701, 704, 706, 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 353, 355, 360, 360c–360f, 360h–360j, 371, 374, 376, 381); secs. 215, 301, 351, 352 of the Public Health Service Act (42 U.S.C. 216, 241, 262, 263); secs. 2–12 of the Fair Packaging and Labeling Act (15 U.S.C. 1451–1461).

4. Subpart E consisting of §§ 601.40 through 601.45 is added to read as follows:

Subpart E—Accelerated Approval of Biological Products for Serious or Life-Threatening Illnesses

Sec.

Subpart E—Accelerated Approval of Biological Products for Serious or Life-Threatening Illnesses

§ 601.40 Scope.

This section applies to biological products that have been studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit to patients over existing treatments (e.g., ability to treat patients unresponsive to, or intolerant of, available therapy, or improved patient response over available therapy).

§ 601.41 Approval based on a surrogate endpoint or on an effect on a clinical endpoint other than survival or irreversible morbidity.

FDA may grant marketing approval for a biological product on the basis of adequate and well-controlled clinical trials establishing that the biological product has an effect on a surrogate endpoint that is reasonably likely, based on epidemiologic, therapeutic, pathophysiologic, or other evidence, to predict clinical benefit or on the basis of an effect on a clinical endpoint other than survival or irreversible morbidity. Such approval will be subject to the requirement that the applicant study the biological product further, when determined necessary by FDA, to verify and describe its clinical benefit, where there is uncertainty as to the relation of the surrogate endpoint to clinical benefit, or of the observed clinical benefit to ultimate outcome. Postmarketing studies would not necessarily be required and would usually be studies already underway. The applicant shall carry out any such studies with due diligence.

§ 601.42 Approval with restrictions to ensure safe use.

(a) If FDA concludes that a biological product shown to be effective can be safely used only if distribution or use is restricted, FDA will require such postmarketing restrictions as are needed to ensure safe use of the biological product, such as:

(1) Distribution restricted to certain facilities or physicians with special training or experience; or

(2) Distribution conditioned on the performance of specified medical procedures.

(b) The limitations imposed will be commensurate with the specific safety concerns presented by the biological product.

§ 601.43 Withdrawal procedures.

(a) For circumstances of withdrawal for biological products approved under §§ 601.40 and 601.42, FDA may withdraw approval, following a hearing as provided in part 15 of this chapter, as modified by this section, if:

(1) A postmarketing clinical study fails to verify clinical benefit;

(2) The applicant fails to perform the required postmarketing study with due diligence;

(3) Use after marketing demonstrates that postmarketing restrictions are inadequate to ensure safe use of the drug product;

(4) The applicant fails to adhere to the postmarketing restrictions agreed upon;

(5) The promotional materials are false or misleading; or

(6) Other evidence demonstrates that the biological product is not shown to be safe or effective under its conditions of use.

(b) *Notice of opportunity for a hearing.* The Director of the Center for Biologics Evaluation and Research will give the applicant notice of an opportunity for a hearing on the Center's proposal to withdraw the approval of an application approved under § 601.40 or § 601.41. The notice, which will ordinarily be a letter, will state generally the reasons for the action and the proposed grounds for the order.

(c) *Submission of data and information.* (1) If the applicant fails to file a written request for a hearing within 15 days of receipt of the notice, the applicant waives the opportunity for a hearing.

(2) If the applicant files a timely request for a hearing, the agency will publish a notice of hearing in the **Federal Register** in accordance with §§ 12.32(e) and 15.20 of this chapter.

(3) An applicant who requests a hearing under this section must, within

30 days of receipt of the notice of opportunity for a hearing, submit the data and information upon which the applicant intends to rely at the hearing.

(d) *Separation of functions.* Separation of functions (as specified in § 10.55 of this chapter) will not apply at any point in withdrawal proceedings under this section.

(e) *Procedures for hearings.* Hearings held under this section will be conducted in accordance with the provisions of part 15 of this chapter, with the following modifications:

(1) An advisory committee duly constituted under part 14 of this chapter will be present at the hearing. The committee will be asked to review the issues involved and to provide advice and recommendations to the Commissioner of Food and Drugs.

(2) The presiding officer, the advisory committee members, a representative of the applicant, and a representative of the Center may question any person during or at the conclusion of the person's presentation. No other person attending the hearing may question a person making a presentation. The presiding officer may, as a matter of discretion, permit questions to be submitted to the presiding officer for response by a person making a presentation.

(f) *Judicial review.* The Commissioner's decision constitutes final agency action from which the applicant may petition for judicial review. Before requesting an order from a court for a stay of action pending review, an applicant must first submit a petition for a stay of action under § 10.35 of this chapter.

§ 601.44 Postmarketing safety reporting.

Biological products approved under this program are subject to the postmarketing recordkeeping and safety reporting applicable to all approved biological products.

§ 601.45 Promotional materials.

For biological products being considered for approval under this subpart, applicants must submit to the agency for consideration during the approval process copies of all promotional materials, including promotional labeling as well as advertisements, intended for dissemination or publication upon marketing approval.

Subsequent to marketing approval, unless otherwise informed by the agency, the applicant must submit promotional materials at least 30 days prior to the intended time of initial dissemination of the labeling or initial publication of the advertisement.

David A. Kessler,

Commissioner of Food and Drugs.

Dated: April 9, 1992.

Louis W. Sullivan,

Secretary for Health and Human Services.

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Wednesday
April 15, 1992

Part V

Department of Health and Human Services

Food and Drug Administration
Public Health Service

21 CFR Part 312
Investigational New Drug, Antibiotic, and Biological Product Applications; Clinical Hold and Termination; Final Rule

Expanded Availability of Investigational New Drugs Through a Parallel Track Mechanism for People With AIDS and Other HIV-Related Disease; Notice

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 312

[Docket No. 89N-0510]

RIN 0905-AD19

Investigational New Drug, Antibiotic, and Biological Product Applications; Clinical Hold and Termination

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final regulation that provides additional grounds for placing an investigation on "clinical hold" and for terminating an investigational new drug application (IND). Under this rule, FDA may require sponsors to cease distributing an experimental drug in an open, nonconcurrently controlled investigation if any of several specified conditions exist. This final rule is part of the Public Health Service's (PHS's) efforts to make promising drugs widely available to people with acquired immunodeficiency syndrome (AIDS) or human immunodeficiency virus (HIV)-related disease who lack satisfactory alternative therapies, while simultaneously ensuring that the adequate and well-controlled clinical trials essential to establishing a new drug's safety and effectiveness are expeditiously conducted.

EFFECTIVE DATE: June 15, 1992.

FOR FURTHER INFORMATION CONTACT: Philip L. Chao, Center for Drug Evaluation and Research (HFD-362), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-295-8049.

SUPPLEMENTARY INFORMATION:

I. Introduction

In the **Federal Register** of May 21, 1990 (55 FR 20856), PHS published a proposed policy to make promising new drugs more widely available to people with AIDS and other HIV-related diseases through nonconcurrently controlled studies. These studies would be conducted in parallel with controlled clinical trails; thus, the policy became known as the "parallel track" policy. Published elsewhere in this issue of the **Federal Register** is a notice issued by PHS announcing a final policy.

The parallel track policy has the potential to provide investigational new drugs to large numbers of patients with HIV-related diseases at an early stage during drug development. To help ensure that patients are adequately protected and that safety and effectiveness information concerning experimental drugs can be developed, in the **Federal Register** of May 21, 1990 (55 FR 20802), FDA published a proposed rule that would amend its IND regulations. The amendments would permit FDA to place on clinical hold or to terminate studies that are not designed to be adequate and well-controlled, including nonconcurrently controlled studies. The current regulation gives FDA the authority to place a Phase 1, Phase 2, or Phase 3 study on clinical hold or terminate the study under specified grounds, such as exposure of subjects to unreasonable and significant risks, unqualified clinical investigators, and insufficient information in the IND to assess the risk to subjects. (See 21 CFR 312.42(b)(1) and (b)(2) and 312.44(b).) FDA published the proposed rule to add additional grounds for placing nonconcurrently controlled studies on clinical hold and terminating them.

II. Highlights of the Final Rule

This document finalizes the provisions that were contained in the proposed rule. In general, a nonconcurrently controlled study may be placed on clinical hold or terminated if certain conditions apply.

The amended regulation (21 CFR 312.42(b)) states that a study may be placed on hold for reasons specified in the current regulations. For a nonconcurrently controlled study in Phase 1, these conditions include the presence of an unreasonable and significant risk to the subjects, unqualified investigators, misleading or erroneous investigators' brochures, and insufficient information to assess risk. For Phase 2 and Phase 3 studies, a clinical hold may be imposed if any of the reasons for halting a Phase 1 study apply or if the study's plan or protocol is clearly deficient in its design. Under the amended regulation these grounds for clinical hold are applicable to nonconcurrently controlled studies, regardless of the "phase" designation.

In addition, under the revised regulation, a nonconcurrently controlled study may be placed on clinical hold if any of the following reasons apply:

(1) There is reasonable evidence that the nonconcurrently controlled study is impeding enrollment in, or interfering with, an adequate and well-controlled study of the same or another investigational drug;

(2) Insufficient quantities of the drug exist to conduct the adequate and well-controlled studies and the nonconcurrently controlled study;

(3) An adequate and well-controlled study strongly suggests that the drug is not effective;

(4) Another drug under investigation or approved for the same indication has shown a better potential benefit/risk balance;

(5) The drug is approved for the same indication in the same patient population;

(6) The drug's sponsor is not actively pursuing marketing approval with due diligence; or

(7) The Commissioner determines that conducting or continuing the nonconcurrently controlled study would not be in the public interest.

FDA ordinarily intends that clinical holds under (2), (3) and (5) listed above would apply only to additional enrollment in nonconcurrently controlled trials, rather than eliminating continued access to individuals already receiving the investigational drug.

FDA is finalizing these additional grounds for placing on hold or terminating a study that is not designed to be adequate and well-controlled. In response to comments seeking clarification of the relationship between parallel track or expanded access studies and treatment IND's, this rule also makes a minor clarification to §§ 312.34 and 312.35 (21 CFR 312.34 and 312.35) to make clearer that approval for a protocol must be obtained under §§ 312.34 and 312.35 if the criteria for §§ 312.34 and 312.35 are satisfied.

The amended regulation also provides that a study may be terminated if the sponsor fails to delay or suspend a study that has been placed on hold for any of the reasons specified in the amended regulation (21 CFR 312.44).

III. Comments on the Proposed Rule

FDA received six comments on the proposed rule. Most sought clarification on specific provisions or suggested minor changes to the proposed rule. Most of the comments focused on how this rule would affect parallel track studies. FDA notes that the responses to comments that address parallel track studies also apply to other nonconcurrently controlled studies.

1. Two comments asked FDA to clarify what constitutes "reasonable evidence" under proposed § 312.42(b)(4)(ii). The proposed rule would permit FDA to place a proposed or ongoing investigation that is not designed to be adequate and well-controlled on clinical hold if FDA found there is reasonable evidence the investigation that is not designed to be

adequate and well-controlled is impeding enrollment in, or otherwise interfering with the conduct or completion of, a study that is designed to be an adequate and well-controlled investigation of the same or another investigational drug.

The preamble to the proposed rule gave examples of the types of evidence FDA would examine to determine whether the conduct or completion of an adequate and well-controlled trial has been impeded. The preamble stated that FDA would examine whether enrollment in the adequate and well-controlled trial was proceeding at the expected rate and whether an adequate number of subjects were completing the trial (55 FR 20802 at 20803). An unexpectedly slow enrollment rate or an unusually high drop-out rate that is not attributable to adverse drug experiences generally would be considered as reasonable evidence that the nonconcurrently controlled study is interfering with the conduct or completion of the adequate and well-controlled study. There may be other reasonable evidence of interference, such as affirmative statements from patients or physicians that potential participants in controlled trials are choosing not to enroll in the controlled trials, but rather are choosing to gain access to the uncontrolled trials. The facts concerning each study would be examined to determine whether a clinical hold was warranted.

2. One comment suggested deleting the phrase "or another investigational drug" at the end of proposed § 312.42(b)(4)(ii). The comment claimed that imposing a clinical hold due to the effect on another drug being studied for the same use in the same population could act as a penalty against the firm conducting the nonconcurrently controlled study.

The Federal Food, Drug, and Cosmetic Act (the act) requires sponsors to demonstrate that a new drug is both safe and effective before it can be marketed (21 U.S.C. 355(a) and (b)). This must be done through the use of adequate and well-controlled clinical trials (21 U.S.C. 355(d)). Interference with controlled clinical trials impedes the accumulation of information that is crucial to the development of new therapies. The PHS policy statement on the parallel track mechanism recognizes this fact, and the policy states that "it would be critical that the sponsor work with participating physicians to assure that reasonable efforts are made to encourage persons to enter controlled clinical trials for which they are eligible" (55 FR 20856 at 20859).

To the extent a nonconcurrently controlled study impedes or interferes with the development of important safety and efficacy data in clinical studies, it is important that FDA have the authority to impose a clinical hold on such a study. This provision is not meant to penalize sponsors of nonconcurrently controlled studies. Rather, this provision is to help ensure that the primary objective of identifying the safety and effectiveness of drugs is met. Nonconcurrently controlled studies may interfere with adequate and well-controlled studies not only of the same drug but also of other drugs being studied for the same indication. FDA, therefore, disagrees with the comment.

3. One comment suggested that FDA develop a mechanism for "recognizing the efficacy of the agent using other methods than continuation of the planned prospective controlled clinical trial." The comment argued that the rule "would coerce participation in a controlled clinical trial and force some patients into control groups and deny them access to breakthrough therapy."

The comment seems to assume that the effectiveness of experimental drugs can be determined most rapidly through mechanisms other than controlled trials. FDA disagrees with this implicit assumption. Evidence demonstrating effectiveness can be developed most expeditiously through adequate and well-controlled studies. As discussed more fully in comment 2 above, interference with the controlled trials impedes approval of new drugs. Rather than denying patients access to "breakthrough therapy," controlled trials constitute the most expeditious way of determining that a new and more effective, or "breakthrough," therapy exists.

FDA's desire to prevent impediments to the drug development process is not intended to "coerce" patients into entering controlled clinical trials. Eligible patients are free to choose whether or not to participate in clinical trials. The agency's informed consent requirements are designed to permit patients to decide whether or not to enroll in studies based on adequate information about possible risks and benefits. Drugs being studied in clinical trials are by their very nature "investigational" and not yet proven to be safe and effective for the use under study. Study participants assigned to control groups, who often receive therapy of proven effectiveness, make a necessary contribution to the determination of whether the experimental therapy is in any way useful.

4. Two comments addressed proposed § 312.42(b)(4)(iii). The proposed rule would permit FDA to place a proposed or ongoing investigation that is not designed to be adequate and well-controlled on clinical hold if FDA found that insufficient quantities of the investigational drug exist to adequately conduct both the investigation that is not designed to be adequate and well-controlled and the investigations that are designed to be adequate and well-controlled. One comment asked who would determine whether drug supplies were insufficient to conduct the controlled clinical trial and the nonconcurrently controlled study. The second comment argued that sufficient quantities of the drug should be prepared and assigned to the nonconcurrently controlled study before that study is begun or else the rule would coerce patients into the controlled trial.

If a sponsor does not believe that it can produce sufficient quantities of the drug for the controlled studies as well as the nonconcurrently controlled study, it would not be appropriate for the sponsor to submit a protocol for the nonconcurrently controlled study. As discussed in the proposed parallel track policy statement (55 FR 20858), FDA generally will interact with sponsors in the development of a study protocol. This interaction should permit FDA to determine to some extent whether sufficient quantities of a drug exist or can be produced.

FDA disagrees with the second comment's assertion that sufficient quantities of a drug should be prepared and assigned to the parallel track or other nonconcurrently controlled study before it is begun. The sponsor's financial and manufacturing resources may not permit production of all of the product needed before the trials begin. Reasonable estimates of the amounts of drug needed for completion of the studies can be made, with allowance for changes as the studies progress. At the same time, a production schedule can be established to meet the estimated needs. Requiring production of the estimated quantities of drug before the studies can begin could delay completion of the studies considerably with no substantial benefit.

Allowing the studies to begin before the estimated quantities of drug are manufactured would not coerce patients into the controlled trials. In general, under the parallel track policy, patients are not eligible for enrollment in the nonconcurrently controlled trials unless they are ineligible or otherwise cannot participate in the controlled trials. If a patient enrolls in a parallel track study that is subsequently discontinued because of insufficient quantities of

drug, the patient would not, thereby, be forced into participation in the controlled trials.

5. One comment concerned proposed § 312.42(b)(4)(iv). The proposed rule would permit FDA to place a proposed or ongoing investigation that is not designed to be adequate and well-controlled on clinical hold if FDA found that the drug has been studied in one or more adequate and well-controlled investigations that strongly suggest lack of effectiveness. The comment recommended requiring "two or more adequate and well-controlled investigations" because, the comment explained, a single study is inadequate to tell whether a drug truly works. The comment stated that the provision would be satisfactory if FDA accepted one adequate and well-controlled study "to approve the drug in these situations."

As discussed in the parallel track policy statement, one reason for allowing expanded access to drugs during the early stages of investigation is that the available data show the drug to be promising. However, earlier availability of experimental drugs on a wide scale also exposes larger numbers of patients to greater uncertainties.

If data from one well-controlled study strongly suggest that the experimental drug lacks effectiveness, exposing larger numbers of patients to the uncertainties may no longer be justified. It does not follow that, because two adequate and well-controlled studies are required to approve a drug for marketing, therefore, two adequate and well-controlled studies should be required to place a nonconcurrently controlled study on hold. One adequate and well-controlled study may raise serious enough questions about the drug's risk/benefit potential to warrant discontinuing the nonconcurrently controlled study.

6. Proposed § 312.42(b)(4)(v) would permit FDA to place a proposed or ongoing investigation that is not designed to be adequate and well-controlled on clinical hold if FDA found that another drug under investigation or approved for the same indication and available to the same patient population has demonstrated a better potential benefit/risk balance. One comment suggested that, under proposed § 312.42 (b)(4)(iv) and (b)(4)(v), any information on effectiveness be provided to institutional review boards (IRB's), investigators, and subjects. The comment suggested a "decentralized" approach to the options concerning continuation of studies.

The current IND regulations require sponsors to keep each investigator informed of "new observations discovered by or reported to the sponsor on the drug, particularly with respect to adverse effects and safe use" (21 CFR 312.55(b)). A sponsor is also required to notify investigators and IRB's if it determines that an investigational drug presents an "unreasonable and significant risk to subjects" (21 CFR 312.56(d)). IRB's may then require that information be given to subjects if, in the IRB's judgment, "the information would meaningfully add to the protection of the rights and welfare of subjects" (21 CFR 56.109(b)). Furthermore, the informed consent regulations state that, where appropriate, subjects shall receive a "statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation * * *." (21 CFR 50.25(b)(5).)

FDA agrees with the comment's concern that information be shared with IRB's, investigators, and subjects; FDA notes that the existing requirements accomplish that goal. FDA also believes, however, that it may be appropriate for the agency to place on clinical hold a nonconcurrently controlled study, which may include subjects in many locations throughout the country. Section 312.42(b)(4)(iv) and (b)(4)(v) allows FDA to review risk/benefit analyses and to place studies on clinical hold without requiring individual IRB's, investigators, or subjects to review the information and make separate determinations before the study can be halted.

7. FDA received three comments on drug benefit/risk determinations under proposed § 312.42(b)(4)(v). The comments questioned whether a benefit/risk could be determined for investigational drugs at an early stage of drug development. One comment suggested deleting the provision entirely, while a second comment asked what type of evidence would be sufficient to show that "unreasonable and significant risks" existed. Another comment challenged FDA's authority to impose a clinical hold under such circumstances, claimed that the rule would "prioritize" pharmaceutical development, and declared that FDA cannot control or terminate investigational studies based on the perceived merits of another drug product.

The preamble to the proposed rule recognized that benefit/risk determinations may be difficult to make at an early stage of drug development (55 FR 20802 at 20803 and 20804). The preamble stated that "such [benefit/risk] judgments based on as much information as is available are appropriate in determining whether expanded access should be continued," and that evidence of "relative toxicity or effectiveness" would be examined. Id. (emphasis added). FDA agrees with the comments that benefit/risk determinations may be difficult for investigational new drugs. FDA does not, however, agree that this difficulty justifies deleting the provision. If is not possible to describe the precise risks that may be viewed as unacceptable in light of the perceived benefits in a general regulation. The circumstances of each experimental drug must be considered in judging whether a study should be allowed to continue.

FDA believes that it has clear statutory authority to promulgate these clinical hold regulations. Section 505(i) of the act (21 U.S.C. 355(i)) specifically authorizes the promulgation of regulations governing the investigational use of new drugs. Such regulations may establish "conditions relating to the protection of the public health." New § 312.42(b)(4)(v) is intended to protect the public health by providing explicit clinical hold authorization when the continued use of a drug in an uncontrolled trial is not warranted because of the potential benefit/risk balance.

As for the comment that placing a study on clinical hold based on an unfavorable benefit/risk assessment is akin to denying approval of a new drug solely because the drug is not as effective as an already approved drug, the agency does not agree that these are analogous circumstances. There is an analogy, however, between benefit/risk determinations in the new drug application context and in the IND context. The agency may deny approval of a new drug product based upon an unfavorable benefit/risk assessment; similarly, the agency may place an uncontrolled trial of an investigational drug on clinical hold based upon such an unfavorable assessment. Uncontrolled trials can mean that large numbers of patients are exposed to investigational new drugs at early stages of drug development. Although such trials can provide useful information on the safety of the drug, uncontrolled trials cannot in themselves generate sufficient information on the drug's safety and effectiveness to make a determination on whether the drug should be approved. Exposing participants in uncontrolled trials to an investigational drug when the risk/benefit assessment indicates that such exposure is unwarranted would be contrary to the interests of the public health. Nothing in the statute prohibits

the agency from protecting the public health against unwarranted investigational uses in this manner.

FDA also does not believe that clinical holds based upon unfavorable benefit/risk assessments impermissibly "prioritize" pharmaceutical development. In accordance with sponsors' support, appropriate studies of all investigational drugs with acceptable benefit/risk balances may continue as rapidly as possible. That is, putting a protocol for an uncontrolled trial on clinical hold does not mean that ongoing controlled trials are also put on hold. The controlled trials, which would provide the primary basis for an ultimate determination on the drug's approvability, would continue unless indepenedent reasons existed to discontinue the controlled trials.

8. Two comments objected to proposed § 312.42(b)(4)(vi). The proposed rule would permit FDA to place a proposed or ongoing investigation that is not designed to be adequate and well-controlled on clinical hold if FDA found that the drug has received marketing approval for the same indication in the same patient population. One comment stated that the provision was unnecessary because a parallel track study will not affect a drug's availability and could generate safety data. The second comment argued that the provision would limit access to drug products because subjects would be obliged to purchase the approved drug to continue treatment. The comment suggested giving subjects the option to continue their participation in the parallel track study so sponsors would be compelled to "price their approved drug in a manner which will recruit patients from parallel track investigations."

As discussed in the preamble to the proposed rule (55 FR 20802 at 20804), if a competing version of the same drug itself has received marketing approval for use in the same population for the same indication, there is no longer adequate justification for expanded availability. Under these circumstances, another product will have been demonstrated to be safe and effective and approved for distribution.

FDA does not believe that it would be appropriate to use its authority over investigational products to try to force manufacturers to modify prices of approved drugs. Issues of drug affordability are more appropriately dealt with under other statutes implemented by other agencies.

9. One comment asked FDA to define "due diligence" under proposed § 312.42(b)(4)(vii). The proposed rule would permit FDA to place a proposed or ongoing investigation that is not designed to be adequate and well-controlled on clinical hold if FDA found that the sponsor is not actively pursuing marketing approval of the investigational drug with "due diligence."

"Due diligence," for purposes of this regulation, denotes a good faith effort to pursue drug development and marketing approval in a timely manner. The term "due diligence" was discussed in the preamble to the treatment IND final rule (52 FR 19466 at 19470 and 19471, May 22, 1987). Similar considerations would apply in the context of nonconcurrently controlled studies under § 312.42(b)(4)(vii).

10. Proposed § 312.42(b)(4)(viii), would permit FDA to place a proposed or ongoing investigation that is not designed to be adequate and well-controlled on clinical hold if the Commissioner determined that it would not be in the public interest for the study to be conducted. One comment objected to this provision because it would give the Commissioner "carte blanche extermination rights." The comment suggested revising the rule to provide examples of instances where the public interest would justify a clinical hold.

As stated in the preamble to the proposed rule, the provision giving the Commissioner the authority to impose a clinical hold, if it would be in the public interest, is designed to be flexible (55 FR 20802 at 20804). Experience with other regulations has shown that it is extremely difficult to illustrate comprehensively how a regulation would be employed. Even short lists of examples are often misconstrued as being exhaustive. This difficulty is especially true here because the public interest in imposing a clinical hold can stem from a number of sources, such as questions concerning a drug's manufacture, storage, and distribution or inspections involving the manufacturer, physician, clinical investigator, or IRB.

Furthermore, the rule does not give the Commissioner arbitrary authority to terminate a noncurrently controlled study. The clinical hold regulation states that FDA will, unless patients are exposed to immediate and serious risk, attempt to discuss and resolve matters with the sponsor before issuing a clinical hold order (21 CFR 312.42(c)). If a sponsor disagrees with the reasons cited for a clinical hold, the sponsor may request reconsideration in accordance with the dispute resolution provisions at 21 CFR 312.48. (See 21 CFR 312.42(f).) These and other procedural regulations in 21 CFR part 312 provide for notice to sponsors of deficiencies or problems and give sponsors an opportunity to correct those problems or to respond to the notice.

11. FDA also received several comments on the parallel track policy. Some comments, such as those suggesting that the parallel track policy consider a subject's economic status or provide financial incentives to sponsors, are outside the scope of this regulation and FDA's authority. Other comments asked how the policy would affect other FDA requirements. One comment asked FDA to "streamline" paperwork requirements for investigators.

FDA declines to accept the comment to the extent it asks for the elimination of recordkeeping and reporting requirements. As noted in the final policy on parallel track, the system for data collection should be specified in the parallel track protocol and should be efficient and not unnecessarily burdensome. The recordkeeping and reporting requirements for investigators under 21 CFR part 312 help FDA determine that investigational new drugs are properly distributed and administered and that adverse effects are promptly reported. Such information is particularly important for investigational new drugs that are used during early stages of drug development.

12. One comment asked whether FDA would apply the treatment IND requirements at Phase 2 and parallel track requirements at Phase 1.

Neither the treatment IND nor the parallel track policy mechanism is restricted to drugs in a particular phase. Normally, however, evidence to support treatment IND's for drugs intended for use in a serious disease has been available during Phase 3 or after all clinical trials have been completed. In a number of appropriate circumstances, such evidence was available during Phase 2. For drugs intended for use in an immediately life-threatening disease, a treatment IND is possible before Phase 3, but ordinarily not before Phase 2 (21 CFR 312.34(a)). Under the parallel track mechanism, it is expected that most drug products will be in Phase 2 or Phase 3. (See 55 FR 20802.)

13. One comment asked whether a drug in the parallel track protocol qualified for expedited review. The comment stated that a drug's eligibility for the parallel track mechanism should be a priori evidence for receiving expedited review.

Expedited review is available for new drug, antibiotic, and biological products that are being studied for their safety and effectiveness in treating life-threatening or severely debilitating diseases. The expedited review

regulations define "life-threatening" diseases or conditions to be those where the "likelihood of death is high unless the course of the disease is interrupted" or those having "potentially fatal outcomes, where the end point of clinical trial analysis is survival" (21 CFR 312.81(a)(1) and (a)(2)). The regulation defines "severely debilitating" diseases as "diseases or conditions that cause major irreversible morbidity" (21 CFR 312.81(b)). Under these definitions, drugs in the parallel track mechanism would qualify for expedited review if the therapy is being studied in clinical trials designed to investigate whether the therapy increases survival or decreases irreversible morbidity.

14. One comment noted that the rule does not give sponsors any authority to restrict, modify, or suspend a parallel track study.

The clinical hold regulation only refers to FDA's ability to impose a clinical hold. Companies are free to decide whether they wish to participate in a parallel track study, and, as with adequate and well-controlled studies, can restrict, modify, or even terminate a parallel track study in accordance with 21 CFR part 312.

15. Several comments expressed confusion over the relationship between the parallel track studies covered by this rule and treatment IND studies, and whether the two types of studies overlapped. One comment stated its belief that parallel track protocols would be granted under the provisions of the treatment IND regulations. Other comments stated that it was unclear how the parallel track proposal differed from the treatment IND program, and urged FDA to clarify the distinction between parallel track protocols and treatment IND protocols.

FDA believes that it is appropriate to clarify that parallel track protocols will be granted under the criteria specified in the parallel track policy statement, not under the provisions of the treatment IND regulations, and that the two programs are not intended to overlap. In general, FDA may grant a request for a treatment protocol for a drug if the drug is for a serious or immediately life-threatening disease, and FDA finds that the criteria in § 312.34 are met. The parallel track policy statement applies at this time to nonconcurrently controlled safety studies of only drugs for HIV-related disease. FDA may permit a parallel track protocol to begin if it satisfies the criteria in the parallel track policy statement. If a drug for HIV-related disease meets the criteria for a treatment IND, then FDA will permit use under a treatment protocol; a parallel track protocol for the same drug for precisely the same indication in the same patient population would not be permitted to go forward because the treatment IND criteria would have been met. However, if the criteria for a treatment IND are not satisfied, but the criteria for a parallel track protocol have been met, then the parallel track protocol may go forward. To clarify further the regulatory distinction between parallel track and treatment IND protocols, FDA has amended §§ 312.34 and 312.35 to clarify that the approval for any protocol that meets the treatment IND criteria must occur under the provisions of §§ 312.34 and 312.35.

The concerns raised in discussion about the proposed parallel track policy statement provided the primary impetus for the proposed changes in the clinical hold and termination regulations. However, the same or similar concerns exist for nonconcurrently controlled studies that are not part of the parallel track mechanism. Consequently, the regulation providing additional grounds for clinical hold and termination was proposed to apply to "any study that is not designed to be adequate and well-controlled" (proposed § 312.42(b)(4)). Such studies would include not only parallel track studies, but also treatment IND protocols and other uncontrolled studies, even if the disease being studied is not HIV-related or is not serious or life-threatening. To make it clearer that the provisions of proposed § 312.42(b)(4) would apply to all uncontrolled studies, including treatment IND studies, the agency is adding new § 312.42(3)(iii) to specifically cross-reference § 312.42(b)(4) in the provision on clinical holds for treatment IND studies.

IV. Economic Impact

The agency has examined the economic impact of this rule and has determined that it does not require either a regulatory impact analysis, as specified in Executive Order 12291, or a regulatory flexibility analysis, as defined in the Regulatory Flexibility Act (Pub. L. 96–354). This rule amends the regulations governing investigational new drugs to provide additional grounds for placing an investigation on clinical hold and for terminating an IND.

These amendments are applicable where FDA permits promising investigational new drugs to be more widely available in nonconcurrently controlled trials during the same period that adequate and well-controlled studies on the same drugs for the same indication are being conducted. The rule provides necessary safeguards in connection with nonconcurrently controlled studies. This rule does not impose additional requirements on sponsors, nor does it require the expenditure of significant resources.

Accordingly, FDA concludes that the rule is not a major rule as defined in Executive Order 12291. Further, FDA certifies that the rule does not have a significant impact on a substantial number of small entities as defined in the Regulatory Flexibility Act.

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. Paperwork Reduction Act of 1980

This final rule does not contain new collection of information requirements. Section 312.44, which is amended by the rule, contains collection of information requirements that were previously submitted for review to the Director of the Office of Management and Budget (OMB) under section 3504 of the Paperwork Reduction Act of 1980 and approved under OMB control number 0910–0014.

List of Subjects in 21 CFR Part 312

Drugs, Exports, Imports, Investigations, Labeling, Medical research, Reporting and recordkeeping requirements, Safety.

Therefore, under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 312 is amended as follows:

PART 312—INVESTIGATIONAL NEW DRUG APPLICATION

1. The authority citation for 21 CFR part 312 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 505, 506, 507, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 357, 371); sec. 351 of the Public Health Service Act (42 U.S.C. 262).

2. Section 312.34 is amended in paragraph (a) by adding a new sentence at the end of the paragraph to read as follows:

§ 312.34 Treatment use of an investigational new drug.

(a) * * * If a protocol for an investigational drug meets the criteria of this section, the protocol is to be

submitted as a treatment protocol under the provisions of this section.

* * * * *

3. Section 312.35 is amended in paragraph (a) by revising the first sentence and by adding a new sentence after it, to read as follows:

§ 312.35 Submissions for treatment use.

(a) * * * Any sponsor of a clinical investigation of a drug who intends to sponsor a treatment use for the drug shall submit to FDA a treatment protocol under § 312.34 if the sponsor believes the criteria of § 312.34 are satisfied. If a protocol is not submitted under § 312.34, but FDA believes that the protocol should have been submitted under this section, FDA may deem the protocol to be submitted under § 312.34.

* * *

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4. Section 312.42 is amended by adding new paragraphs (b)(3)(iii) and (b)(4) to read as follows:

§ 312.42 Clinical holds and requests for modification.

* * * * *

(b) * * *

(3) * * *

(iii) FDA may place a proposed or ongoing treatment IND or treatment protocol on clinical hold if it finds that any of the conditions in paragraph (b)(4)(i) through (b)(4)(viii) of this section apply.

(4) *Clinical hold of any study that is not designed to be adequate and well-controlled.* FDA may place a proposed or ongoing investigation that is not designed to be adequate and well-controlled on clinical hold if it finds that:

(i) Any of the conditions in paragraph (b)(1) or (b)(2) of this section apply; or

(ii) There is reasonable evidence the investigation that is not designed to be adequate and well-controlled is impeding enrollment in, or otherwise interfering with the conduct or completion of, a study that is designed to be an adequate and well-controlled investigation of the same or another investigational drug; or

(iii) Insufficient quantities of the investigational drug exist to adequately conduct both the investigation that is not designed to be adequate and well-controlled and the investigations that are designed to be adequate and well-controlled; or

(iv) The drug has been studied in one or more adequate and well-controlled investigations that strongly suggest lack of effectiveness; or

(v) Another drug under investigation or approved for the same indication and available to the same patient population has demonstrated a better potential benefit/risk balance; or

(vi) The drug has received marketing approval for the same indication in the same patient population; or

(vii) The sponsor of the study that is designed to be an adequate and well-controlled investigation is not actively pursuing marketing approval of the investigational drug with due diligence; or

(viii) The Commissioner determines that it would not be in the public interest for the study to be conducted or continued. FDA ordinarily intends that clinical holds under paragraphs (b)(4)(ii), (b)(4)(iii) and (b)(4)(v) of this section would only apply to additional enrollment in nonconcurrently controlled trials rather than eliminating continued access to individuals already receiving the investigational drug.

* * * * *

5. Section 312.44 is amended by adding new paragraph (b)(1)(xi) and by revising paragraph (b)(2)(i) to read as follows:

§ 312.44 Termination.

* * * * *

(b) * * *

(1) * * *

(xi) The sponsor fails to delay a proposed investigation under the IND or to suspend an ongoing investigation that has been placed on clinical hold under § 312.42(b)(4).

(2) * * *

(i) Any of the conditions in paragraphs (b)(1)(i) through (b)(1)(xi) of this section apply; or

* * * * *

Dated: April 8, 1992.

David A. Kessler,

Commissioner, Food and Drug Administration.

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BILLING CODE 4160-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Expanded Availability of Investigational New Drugs Through a Parallel Track Mechanism for People With AIDS and Other HIV-Related Disease

AGENCY: Public Health Service, HHS.

ACTION: Notice Final Policy Statement.

SUMMARY: The Public Health Service (PHS) is announcing a final policy to make promising investigational drugs for AIDS and other HIV-related diseases more widely available under "parallel track" protocols while the controlled clinical trials essential to establish the safety and effectiveness of new drugs are carried out. The "parallel track" initiative establishes an administrative system designed to expand the availability of promising investigational agents and to make these agents more widely available to people with AIDS and other HIV-related diseases who have no therapeutic alternatives and who cannot participate in the controlled clinical trials.

FOR FURTHER INFORMATION CONTACT: Donald Pohl, Office of AIDS Coordination (HF-12), Food and Drug Administration/PHS 5600 Fishers Lane, Rockville, MD 20857, 301-443-0104.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of May 21, 1990 (55 FR 20856), the PHS published a proposed policy for the expanded availability of investigational new drugs through parallel track for people with HIV infection and AIDS. 1,210 comments were received; of these, 200 were unique while the other 1,010 were form letters.

As with the proposed policy, the final policy was developed by a PHS workgroup composed of representatives from the National Institutes of Health (NIH), the Food and Drug Administration (FDA), the Office of the General Counsel, and the National AIDS Program Office (NAPO), with significant input from community advocates, community physicians, clinical researchers, and industry representatives.

I. Comments

A. Expansion to Other Life-Threatening Diseases

Many comments supported the expansion of the parallel track mechanism to other life-threatening diseases. A number of comments stated that the policy as it applies to AIDS and other HIV-related disease should be evaluated before applying the policy to other diseases, while some comments supported immediate expansion to other diseases. Comments from individuals as well as manufacturers and professional associations expressed the view that the parallel track policy for AIDS and other HIV-related disease should serve as a pilot project to work out specific appropriate administrative procedures. Some individuals stated that a policy similar to parallel track for other life-threatening diseases should be developed only after consultation with advocates for patients with those other diseases.

A variety of regulatory mechanisms exists to make promising investigational agents more widely available for serious and life-threatening diseases.

These specific processes (such as the NIH AIDS Research Advisory Committee (ARAC) and the specific National Human Subjects Panel described below) are not applicable to other life-threatening diseases. This parallel track policy describes processes specifically for AIDS and other HIV-related diseases. However, PHS invites patient groups, physicians and sponsors interested in developing a similar process for other life-threatening diseases to work with PHS on issues concerning expanding the parallel track mechanism for other life-threatening diseases.

Currently, other mechnisms exist for making investigational drugs available prior to approval to persons with life-threatening diseases for which there is no satisfactory alternative therapy. Under the treatment IND procedures, eligible patients can have access to investigational drugs intended to treat serious or life-threatening diseases that meet established criteria. For cancer patients in particular, FDA and the National Cancer Institute (NCI) have described a special category of drugs, "Group C" drugs, which may be provided to eligible patients through protocols outside the controlled clinical trials prior to approval. In many instances it appears these mechanisms adequately address demand for early access.

PHS intends to evaluate the parallel track experiences specifically to determine whether worthwhile benefits are provided in addition to those available under mechanisms such as the treatment IND or Group C approaches. The evaluation would also include a consideration of whether parallel track has had detrimental effects on individuals or on the ability to determine the safety and effectiveness of promising therapies.

Even though a combination of safeguards has been built into this policy (including careful product selection, informed consent, patient and physician education, a national human subjects protections review panel, community involvement, and oversight), allowing increased availability of drugs prior to definitive evidence of either safety or efficacy carries potential risks for the participants.

B. NIH AIDS Research Advisory Committee (ARAC)

1. Role of the ARAC in Review of Drugs for Parallel Track

Some comments endorsed the proposed role of the AIDS Research Advisory Committee (ARAC) in reviewing sponsors' requests and in making recommendations regarding parallel track protocols. Other comments requested further clarification of the ARAC's role in the parallel track process. Two comments stated that sponsors should not have the option of bypassing ARAC review.

As outlined in the policy, IND sponsors will submit parallel track proposals to FDA as amendments to existing INDs. The sponsor may be the manufacturer of the drug or another organization conducting drug trials. Unless the sponsor objects, FDA will refer the parallel track proposal to the ARAC for consideration. Requests for ARAC review will be processed and scheduled by National Institute for Allergy and Infectious Diseases (NIAID) Committee staff. After review of the proposal, the ARAC will make a recommendation to the Director, NIAID. The Director of NIAID will then forward a recommendation through the Director of NIH to the FDA Commissioner.

In this process, the ARAC serves as an expert advisory panel composed of persons with HIV-related disease, physicians, non-government scientists, and representatives of activist organizations. In addition to reviewing and making recommendations on parallel track proposals generated by IND sponsors, the ARAC may make recommendations, based upon available evidence, concerning termination of parallel track protocols. While the ARAC plays a vital role in the review of parallel track protocols, the policy will still allow sponsors to request that their protocols not be reviewed by the ARAC.

2. Non-Sponsor Requests for ARAC Consideration

A number of comments stated that in addition to sponsors, any interested person should be able to petition the

ARAC to consider the appropriateness of parallel track protocols for specific drug products.

An entity which is authorized to distribute the drug, which has access to all data necessary to support an IND, and which is willing and able to carry out the responsibilities of the sponsor of an investigational new drug application is necessary for the initiation of a parallel track protocol. As discussed in the proposed policy statement, deliberations about whether or not a specific drug is appropriate for parallel track study can best be accomplished through the review of a detailed parallel track protocol in conjunction with the controlled clinical trials protocols for that same drug.

Information needed to evaluate the benefits and risks of a drug is ordinarily information that is proprietary to the drug manufacturer. Unless the sponsor of an investigational drug indicates a willingness to provide the necessary information and to conduct a parallel track study, the ARAC would be frustrated in its attempt to review a drug for appropriateness for parallel track availability.

The NIH, as part of its research mandate, has a public responsibility to ensure that research showing high promise is pursued and supported. Therefore, the NIH can be requested to take on the obligation of developing a drug lacking private sector sponsorship, and in that role also assume any responsibilities for implementing a parallel track program. The decision to assume these obligations would, of course, be guided by the available resources and competing needs for those resources. The ARAC, which has programmatic advisory responsibilities for NIAID, might be consulted in such decisions.

There may be extraordinary circumstances in which a non-sponsor has sufficient information about the drug and its potential usefulness for the intended patient population and condition to be treated, and about the clinical trials to permit meaningful review of a parallel track proposal. In such circumstances, the non-sponsor could request NIAID to refer the matter to the ARAC for review and recommendation. If NIAID determined that a meaningful review and recommendation could be accomplished, it could refer the matter for ARAC consideration. Because PHS expects that such circumstances would be rare, the policy statement has not been amended to refer specifically to such requests by non-sponsors.

3. ARAC's Role in Defining "Standard Treatment"

A number of comments stated that the ARAC should have the authority to define "standard treatment" as applied to the eligibility criteria for each parallel track protocol. The ARAC may make recommendations with respect to any aspect of a proposed parallel track protocol, including the section dealing with eligibility criteria. The ARAC may review the description of standard treatment, as well as the descriptions of when it will be considered that standard treatment "cannot be tolerated" or is "no longer effective".

As with the other aspects of approval for parallel track protocols, FDA has the authority to make the final determination on the acceptability of the eligibility criteria in the protocol. In making determinations regarding parallel track protocols, FDA will consider the ARAC's recommendations on each issue. Further discussion of "standard treatment" appears below, at F. "Eligibility Criteria." Even when a sponsor elects not to have ARAC review, FDA may elect to consult ARAC on the appropriateness of the description of standard therapy.

4. ARAC as the Interim National Human Subjects Protections Review Panel (National Human Subjects Panel)

Several comments raised concerns about the proposal to have an ad hoc subcommittee of the ARAC function as an interim national human subjects protections review panel. PHS has determined that it would be more appropriate to have the AIDS Program Advisory Committee (APAC) at NIH serve as this interim panel. The comments regarding this interim group and other institutional review board (IRB) issues are described more fully below under M. "Human Subjects Protections."

C. Review Criteria

Some comments criticized the proposed parallel track review criteria and process as overly complex and likely to delay access to experimental treatments. One comment stated that the ambiguity of the criteria makes it difficult to assess the potential impact of the policy on drug availability. The proposed policy statement listed eight categories of information that the FDA and the ARAC would ordinarily consider in reviewing a proposal to make an investigational drug available through a parallel track protocol. In general, PHS believes that this is the minimum information needed to enable the decision makers to assess potential risks and benefits to the recipients of the drug in parallel track studies and the potential effect on the controlled trials.

Unless the information specified for review is available, PHS does not believe that it would have sufficient information to justify exposing large numbers of subjects to the investigational drug through parallel track protocols. By enumerating the kinds of information to be provided, PHS believes that a sponsor can more readily prepare an acceptable parallel track proposal, which the FDA and the ARAC can review without delays to request additional needed information. If adequate, the expanded access studies can be permitted to go forward expeditiously.

The policy statement describes in general terms the kinds of information needed to support a parallel track proposal; it allows flexibility and room for appropriate adaptation to the unique circumstances of particular drugs or patient populations. Involving the FDA, the NIH, and the ARAC in the review process is intended to provide a variety of expert opinions on the merits of a parallel track proposal. PHS believes that the procedures provide a reasonable approach to dealing with the complexities of expanded access and should not result in any undue delay in drug availability.

D. Impact of Parallel Track on Clinical Trials

Some comments suggested that parallel track studies should be delayed for a period of time to allow for Phase 2 controlled trial accrual. One comment stated that the controlled trial enrollment should be completed before a drug is made available through parallel track. Others expressed the view that individuals enrolled in expanded access trials were ineligible for controlled trials, and the low accrual rates in controlled trials were due instead to overly restrictive enrollment criteria.

The proposed policy statement indicated that Phase 2 controlled clinical trial protocols are to be approved by the FDA and patient enrollment initiated prior to or simultaneously with release of drugs for expanded availability under the parallel track protocol. As discussed in the proposed policy statement, PHS recognizes that well controlled clinical trials are crucial to establishing the safety and effectiveness of new treatments. It is therefore extremely important that the parallel track studies not delay or compromise the controlled trials to support product approval.

The combination of specific enrollment criteria and the timing of beginning enrollment in the controlled trials and the parallel track studies should adequately prevent the parallel track studies from having a detrimental effect on the controlled trials. As some of the comments pointed out, patients are not eligible for parallel track protocols unless they cannot participate in the controlled trials. Once the controlled clinical trials have been approved, the eligibility criteria for those trials are clear. If the eligibility criteria for the parallel track protocol are honored, the start of accrual in the parallel track protocols should not interfere with accrual in the controlled trials. PHS recognizes, however, that if physicians enroll patients in the parallel track protocol who are in fact eligible for a controlled trial, accrual in the controlled trials may be adversely affected. PHS will consider methods of monitoring parallel track enrollment to determine whether eligibility criteria are being followed.

PHS believes that it is important that patient enrollment in the controlled trials be initiated prior to or simultaneously with release of drug for expanded availability under a parallel track protocol. PHS does not believe that it is necessary to require that the enrollment in the controlled trials be completed before beginning accrual in the parallel track protocols. Accrual in large studies can take many months or longer before complete enrollment; in the absence of extraordinary circumstances, such a delay in beginning studies with different eligibility criteria would not be appropriate. In some situations it may be appropriate for accrual in the controlled trial to have already begun before initiating the expanded access trials. Such determinations should be made based upon the circumstances of the particular drug patient population.

Regardless of when accrual in the controlled trial begins, if there is evidence that the parallel track study is interfering with the successful enrollment in, and completion of, the controlled trials, FDA may terminate the parallel track study. (See discussion below at 0. "Terminating Protocols.") In addition, PHS is prepared to appropriately revise this policy if a more systematic interference of controlled trials becomes obvious.

E. Protocol Development

A number of comments asked for assurance that there would be input from people with AIDS, the FDA, the ARAC, community physicians, the primary care physicians in the design of parallel track protocols. One comment requested that specific criteria for the design of protocols be required.

As discussed in the proposed policy statement, FDA regulations set forth the general elements required to be contained in protocols for studies of investigational drugs (21 CFR 312.23(a)(6)). The sponsor would develop the protocol, which is then reviewed by others, including the ARAC, under parallel track procedures. Representation of people with HIV disease and community and primary care physicians on the ARAC provides one opportunity for input of theses groups in the development of the protocol design. The FDA will review the design of the protocol as part of determining the acceptability of the sponsor's parallel track submission . Sponsors of parallel track studies who desire waiver of local IRB review under 21 CFR parts 56 and 45. CFR part 46 may include such requests in their submissions.

F. Eligibility Criteria

1. Patient's Inability To Take Standard Treatment

Several comments stated that the non-response to Zidovudine (ZDV/AZT) or Dideoxyinosine (ddI) as well as intolerance should establish eligibility of a patient for a parallel track study. Similarly, a number of comments stated that a drug available under a treatment IND should not be considered "standard treatment" for purposes of the parallel track eligibility criteria. Conversely, another comment stated that a patient should be intolerant of AZT or geographically distant from clinical trials to qualify for parallel track.

A basic premise regarding drugs under consideration for parallel track protocols is that there is not yet sufficient evidence of the drug's safety and effectiveness to support approving the drug for marketing.

Because of the increased uncertainties as to a product's safety and effectiveness when drugs are made available at such an early stage of the development of safety and effectiveness information, it is appropriate that enrollment in parallel track studies be limited to those patients who cannot take therapies already shown to have acceptable benefit/risk ratios. Approved products have been found to have acceptable benefit/risk ratios for labeled indications based upon adequate and well-controlled studies as well as other available information. PHS believes that in most circumstances it will be clear that the available information supports the conclusion that only patients who cannot take or do not respond to either an approved drug or one available under a treatment IND, for the same clinical condition for which the parallel track investigational drug is being studied, should be eligible for the parallel track protocol.

Nevertheless, PHS also believes that those preparing and reviewing the proposed protocol should have flexibility in determining what constitutes standard treatment for the particular condition and patient population identified in the proposed parallel track study, in order to take into account unique circumstances. To allow the determination to be made on a case-by-case basis, PHS has removed from the policy statement the parenthetical phrase defining standard therapy as "a drug approved for marketing or available under a treatment IND for the same clinical condition for which the investigational drug is being studied." PHS expects that in many circumstances standard treatment would include both approved drugs and drugs available under a treatment IND. With regard to the eligibility of those patients who do not respond to standard therapy or drugs available under treatment IND, this determination will also be made on a protocol specific basis. For many protocols, the criterion of "the patient cannot take standard treatment because it is . . . no longer effective" will most likely include circumstances under which the drug was never effective.

2. Patient's Health Status

A number of comments expressed concern that people who are HIV-positive and asymptomatic should have access to experimental therapies before they become clinically ill.

The proposed policy statement included as a criterion of patient eligibility that the patient have clinically significant HIV-related illness or be at imminent health risk due to HIV-related immunodeficiency. HIV-positive individuals who are not manifesting clinical symptoms may still be at imminent risk because of their immune status. Such individuals may be eligible for appropriate parallel track protocols.

Each parallel track protocol will identify the intended patient population, as well as the condition being studied. The parallel track policy permits submission and acceptance of appropriate protocols for studies of asymptomatic individuals at imminent health risk due to HIV-related immunodeficiency.

3. Access to Parallel Track Studies for Underserved Populations

A number of comments expressed concern that parallel track studies be accessible to underserved populations, especially women and minorities. Others also raised questions about the eligibility of those who cannot afford standard therapy to participate in parallel track studies.

The eligibility criteria for a parallel track protocol should not arbitrarily exclude specific patient populations without adequate scientific justification. The question of access to parallel track studies for all eligible patients who wish to participate can be addressed to some extent through educational programs. The educational program, which is to be addressed in each protocol, includes education of physicians, patients, IRBs, community-based health institutions, community and migrant health centers, the general public, and affected communities. Educational initiatives in community health centers and drug treatment centers, as well as in such programs as the AIDS Clinical Trails Groups (ACTG) and the Community Program for Clinical Research on AIDS (CPCRA), should facilitate enrollment from all eligible groups.

Involvement of community physicians and community-based programs should help to provide access to parallel track studies for traditionally underserved populations. The system for collecting and reporting data should be efficient and not unnecessarily burdensome to encourage community physician participation (see "Patient Data" section).

PHS believes that economic status is not an appropriate criterion for enrollment in clinical trials and that economic issues should be addressed through other means. However, PHS recognizes that economic problems impede access to therapy for low-income patients. There are public health care programs, not within the purview of PHS, established to make approved drugs available to those patients who need the drugs but cannot afford to pay for them. A further discussion of cost issues related to parallel track studies appears below at L. "Economic Concerns."

G. Geographic Concerns

Most of those who commented on geographic concerns stated that a benefit of parallel track would be to make therapies available outside of urban centers. One comment stated that the geographic dispersion of patients in parallel track protocols might compromise the value of the data collected. Another comment stated that expanded access should be restricted to a limited number of patient subsets—including those denied access to clinical trials due to geographic location.

Parallel track studies are intended to provide access to promising investigational drugs for patients who cannot participate in the controlled trials while generating data on the safety and effectiveness of the drug. The proposed policy statement included undue hardship among the reasons for inability to participate in the controlled trials and defined undue hardship as including excessive travel time to the study site.

PHS recognizes that the geographical dispersion of the clinical investigators can create some difficulties in collecting the data from parallel track trials. However, all participating physicians will be required to report data as specified in the protocol, and the sponsor will be responsible for gathering and organizing the data. Appropriate design and conduct of the data collection process should minimize the problems created by geographical dispersion. Additional concerns about data collection are discussed below at I. "Patient Data."

Although PHS agrees that parallel track studies should be available for those who cannot participate in controlled trials because of geographical distance, PHS does not believe that parallel track studies should be restricted by geographic location. For example, patients who live near the location of a controlled trial site may be ineligible to participate in the controlled trials for other reasons. They may not meet the entry criteria, they may be too sick, or the controlled trials may be fully enrolled. PHS believes that these patients should not be excluded from parallel track studies solely because of geographic proximity to the study site of the controlled trials.

H. Physician Criteria

Some comments addressed the qualifications for physicians who participate in parallel track studies. Of these comments, some stated that participating "physicians" should include physician groups, clinics, and community-based health care facilities because many patients have no primary physician. Other comments raised questions about the training of physicians, specific minimum qualifications, and incentives for physicians to participate.

As discussed in the proposed policy statement, physicians administering investigational drugs under parallel track protocols become clinical investigators subject to all the obligations and responsibilities of investigators. The protocol should specify the minimum qualifications for participating physicians and the process by which a physician may be accepted by the sponsor as a clinical investigator under the expanded availability protocol.

Physician groups, clinics, and other community-based facilities are eligible if they meet the specified qualifications. The data collection and reporting procedures, as well as the education and training programs, for participating physicians should be designed to ensure an adequate and appropriate study without creating unnecessary burdens or disincentives for the physicians. The opportunity to provide a treatment option for patients who cannot participate in the controlled trials or take standard therapy should be a significant incentive for physicians to participate in parallel track studies.

I. Patient Data

The comments identified a number of concerns regarding data collection, including the need for well-defined data collection requirements and a cost efficient, time efficient, uncomplicated data collection system. Some comments urged permitting community research groups to collect data on effectiveness as well as safety. Other comments raised concerns about the confounding of results due to patient noncompliance with protocols and difficulty analyzing data without control group study designs. Some comments requested that FDA consider data generated in parallel track studies in granting marketing approval. In addition, questions were raised about who will pay for the cost of data collection, who will analyze the data, and what incentives exist for physicians to submit data.

PHS agrees that well-defined data collection requirements should be specified in the parallel track protocol. The system for collecting and reporting data should be efficient and not unnecessarily burdensome for the participating physicians. All participating physicians will be required to report safety data.

PHS agrees that parallel track protocols may appropriately provide for community research groups or other specified investigators to collect data on effectiveness as well as safety. The nature and extent of effectiveness data collection may vary in different clinical settings.

The sponsor will analyze the parallel track data and report the results to FDA under the IND. Ongoing review of available data will be provided by a

Data and Safety Monitoring Board or its equivalent established by the sponsor. In general, the sponsor will be responsible for the costs of the parallel track protocol. Economic considerations are discussed more fully below at L. "Economic Concerns."

PHS also agrees that the interpretation of data from uncontrolled studies can be difficult. As with all clinical trials, it is important that participating patients comply with the protocols to produce reliable and interpretable data. Data from the parallel track studies can be included in any submission for marketing approval made by the sponsor. Such data may provide corroborating information; however, data from adequate and well-controlled studies demonstrating effectiveness and from all reasonably applicable studies demonstrating safety are required, by law, for marketing approval.

J. Monitoring

A number of comments stated that monitoring the parallel track studies for both safety and effectiveness was desirable, but may not be possible. These comments urged that monitoring for safety information should be given a higher priority. Some comments also argued that appropriate training and adequate informed consent procedures should help to provide quality control for the studies.

As previously stated, all participating physicians will be required to provide safety data from their patients enrolled in parallel track protocols. Each protocol will provide a specific monitoring system, which will include the establishment of a Data and Safety Monitoring Board (DSMB) or its equivalent. The DSMB, or its equivalent, will monitor the studies and gather information from all studies in which the investigational drug is being tested. As the information accumulates, it will be used to update the informed consent document or to take other appropriate action, including terminating the study.

PHS also intends that the ARAC and others periodically review the parallel track program as a whole to help assess its benefits and potential or possible detrimental effects.

K. Education and Information

Some comments called for more specific language in the policy statement outlining what is required of parallel track proposal sponsors in developing an education program. The comments agreed that the success of parallel track will depend on the education of physicians and other caregivers on management of HIV disease, parallel track drugs, conduct of trials, and data collection, as well as on the education of the public and people with HIV-related disease concerning available treatment options.

PHS agrees that the education program accompanying a parallel track study is extremely important. Because of the varieties of potential investigational drugs, patient populations, caregivers, and conditions to be treated, it is not feasible to try to specify the details of an education program applicable to every protocol. In general, each program should be designed to adequately educate patients, physicians and other caregivers, IRBs, affected communities, and the general public. It is extremely important that participating physicians and potential recipients have sufficient knowledge of the potential risks and benefits of the parallel track drug, as well as, the risks and benefits of other treatment options.

The sponsor will be required to specify in the parallel track protocol the particular educational program for the investigational drug to be administered under the protocol. FDA will review the description of the educational program as part of the determination of acceptability of the protocol as a whole. Ordinarily, the ARAC will also review and make recommendations concerning this portion of the protocol, as well as others.

Other institutions, including the Health Resources and Service Administration (HRSA), FDA, NIH, manufacturers, and professional organizations will collaborate in disseminating information and providing general training and education concerning HIV-related disease and the parallel track policy.

L. Economic Concerns

Many comments addressed the issue of access to health care, and the affordability of therapies for underserved populations. Some comments stated that the success of parallel track will depend on providing therapies to the uninsured and the underinsured. Other comments stated that there should be third-party reimbursement for parallel track studies.

Several comments expressed concern about the costs to drug manufacturers participating in parallel track. The concerns raised included the costs of increased production of the drug for parallel track use without the guarantee of approval, as well as insurance and other potential product liability costs. Questions were raised about eligibility for cost recovery under parallel track protocols. One comment asked that eligibility of a drug for parallel track be sufficient for the drug to receive review under FDA's expedited review procedures.

Although not within its purview, PHS recognizes the importance of the reimbursement issues concerning experimental therapies and reaffirms its commitment to help facilitate consideration of these issues.

PHS also recognizes that there can be significant costs to manufacturers in sponsoring or participating in parallel track studies. However, PHS has no control over manufacturers' costs, such as insurance costs, or potential product liability exposure. IND sponsors are ordinarily not permitted to charge for investigational drugs. However, under 21 CFR 312.7, sponsors may request approval from FDA for charging based upon an explanation of why charging is necessary to undertake or continue the study. As with other clinical trials, sponsors of parallel track studies may make requests under this provision. Even if such approval is obtained, under no circumstances may a sponsor commercialize a product by charging more than needed for cost recovery.

A drug cannot be approved for marketing without evidence from adequate and well-controlled studies demonstrating effectiveness and all reasonably applicable studies demonstrating safety, acceptance of a parallel track protocol does not represent any guarantee that the drug will ultimately be approved for marketing. However, FDA's expedited review procedures, described in subpart E of 21 CFR part 312, are applicable to new drug, antibiotic, and biological products that are being studied for their safety and effectiveness in treating life-threatening or severely debilitating diseases. Parallel track therapies, like other therapies being studied for the treatment of HIV-related diseases, will be eligible for FDA's expedited review procedures, if the therapy is being studied in clinical trials designed to investigate whether the therapy increases survival or decreases irreversible morbidity. The FDA gives AIDS-related drugs the highest priority review and encourages IND sponsors to consult with the agency as early as possible in the drug development process.

M. Human Subjects Protections

1. Need for Local IRB Review

Some comments suggested that local IRB review of parallel track protocols should not be waived under 21 CFR part 56 or 45 CFR part 46. Some comments supported the concept of giving the local

IRB jurisdiction over trials in their area, while a national human subjects protections review panel (national human subjects panel) would establish guidelines and protocols and have general oversight responsibilities for parallel track. Others argued that a national panel would simply duplicate the work of the local board, resulting in delay of initiation of studies, confusion over authority, and additional costs. The benefits of local IRB review were cited as the following:

(1) Having established relationships with local investigators and physicians;

(2) Having knowledge of state and local laws and requirements;

(3) Having access to local knowledge and expertise; and

(4) Being able to satisfy the requirement of many institutions that local IRBs review all research involving human subjects conducted by their physicians, faculty members, and other investigators.

As noted in the proposed policy statement, even if the requirement for local IRB review is waived, local IRBs would continue to have the option of reviewing expanded availability protocols. PHS recognizes the benefits of local IRB review, and reaffirms its position that such review is ordinarily most appropriate. However, as noted in the policy discussing the HHS regulations, in the context of parallel track protocols, loal IRB review and a written assurance of compliance is generally not practical for many reasons:

(1) Local review could slow the dissemination of drugs under parallel track policies and procedures;

(2) Local review could be made without sufficient information on which to base a recommendation;

(3) Local review could result in considerable delays if physicians are required to form their own IRBs; and

(4) Local review might place IRBs in a situation in which it is difficult to monitor activities of physicians for whom they are not otherwise responsible.

Consequently, PHS continues to believe that a national human subjects panel can provide sufficient protection for patients in parallel track studies and that waiver of local review is generally appropriate.

The national human subjects panel should be composed of broad-based membership, including appropriate geographic, racial, ethnic, and gender representation. PHS does not believe that the national panel review would cause any additional delay, confusion, or cost. If a local IRB decides to review a protocol, the expert review, analysis, and guidance of the national human subjects panel would be helpful to the local panel in its review, which could be conducted more efficiently and expeditiously.

2. The Identity of the Interim National Panel

Some comments expressed concern that the ARAC should not function as the interim national human subjects panel. The comments argued that ARAC's main role in evaluating and making recommendations regarding therapies for parallel track conflicted with the role of an IRB; that ARAC members were selected for their scientific and medical expertise, and that IRB membership should be more broad based; and the ARAC would be overburdened with the additional responsibility.

PHS agrees with the comments that it would be more appropriate for the ARAC not to serve the additional function of the interim national human subjects panel. PHS has determined that the AIDS Program Advisory Committee (APAC), an advisory committee to NIH, should function as the focus of the national human subjects panel until a permanent body is established. The APAC has broad-based membership and familiarity with clinical research and, with respect to parallel track, will perform the function of human subjects protections review.

N. Informed Consent

A few comments stated that reaching traditionally underserved communities would require extensive informed consent, outreach, and on-going education. One comment expressed concern that the absence of standard therapy would cloud the judgment of individuals opting for parallel track. Another stated that even those individuals who can take standard therapy should be permitted to choose experimental treatment if fully informed of the risks. One comment also stated that the informed consent procedure for parallel track need only be altered slightly from the procedure currently used for controlled trials and treatment INDs. One group commented that a mechanism should be developed to enhance physician awareness of the importance of the informed consent process.

PHS emphasizes that adequate and appropriate informed consent procedures are fundamentally important to parallel track protocols. The informed consent document and the process for updating the document as information about the drug becomes available are intended to ensure that all subjects can understand the potential risks and benefits of the investigational drug and of other treatment options. The informed consent process should be presented in appropriate language to enable the individual patient to make an informed decision. It is crucial that participating physicians fully appreciate the importance of obtaining adequate informed consent. PHS agrees that the procedures currently used for controlled trials and treatment INDs can provide valuable guidance for developing informed consent procedures in the parallel track context. PHS does not agree that informed consent can completely substitute for the eligibility criteria set forth in the policy statement, which provide additional protection for individuals against uncertainties from drugs still in the early stages of development.

O. Terminating Protocols

A few comments on the policy statement discussed the criteria for terminating or curtailing a parallel track protocol. One comment agreed with the general concept, but suggested clarification of the criteria. Another comment expressed concern about terminating a protocol if it is determined that another product demonstrates a better potential balance of risks and benefits. That comment also questioned FDA's legal authority to terminate a drug study based on relative risks and benefits.

PHS continues to believe that it is important that parallel track protocols be terminated or curtailed if the circumstances set forth in the policy statement develop. The general criteria for termination are intended to protect individual subjects as well as to enable the contolled clinical trials essential to establish the safety and effectiveness of new drugs to be carried out.

A proposed regulation detailing the FDA's authority to terminate studies was published in the same issue of the Federal Register as the proposed policy statement (55 FR 20802). Comments relating to the substance of the criteria for termination and the FDA's legal authority are addressed in the preamble to the final regulation, published elsewhere in this issue of the Federal Register.

II. Final Statement of Policy

PHS is prepared to work with patient groups, physicans and sponsors on issues concerning the development of comparable mechanisms for other life-threatening diseases when there is significant support to do so. The final statement of PHS policy on expanded

availability of investigational new drugs through a parallel track mechanism for people with AIDS and HIV-related diseases follows:

Introduction

Through this notice, the Public Health Service is announcing a final policy under the Food, Drug and Cosmetic Act (the Act). The purpose of this policy is to permit promising investigational agents to be made available to people with AIDS and HIV-related diseases who are not able to take standard therapy, or for whom standard therapy is no longer effective, and who are not able to participate in ongoing controlled clinical trials. Through this policy, promising new drugs would be made available through studies without concurrent control groups to monitor drug safety that are conducted in parallel with the principal controlled clinical investigations (hence the name "parallel track").

This policy, developed by the Public Health Service with significant input from community advocates, industry representatives, the research community, and other interested members of the public, represents a further step in expanding availability of promising investigational drugs under the Act to those persons with AIDS and HIV-related diseases who are without satisfactory alternative therapy and who cannot participate in the controlled clinical trials. Because some investigational drugs for these conditions may be more widely available at a very early point in the drug development process, this procedure recognizes the need for participating physicians and their patients to consider what is and is not known about the risks and benefits of a variety of potential therapeutic agents when making clinical decisions.

Patients and physicians must recognize that products available under this procedure will be in the very early stages of product development and will only be made available to provide potential therapeutic options to those people with serious and life-threatening HIV-related disease who have no satisfactory alternative therapy. It must be clearly understood that the earlier availability of experimental treatments on a wide scale exposes larger number of patients to greater uncertainty and the risk of unforeseen and serious reactions.

There are many issues and problems related to providing potential therapies to individuals with HIV-related diseases. Although certain problems have been addressed in this document, others, in particular some that are not within the purview of the Public Health Service still require attention, but will not be discussed in this publication. For example, this policy does not deal with aspects of the health care system that can affect the availability and affordability of parallel track mechanisms to underserved groups. It also does not address the role of third-party payers in covering the costs of medical services associated with the use of parallel track drugs, nor does the policy address the liability of manufacturers sponsoring a parallel track drug. While the Public Health Service recognizes the importance of these issues, and will attempt to facilitate a broader consideration of them, they are beyond the scope of this policy.

In the development of this policy, it was recognized that well conducted clinical trials are crucial to the development of new treatments. While the goal of making promising investigational agents more widely available to persons with HIV infection and no therapeutic alternatives is an important one, controlled clinical trials that yield definitive information on the safety and effectiveness of investigational new drugs must continue. This policy includes sufficient safeguards and oversight to ensure that it neither delays nor compromises the controlled clinical trials.

Background

Normally, the development of a new experimental therapy proceeds through a systematic series of clinical trials that yield data growing from an initial understanding of appropriate dosing, side effects, and initial hints of efficacy, to a substantial body of definitive evidence of safety and effectiveness sufficient to support product marketing. This often lengthy approach is based upon well substantiated and widely accepted scientific and ethical principles and a mandate from society that protection of individuals from undue risks of experimental therapy is essential.

Although the AIDS epidemic has heightened interest in expanded access to investigational drugs, the issue is not new. Persons with life-threatening diseases for which no satisfactory alternative therapy is available have at times requested an investigational new drug prior to the drug's approval by the Food and Drug Administration (FDA). The issue has been dealt with by FDA in the past in both formal and informal ways. In the 1970's a number of large protocols were developed in which physicians, generally at academic referral centers, had access to investigational drugs for persons with serious or life threatening conditions who were without satisfactory alternative therapy. The drugs in these protocols were usually under active development in controlled trials and some of these protocols involved large numbers of patients. A similar mechanism was developed to provide investigational drugs to persons with cancer.

The FDA and National Cancer Institute (NCI) have described a special category of investigational drugs, "Group C" drugs, which may be provided by oncologists to appropriately chosen patients through protocols outside the controlled clinical trials prior to the drug's approval.

In 1987, FDA incorporated into a final regulation the treatment investigational new drug application (Treatment IND). Under a Treatment IND protocol, eligible patients have access to investigational drugs intended to treat serious or life-threatening diseases. A Treatment IND may be granted after sufficient data have been collected to show that the drug "may be effective" and does not have unreasonable risks, but before marketing approval has been granted. Treatment IND status has been granted for 18 investigational new drugs, 6 of these for AIDS-related conditions.

Under this policy, expanded availability protocols might be approved for promising investigational drugs when the evidence for effectiveness is less than that generally required for a Treatment IND. The expanded availability protocol may include one or more studies without concurrent control groups and may be accompanied by a Treatment IND protocol. All drugs distributed under the parallel track mechanism will be under a study protocol. Data, particularly pertaining to side effects and safety will be collected under these studies. However, most of the data essential for market approval will come from the controlled clinical trials.

As is the case for all investigational uses of drugs, FDA has authority for approving and monitoring the study protocols that are developed under this expanded availability policy. A regulation detailing the FDA's authority to terminate nonconcurrently controlled studies is published elsewhere in this issue of the **Federal Register.**

Selection of Investigational Therapeutic Agents for Expanded Availability Through Parallel Track

FDA encourages potential parallel track sponsors (as defined at 21 CFR 312.3(b)) to seek advice and information

from FDA and other scientists outside the agency as early, and as frequently as possible, during the pre-application process.

The FDA authority for the final decisions regarding which investigational agents will be placed in a program for expanded availability. Applications for experimental therapies to be considered for expanded access (parallel track) are to be submitted to FDA as amendments to existing INDs.

(1) FDA will refer all parallel track proposals to the AIDS Research Advisory Committee (ARAC), a committee chartered by the National Institute of Allergy and Infectious Diseases (NIAID) unless the sponsor indicates otherwise. This committee, composed of outside scientists and physicians experienced with AIDS, persons with HIV-related diseases, and others, will review the available data and make a recommendation to the Director of NIAID. After review, the Director of the NIAID will forward a recommendation, through the Director of the NIH, to the Commissioner of the FDA. In all cases, requests to be presented to the ARAC will be screened and scheduled by NIAID Committee Management Staff.

(2) If the sponsor prefers, the formal parallel track proposal can be submitted to the FDA for review without being forwarded to the ARAC.

Review Criteria

Ordinarly in reviewing a proposal to make an investigational drug available through a parallel track proposal, the ARAC Committee and FDA will consider whether there is:

1. Sufficient information showing:

a. Promising evidence of efficacy based on an assessment of all laboratory and clinical data;

b. Evidence that the investigational drug is reasonably safe, taking into consideration the intended use of the drug and the patient population for which this drug is intended; and

c. Sufficient data to recommend an appropriate starting dose.

2. Preliminary pharmacokinetic and dose-response data and, ideally, data about interactions with other drugs commonly used in the intended patient population.

3. Evidence of a lack of satisfactory alternative therapy for defined patient populations. In general, the investigational drug should meet a serious unfulfilled health need such that the potential benefits justify the considerable risks of very early expansion of use.

4. A description of the patient population to receive the drug under expanded access. Patient priority categories based on clinical condition should be determined if the drug may not be available in sufficient quantities to supply all of those who satisfy the basic eligibility criteria.

5. Assurance that the manufacturer is willing and able to produce sufficient amounts of the drug product for both the controlled clinical trials and the proposed expanded availability study.

6. A statement of the status of the controlled clinical trial protocols. Phase 2 controlled clinical trial protocols are to be approved by the FDA and patient enrollment initiated prior to or simultaneously with release of drugs for expanded availability under the parallel track protocol.

7. An assessment of the impact that the parallel track study may have on patient enrollment for the controlled clinical trials and a proposed plan for monitoring progress of the controlled trials.

8. Information describing the informational, educational and informed consent efforts that will be undertaken to ensure that participating physicians and potential recipients have sufficient knowledge of the potential risks and benefits of the investigational agent being studied in the parallel track process.

In general, deliberations about the advisability of expanded availability for a specific drug can be accomplished best during the review of a relatively detailed protocol for expanded availability in conjunction with the review of the protocols for the controlled clinical trials. While a detailed protocol is not required during the initial discussion stage, an outline of the proposed parallel track study should be provided.

Review and approval of a formal IND protocol is to be carried out by FDA, which may elect to involve one or more advisory committees in the review process. The FDA, through its existing regulations and procedures, may also discuss proposed protocols with appropriate consultants to the Agency.

A decision not to allow expanded availability of an investigational drug would not imply a judgement about a drug's ultimate safety or efficacy nor preclude additional controlled trials.

Protocol Development and Approval

The protocol for distribution and monitoring of an investigational drug under parallel track (expanded access protocol) is to be developed by the manufacturer or other sponsor. The FDA has regulatory authority for approval of the protocol and, in most cases, will interact with the sponsor during its development.

Elements to be contained in the expanded access protocol are to be the same as those for other protocols of investigational agents in clinical trials (21 CFR 312.23 part (a)(6)). Normally, a protocol submission for a parallel track study would include information about: The administration of the protocol; the sponsor's responsibilities under the protocol; patient selection criteria; phasing in of expanded use; physician selection for participation; dosage level and frequency; data reporting requirements and data collection forms; data monitoring procedures by the sponsor; physician and patient educational materials; patient consent documents; and criteria for terminating the protocol.

Eligibility Criteria for Patients To Receive Investigational New Drugs Through Parallel Track

Criteria for patient eligibility are to be included in each protocol for expanded availability. General principles for determining patient eligibility are described below. They are intended to provide flexibility as the specific criteria may vary for different agents and different clinical situations.

The determinants of patient eligibility include all of the following:

1. The patient has clinically significant HIV-related illness or is at imminent health risk due to HIV-related immunodeficiency.

2. The patient cannot participate in the controlled clinical trails because:

(a) The patient does not meet the entry criteria for the controlled clinical trials, or

(b) The patient is too ill to participate, or

(c) Participation in controlled clinical trials is likely to cause undue hardship (e.g. travel time) as defined by the protocol, or

(d) The controlled clinical trials are fully enrolled.

3. The patient cannot take standard treatment because it is contraindicated, cannot be tolerated, or is no longer effective. (The terms "cannot be tolerated" and "no longer effective" should be defined in each protocol. Generally these definitions will include a description of the standard therapy including dosages and the minimum duration of treatment to assess clinical utility, the range and severity of adverse reactions that constitute intolerance, and the clinical conditions or laboratory markers that constitute evidence that the therapy is no longer effective). If the basis for enrollment in the parallel track study is that standard treatment is no longer effective, the patient's physician

or physician group would be required under the protocol to certify that the patient is failing clinically despite reasonable efforts to optimize therapy with the standard treatment.

The protocol should establish patient priority categories if a sufficient quantity of the investigational drug is not likely to be available to all those who would satisfy the basic criteria for eligibility.

Because the primary objective of the IND phase of drug development is to establish the safety and efficacy of the drug through controlled clincial trails, it is critical that the sponsor work with participating physicians to assure that reasonable efforts are made to encourage persons to enter controlled clinical trails for which they are eligible. The protocol should specify a process for determining if a person for whom the investigational drug is being requested under the parallel track protocol is eligible for a controlled clinical trial of the drug, and methods for contacting clinical trial directors for possible inclusion.

The expanded availability protocol should not exclude certain patient populations based on age, sex or medical status unless there is adequate justification. Protocols should also consider and address potential problems associated with use of the drug in such special populations. The regulations for human subjects protections are discussed later in this document.

Criteria for Physician Participation in Parallel Track

As specified in FDA's IND regulations (21 CFR part 312) physicians administering investigational drugs under parallel track protocols become clinical investigators subject to all the obligations and responsibilities of investigators. The protocol will specify the minimum qualifications for participating physicians and the process by which a physician may be accepted by the sponsor as a clinical investigator under the expanded availability protocol. Physicians are required to certify that the patients meet the requirements of the protocol and that all efforts have been made to optimize standard therapy prior to enrollment in parallel track protocols. Because investigational drugs will be made available through parallel track protocols when relatively little is known about the drug, physicians must be familiar with potential adverse effects, willing to instruct patients in the early recognition of these effects and willing to monitor their patients closely. Participation by all physicians, including those serving rural, inner-city, medically indigent, and racial and ethnic minority populations should be encouraged.

Collection of Patient Data in Parallel Track Protocols

The data to be collected by the participating physicians and reported to the sponsor will be specified in each parallel track protocol. All participating physicians will be required to report safety data, while the nature and extent of efficacy data collection may vary in different clinical settings. The frequency of reporting will be specified in the protocol. Because of the early stage at which investigational drugs are to be made available under a parallel track protocol, and the relative lack of information about risk that is likely to exist, it is critical that participating physicians comply with data reporting requirements to provide important information on the risk of the drug and to assure patient safety.

The data collection forms should be designed to be easy to use and as concise as possible. Appropriate data collection and reporting by the administering physician is a prerequisite for continued drug supply.

Monitoring the Protocols

The sponsor of a parallel track protocol should monitor the study closely through a specific monitoring mechanism described in the protocol. The sponsor should establish a Data and Safety Monitoring Board (DSMB) or its equivalent with responsibility for monitoring the parallel track studies and gathering information from all protocols testing the investigational drug. The DSMB or its equivalent may recommend to FDA, the Sponsor, ARAC and other appropriate bodies that the parallel track and/or clinical trial protocols be terminated. (See Terminating Protocols).

The description and mechanism of operation of the DSMB (or other monitoring system) and its precise relationship to the sponsor and other oversight bodies will be specified in the expanded availability protocols.

The sponsor is responsible for submitting reports to the FDA as required in the IND regulations (21 CFR part 312), except where a waiver has been specially granted.

Education and Information

An extremely important accompaniment to a parallel track protocol is a program for the education of physicians, patients, IRBs, community-based health institutions, community and migrant health centers, the general public, and affected communities to ensure that participating physicians and potential recipients have sufficient knowledge of the potential risks and benefits of the parallel track drug as well as the risks and benefits of other treatment options. These programs, as noted in the "Review criteria" section above, should reflect the joint efforts of the PHS, the medical community, industry, academic communities and AIDs-related organizations. These education programs are in addition to the information provided through the informed consent process. Sponsors should specify how their particular education program will be carried out as well as how new information will be collected, analyzed, and publicly circulated.

Economic Considerations

Existing IND regulations permit sponsors to request the recovery of costs for certain investigational drugs in clinical studies, in the unusual circumstance in which the trial could not otherwise continue (see 21 CFR 312.7(d)(1)). FDA approval of a request to charge must be obtained.

Sponsors should specify the extent of economic support they would be willing to provide to pursue the expanded access of the investigational agent through the parallel track. They should also specify the degree of support, if any, they would provide for the administration of the drug for the conduct of necessary laboratory and clinical testing to determine product safety and the monitoring, collection, and distribution of drug-specific information through their education programs.

Human Subjects Protections

There are two sets of relevant federal regulations for the protection of human subjects which include requirements for local institutional review board (IRB) review and informed consent: the FDA regulations (21 CFR parts 50 and 56) that apply to all investigational drug studies, and HHS regulations (45 CFR part 46) which pertain to institutions that receive HHS support for research involving human subjects.

(a) HHS Regulations

Certain requirements of the current HHS regulations cannot reasonably be met for drugs released under the parallel track program. These regulations require local IRB review and approval of each protocol and written Assurance of Compliance from each organization or individual practitioner involved in the research and not affiliated with an assured institution. This is generally not practical for many reasons: (1) Local IRB

review could slow the dissemination of drugs under parallel track policies and procedures; (2) local review could be made by IRBs without sufficient information on which to base a recommendation; (3) local review could result in considerable delays if physicians are required to form their own IRBs; (4) local review might place IRBs in a situation in which it is difficult to monitor activities of physicians for whom they are not otherwise responsible. Consequently, the Secretary of HHS will consider, on a protocol-by-protocol basis, waiving the provisions of 45 CFR part 46.

Other mechanisms, in lieu of local IRB review, to provide for review of the protocol according to established ethical principles and to develop informed consent procedures appropriate to the parallel track program are described below.

(b) FDA Regulations

Prior to proceeding with a parallel track protocol, a sponsor must comply with FDA's IRB regulations. FDA regulations would allow a waiver where FDA determines that it is in the best interests of the subjects and that a national human subjects panel would provide an adequate mechanism for protecting patients. The Commissioner of Food and Drugs will consider a sponsor's request for waivers of the provisions of 21 CFR part 56 dealing with local IRB review, including § 56.107(a).

(c) National Human Subjects Protections Review Panel

While local IRBs would always have the option of reviewing expanded availability protocols, a national human subject protections review panel (national human subjects panel) with a broadly-based membership would be established. This panel will provide for patient protection, including approval of consent procedures and documentation and provide for continuing ethical oversight of each parallel track protocol. It will be particularly important for this body to review the proposed informed consent process of each protocol and review an initial "model" informed consent document, and to review the process to update the procedures and the document as knowledge about the investigational drug becomes available. The national human subjects panel will also ascertain that for each parallel track protocol the sponsor has established an appropriate procedure for data and safety monitoring.

The AIDS Program Advisory Committee (APAC) in NIH will establish an ad hoc subcommittee to carry out the duties of the national human subjects review panel until a permanent body is established. Outside consultants representing the relevant specialties and constituencies will be called on as needed to advise this body. PHS will take steps necessary to create a chartered national human subjects protections review panel with a broadly-based membership.

IRBs would continue to review drugs on the controlled clinical trial side of the "parallel track." In addition, individual institutions have the option to require that their IRBs review the expanded availability protocols when a study is conducted by the institution or its affiliated investigators.

Informed Consent

It is important that potential participants in the parallel track have as much information as is available in order to make informed decisions. The informed consent process must make clear the risks involved in taking a drug about which relatively little is known. The proposal for agents in the parallel track must describe a detailed process for informed consent, including specific information about patient and physician education. A proposed informed consent document is required to be included with the protocol. There should also be a description of how the informed consent document will be updated and how physicians and patients and the national human subjects panel will be notified of new information (e.g. toxicity, adverse reaction reports) after the initial informed consent document has been put into use.

Terminating Protocols

Because the parallel track program allows early, widespread distribution of investigational agents prior to full marketing approval, it is necessary to develop criteria to terminate or curtail a parallel track program. In general, these should include the following:

(1) Evidence that subjects are being exposed to unreasonable and significant risks,

(2) Evidence that the parallel track study is interfering with the successful enrollment in, and completion of, adequate and well-controlled studies of this or other investigational drugs,

(3) Evidence that the sponsor is not in active pursuit of marketing approval,

(4) The product has been studied in an adequately controlled clinical trial that strongly suggests lack of effectiveness,

(5) Another product approved or under investigation for the same indication in the same population demonstrates a better potential balance of risks and benefits,

(6) The drug receives marketing approval for the same indication in the same patient population,

(7) Insufficient product exists to conduct both the parallel track protocols and the controlled clinical trials,

(8) The Commissioner of Food and Drugs determines that, in the interest of the public health, the parallel track study should not be continued.

A principal purpose of the Data and Safety Monitoring Board, or its equivalent, would be to examine data to determine if the parallel track and/or clinical trials should be stopped and to make recommendations to the sponsor, FDA, ARAC, and other oversight bodies. A regulation detailing the FDA's authority to terminate these studies, as well as other uncontrolled studies, is published concurrently with this policy statement.

Periodic Review

A periodic review of the implementation and progress of expanded availability of all investigational drugs being distributed by a parallel track study will be conducted by the PHS. The objective of this periodic review would be to help ensure the continued rapid development and evaluation of therapeutic agents for treatment or prevention of HIV infection and HIV-associated diseases, as well as the safety of participants in these trials.

Dated: April 8, 1992.

James O. Mason,

Assistant Secretary for Health.

David A. Kessler,

Commissioner, Food and Drug Administration.

[FR Doc. 92-8624 Filed 4-14-92; 8:45 am]

BILLING CODE 4160-17-M

federal register

Wednesday
April 15, 1992

Part VI

Department of the Interior

Bureau of Indian Affairs

Indian Gaming; Notice of Approved Tribal-State Compact

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

Indian Gaming

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice of approved tribal-State compact.

SUMMARY: Pursuant to 25 U.S.C. 2710, of the Indian Gaming Regulatory Act of 1988 (Pub. L. 100–497), the Secretary of the Interior shall publish, in the **Federal Register**, notice of approved Tribal-State Compacts for the purpose of engaging in Class III (casino) gambling on Indian reservations. The Assistant Secretary-Indian Affairs, Department of the Interior, through his delegated authority has approved a Tribal-State Gaming Compact between the Crow Creek Sioux Tribe and the State of South Dakota executed on October 4, 1991.

DATES: This action is effective April 15, 1992.

ADDRESSES: Office of Tribal Services, Bureau of Indian Affairs, Department of the Interior, MS/MIB 4603, 1849 "C" Street, NW., Washington, DC 20240.

FOR FURTHER INFORMATION CONTACT: Joyce Grisham, Bureau of Indian Affairs, Washington, DC 20240, (202) 208–7445.

Dated: April 9, 1992.

William D. Bettenberg,

Acting Assistant Secretary—Indian Affairs.

[FR Doc. 92–8724 Filed 4–14–92; 8:45 am]

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federal register

Wednesday
April 15, 1992

Part VII

The President

Proclamation 6421—Education and Sharing Day, U.S.A., 1992

Federal Register
Vol. 57, No. 73
Wednesday, April 15, 1992

Presidential Documents

Title 3—

The President

Proclamation 6421 of April 14, 1992

Education and Sharing Day, U.S.A., 1992

By the President of the United States of America

A Proclamation

The American work force of tomorrow will face unprecedented challenges and opportunities in our increasingly interdependent, technological world. How well our students are prepared to meet them will determine not only their ability to succeed as individuals but also the economic competitiveness of our entire Nation. Indeed, our future standard of living will depend heavily on the standards that we set in education today. That is why we are pressing ahead with AMERICA 2000, our comprehensive strategy to achieve excellence in our schools.

While AMERICA 2000 constitutes a vital investment in the future of the United States, we know that a nation's quality of life depends on much more than worker productivity and economic competitiveness alone. It also depends on the standards of character and conduct that are upheld and cherished by society, since these, in turn, determine the degree of freedom, opportunity, and security enjoyed by each member. Thus, as we focus on excellence in American education, we must also recognize the importance of moral instruction.

As the parent of private virtue and civil order, moral education is vital to the healthy development of our children and to the continued strength and well-being of our Nation. When he took office, President Dwight Eisenhower urged Americans to "proclaim anew" the faith on which the United States is founded. "It is our faith in the deathless dignity of man, *governed by eternal moral and natural laws.*" This challenging yet ennobling view of humankind stands at the heart of America's commitment to freedom, equality, and justice. As President Eisenhower noted, it defines our full view of life. We cannot, therefore, overestimate the importance of education that fosters ethical and moral values in keeping with what our Founders called the "laws of Nature and of Nature's God." Moral education is the means by which we preserve the very foundation of this Nation's great yet precious experiment in self-government.

Public as well as private institutions of learning have both an obligation and a proper interest in advancing principles of ethical conduct and moral virtue. In recent years, we have seen how some "value-neutral" curricula have exploited America's long-cherished commitment to diversity and tolerance by avoiding the teaching of values. By contrast, teachers who affirm the absolute reality of truth and the timeless, universal value of qualities such as honesty, compassion, and personal accountability help their students to develop a sound inner compass.

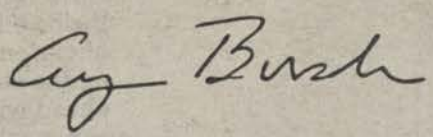
Although school has a role to play in providing direction to our youth, moral education begins at home, in the guidance that parents provide for their children, and in religious institutions, where we learn of our just and loving Creator and of the commandments that He has set before us. Recognizing that "fear of the Lord is the beginning of wisdom," members of the worldwide Lubavitch movement, under the leadership of Rabbi Menachem Mendel Schneerson, have worked to promote greater knowledge of Divine law, including the Biblical injunction to assist those who are needy. Like the Psalmist

who wrote, "Thy word is a lamp to my feet and a light to my path," the individual who possesses such knowledge is well-equipped for a safe and fruitful passage on his or her life's journey.

In recognition of the Lubavitch movement and in honor of the 90th birthday of its leader, Rabbi Schneerson, the Congress, by House Joint Resolution 410, has designated April 14, 1992, as "Education and Sharing Day, U.S.A." and has requested the President to issue a proclamation in observance of this day.

NOW, THEREFORE, I, GEORGE BUSH, President of the United States of America, do hereby proclaim April 14, 1992, as Education and Sharing Day, U.S.A. I invite all Americans to observe this day with appropriate programs and activities.

IN WITNESS WHEREOF, I have hereunto set my hand this fourteenth day of April, in the year of our Lord nineteen hundred and ninety-two, and of the Independence of the United States of America the two hundred and sixteenth.



[FR Doc. 92-8952
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Reader Aids

Federal Register

Vol. 57, No. 73

Wednesday, April 15, 1992

INFORMATION AND ASSISTANCE

Federal Register

Index, finding aids & general information	202-523-5227
Public inspection desk	523-5215
Corrections to published documents	523-5237
Document drafting information	523-5237
Machine readable documents	523-3447

Code of Federal Regulations

Index, finding aids & general information	523-5227
Printing schedules	523-3419

Laws

Public Laws Update Service (numbers, dates, etc.)	523-6641
Additional information	523-5230

Presidential Documents

Executive orders and proclamations	523-5230
Public Papers of the Presidents	523-5230
Weekly Compilation of Presidential Documents	523-5230

The United States Government Manual

General information	523-5230

Other Services

Data base and machine readable specifications	523-3447
Guide to Record Retention Requirements	523-3187
Legal staff	523-4534
Privacy Act Compilation	523-3187
Public Laws Update Service (PLUS)	523-6641
TDD for the hearing impaired	523-5229

FEDERAL REGISTER PAGES AND DATES, APRIL

10973-11260.....1
11261-11424.....2
11425-11552.....3
11553-11670.....6
11671-11904.....7
11905-12176.....8
12177-12402.....9
12403-12694.....10
12695-12862.....13
12863-12988.....14
12989-13266.....15

CFR PARTS AFFECTED DURING APRIL

At the end of each month, the Office of the Federal Register publishes separately a List of CFR Sections Affected (LSA), which lists parts and sections affected by documents published since the revision date of each title.

3 CFR

Proclamations:
6418.....12693
6419.....12863
6420.....12989
6421.....13265
Executive Orders:
12438 (Revoked by EO 12797).....11671
12794.....11417
12795.....11421
12796.....11423
12797.....11671
12799.....12401
12800.....12985
Administrative Orders:
Presidential Determinations:
No. 92-19 of March 16, 1992.....11553
No. 92-21 of April 10, 1992.....12865
Memorandum:
March 20, 1992.....11554

5 CFR

531.....12403
536.....12403
550.....12403
553.....12405
735.....11800
2633.....11800
2634.....11800
2638.....11886
2641.....11673
Proposed Rules:
532.....11586
735.....11586

7 CFR

2.....11261
54.....11425
272.....11218
274.....11218
276.....11218
277.....11218
278.....11218
301.....10973
319.....10974
800.....11427
981.....10976
1240.....11262
1413.....12406
1421.....12406
1455.....12410
1901.....11555
1924.....12991
1940.....11555
1951.....11555
1980.....12991
Proposed Rules:
1001.....11276
1002.....11276
1413.....11588

8 CFR

3.....11568
103.....11568
214.....10978, 12177, 12179
242.....11568
251.....10978
258.....10978
292.....11568

9 CFR

91.....10978
92.....12190
Proposed Rules:
327.....13053

10 CFR

Proposed Rules:
100.....11691

11 CFR

100.....11262
104.....11262
106.....11137
Proposed Rules:
102.....13056
110.....13054, 13056

12 CFR

34.....12190
202.....12202
211.....12992
225.....12992, 13002
263.....12992
265.....12992
556.....12203
563.....12695
564.....12698
567.....12706
571.....12695
932.....12428
941.....12428
1102.....10979
Proposed Rules:
3.....12214, 12218
5.....12222
11.....12222
16.....12222
230.....12735
325.....11005, 11010
337.....11442
545.....12226, 12760
563.....12226
567.....12761
571.....12760
934.....11014
1102.....11017

LIST OF PUBLIC LAWS

Note: No public bills which have become law were received by the Office of the Federal Register for inclusion in today's **List of Public Laws.**

Last List April 6, 1992

Public Laws

102d Congress, 1st Session, 1991

Pamphlet prints of public laws, often referred to as slip laws, are the initial publication of Federal laws upon enactment and are printed as soon as possible after approval by the President. Legislative history references appear on each law. Subscription service includes all public laws, issued irregularly upon enactment, for the 102d Congress, 1st Session, 1991.

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Particularly helpful for those interested in where to go and who to see about a subject of particular concern is each agency's "Sources of Information" section, which provides addresses and telephone numbers for use in obtaining specifics on consumer activities, contracts and grants, employment, publications and films, and many other areas of citizen interest. The *Manual* also includes comprehensive name and agency/subject indexes.

Of significant historical interest is Appendix C, which lists the agencies and functions of the Federal Government abolished, transferred, or changed in name subsequent to March 4, 1933.

The *Manual* is published by the Office of the Federal Register, National Archives and Records Administration.

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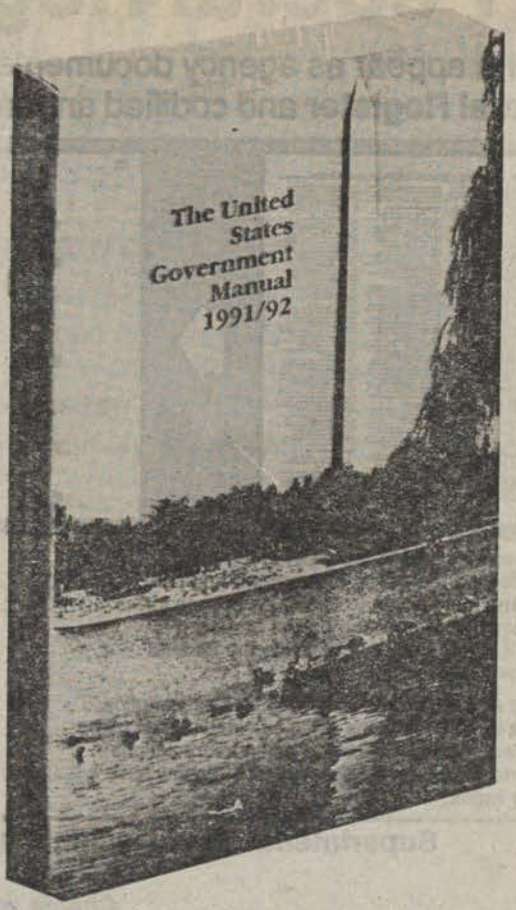

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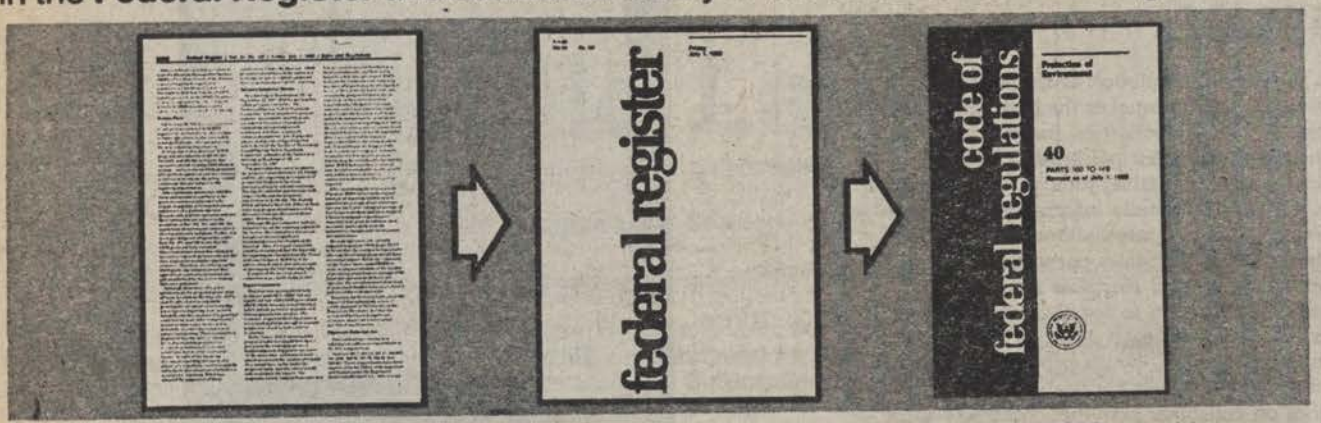

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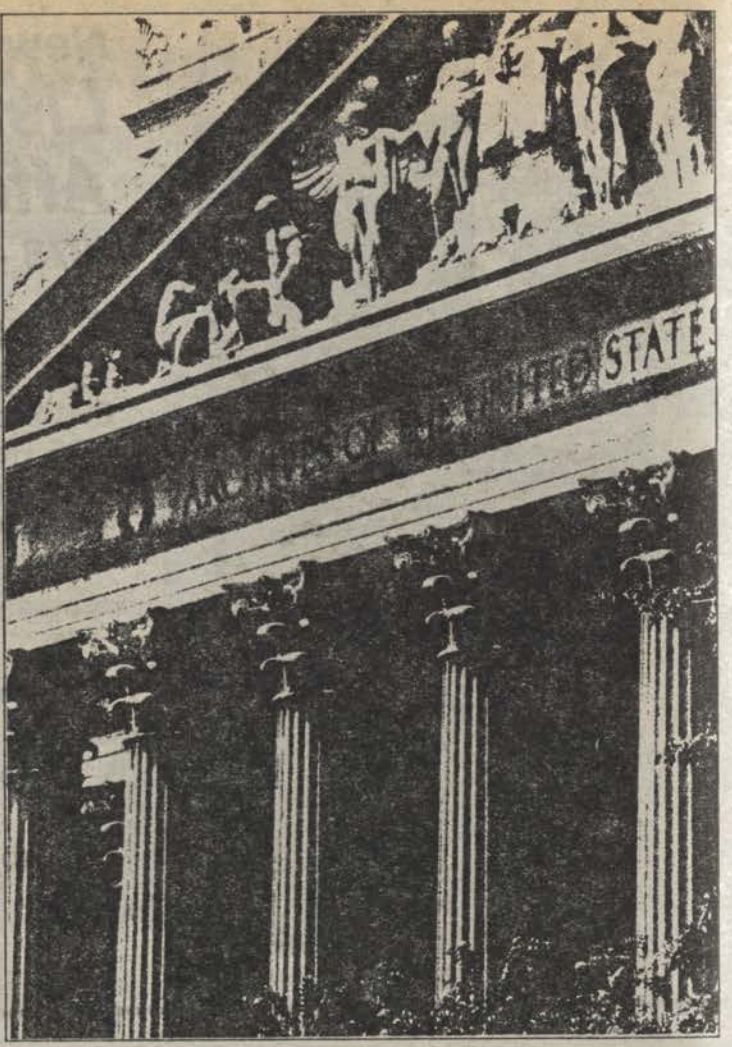

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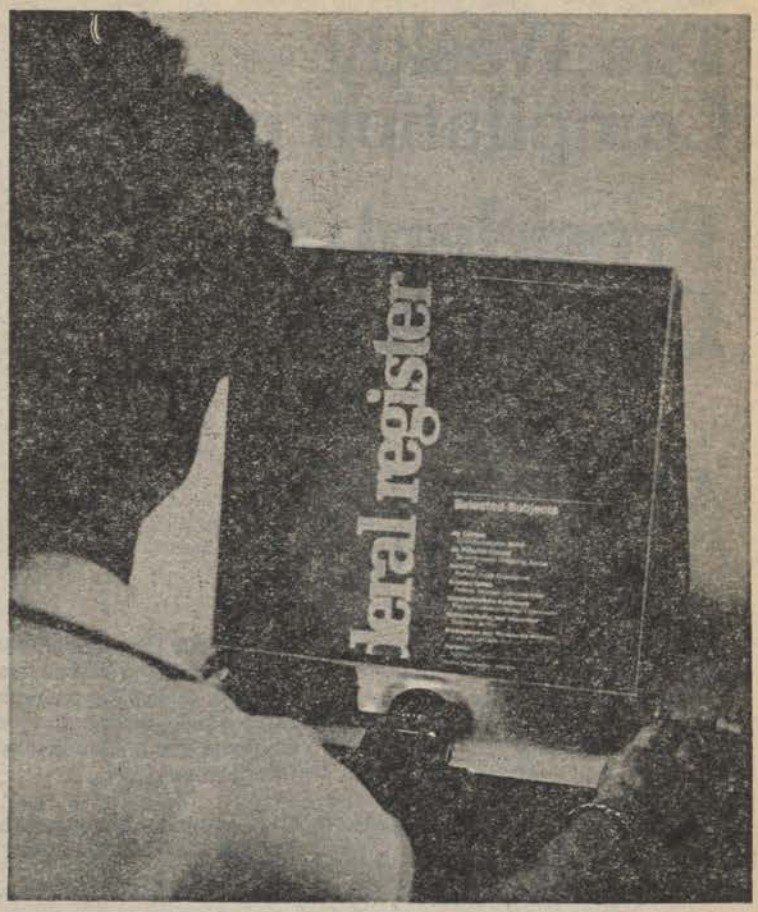

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